

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

019758Orig1s090

Trade Name: CLORAZIL

Generic or Proper Name: (clozapine)

Sponsor: Heritage Life Science Barbados INC.

Approval Date: January 16, 2019

Indication: CLOZARIL is an atypical antipsychotic indicated for:

- Treatment-resistant schizophrenia. Efficacy was established in an active controlled study.
- Reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder. Efficacy was established in an active-controlled study.

CENTER FOR DRUG EVALUATION AND RESEARCH

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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APPROVAL LETTER



NDA 019758/S-90 e

SUPPLEMENTAL APPLICATION

Heritage Life Sciences (Barbados), Inc.
Attention: Shontelle Murrell-Hinkson
Assistant Secretary
The Beach House
Holetown, St. James, Barbados

Dear Ms. Murrell-Hinkson:

Please refer to your Supplemental New Drug Application (sNDA) received July 24, 2018 and amended on December 13, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 19758 Clozaril (clozapine HCl) 25 mg and 100 mg Tablets.

This Prior Approval supplemental new drug application provides for proposed modifications to the approved Clozapine Risk Evaluation and Mitigation Strategy (REMS).

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The single, shared system Clozapine REMS, of which Clozaril is a member, was originally approved on September 15, 2015. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

Your proposed modifications to the REMS consist of the addition of educational materials, changes to the inpatient prescriber certification requirements and patient monitoring, and initiation of the operational restrictions for prescriber and pharmacy certification.

Your proposed modified REMS, submitted on July 24, 2018, amended and appended to this letter, is approved.

The timetable for submission of assessments must be revised. The timetable for submission of assessments of the currently approved program is at 6-months, and 12-months from the date of initial approval of the REMS (September 15, 2015), and then annually thereafter. With this modification the timetable for submission of assessments is: annually beginning February 28, 2020. e

The revised REMS assessment plan must include, but is not limited to, the following:

A. REMS Program Implementation and Operations

1. REMS Program Utilization:

a. Pharmacies, Prescribers, Prescriber Designees, and Distributors:

i. Number of each stakeholder, status of certification or enrollment (as applicable), and method of certification or enrollment (as applicable)

ii. Summary of reasons certification or enrollment is incomplete for each stakeholder (Examples may include “Pharmacy unable to configure pharmacy management system,” “Prescriber missing information on form,” etc.)

b. Patient Treatment Status by Patient Type (general population, BEN patients, NNRMF patients, hospice patients) for the reporting period and cumulatively:

i. Active

ii. Interrupted

iii. Discontinued

c. A nationally estimated number of patients that received a dispensed prescription for clozapine (all dosage forms) from U.S. out-patient retail pharmacies for the reporting period. Provide rationale for discrepancies between this estimate and the number of unique patients enrolled in the clozapine REMS and receiving at least one PDA during the reporting period.

2. Contact Center Report:

a. Number of contacts

b. Summary of reason for contacts (examples may include “Enrollment question,” “Lab query,” etc.) by reporter (i.e., pharmacy, prescriber, patient)

c. Narrative of any corrective actions resulting from issues identified

3. Clozapine REMS Program Compliance (to be included in the REMS Assessment Report after full implementation):

a. Audits

- i. Summary of audit findings for audits conducted during the reporting period
 - ii. Summary of corrective actions taken to address findings, the status of the corrective actions, and any resulting preventative actions that were taken
- b. Number of clozapine prescriptions dispensed that were written by non-certified prescribers (reported or detected through audit):
- i. Actions taken (examples may include “Provision of clozapine program materials,” “Prescriber becomes certified,” etc.)
 - ii. Outcome of actions taken
- c. Number of prescriptions dispensed by noncertified outpatient pharmacies and actions taken to prevent future occurrences (reported or detected through audit)
- d. Number of shipments sent to noncertified pharmacies, source of report, and actions taken to prevent future occurrences
- e. Number of times a clozapine prescription dispensed because a pharmacy bypassed REMS edits; and, if any such events occurred, describe how these events were identified, the root cause of the failure, and any corrective actions taken (reported or detected through audit). Stratify by pharmacy type (switch or non-switch)
- f. Number of times a clozapine prescription was dispensed by a pharmacy for more than a 3 day supply during the 3 day 72-hour *Dispense Rationale* window
- g. Number of patients receiving a clozapine prescription under a *Dispense Rationale* stratified by the number of prescriptions authorized under a *Dispense Rationale* per patient in a 6 month time frame
- i. Summary of outreach to prescribers and number of resulting prescriber certifications.
- h. Number of prescriptions dispensed under a *Dispense Rationale* stratified by prescriber
- i. Number of PDA without current lab value based on the patient’s monitoring frequency (7-31), provided as

- (a) Total number of individual patients receiving PDA without current lab (i.e., aggregate)
 - (b) Number of PDAs for each unique patient without current lab; provide range and average number of PDAs per patient
- j. Noncompliance with the Clozapine REMS Program requirements, source of report, and any corrective action or resolution
 - i. Number of PDAs without ANC (excluding hospice patients) and number of these resulting in clozapine dispensing
 - ii. Number of PDAs without a *Treatment Rationale* provided when the ANC was unacceptable, and number of these resulting in clozapine dispensing
- 4. Barriers or Delays in Patient Access: Provide outcome wherever possible
 - a. False negatives: e.g., all entities are certified, but system generate a prescription rejection notice
 - b. Inadvertent enrollment deactivations or failures to notify enrollees of forthcoming enrollment expirations
 - c. Reported lack of certified prescribers and/or pharmacies in a patient's local area
 - d. Unintended system interruptions and resolutions
 - e. For PDAs via electronic verification: Number of times and reasons that a manual back up system was used to validate a prescription and source of problem (e.g., switch level, pharmacy level, REMS database, etc.)

- . Inappropriate Patient Access:
 - a. Inpatient pharmacy dispensing for outpatient use (reported or detected through audit)
 - b. False positives: e.g., one or all entities were not certified but the system verified dispensing generated a PDA
6. Evaluation of Safe Use Behaviors:
 - a. Prescription Rejections:
 - i. Number of unique prescriptions submitted for authorization
 - ii. Number of unique prescriptions submitted for authorization that did not encounter any REMS related rejections prior to being authorized stratified by authorization type (Clozapine REMS Program Website PDA or pharmacy claims PDA)
 - iii. Number of unique prescriptions submitted for authorization that encountered any REMS related rejections, stratified by authorization type (Clozapine REMS Program Website PDA or pharmacy claims PDA)
 - iv. Mean, median, and range of the duration of time to authorize stratified by authorization type
 - v. Provide reasons for prescription rejections stratified by type of PDA (via pharmacy management system or Clozapine REMS Program Website) and duration of time to authorize prescription if initially rejected
 - b. Treatment Rationales:
 - i. Number of Treatment Rationales submitted, stratified by type
 - ii. Mean number of Treatment Rationales submitted per prescriber
 - c. Number of notifications and alerts sent, stratified by type and stakeholder type (prescriber, pharmacy) and resulting actions by stakeholder (clozapine discontinued, pharmacy became enrolled, etc.)

- (a) For overdue lab notifications and severe neutropenia notifications, provide the number of notifications per unique patient and any actions by stakeholder (clozapine discontinued, pharmacy became enrolled, etc.) resulting from the notification.

7. Evaluation of Knowledge Surveys:

- a. An evaluation of knowledge of certified prescribers of the risk of severe neutropenia, appropriate monitoring of clozapine and REMS requirements
- b. An evaluation of knowledge of authorized representatives and pharmacists of the risk of severe neutropenia, appropriate monitoring of clozapine and REMS requirements
- c. An evaluation of knowledge of patients or caregivers of the risk of severe neutropenia, and the need for appropriate monitoring

8. Evaluation of Required Monitoring:

- d. Total instances of severe neutropenia per unique patients (reported as lowest ANC for each unique patient whose ANC drops below 500/ μ L within each month)
- e. Total instances of neutropenia per unique patients (reported as lowest ANC for each unique patient whose ANC drops below 1500/ μ L, but remains at 500/ μ L or above within each month)

9. Clozapine REMS Program Outreach and Communication after the REMS modification in 01 2019 and after any subsequent modifications that are approved in each assessment period:

- a. Dates of distribution of the *Dear HCP Letter*, *Dear Distributor Letter*, *Dear Professional Society Letter*, *Chain Pharmacy Letter*, *Inpatient Pharmacy Letter*, *Outpatient Pharmacy Letter (Non-switch)*, *Outpatient Letter (Switch)*, and *Prescriber Letter* and the numbers sent on each date. Provide a list of the documents included with each distribution including the revision date
- b. Number of undeliverable and returned communications for each distribution date, by method of distribution
- c. A summary of the Clozapine REMS Program Website utilization for

10. Knowledge Assessments:

- a. Number of completed *Clzapine REMS Knowledge Assessment for Healthcare Providers* (KAs) for certified prescribers and pharmacy authorized representatives, and pharmacy staff that have elected to take the KA, including method of enrollment and number of attempts to complete, by stakeholder
 - b. Summary of the most frequently missed KA questions, stratified by prescriber and pharmacy
 - c. A summary of potential comprehension or perception issues identified with the KA
 - d. Proposed remediation for *Clzapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and or the *Clzapine REMS Knowledge Assessment for Healthcare Providers*
11. The Important Program Update on the Clozapine REMS Program Website is used to communicate important program changes to stakeholders. This section on the website will provide frequent updates to stakeholders regarding the program. A summary of the number of updates communicated in this section of the website will be provided during the assessment reporting period.

The requirements for assessments of an approved REMS under section 314(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 314(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 314(g)(2)(A) of the FDCA. This assessment should include:

- a) An evaluation of how the benefit risk profile will or will not change with the new indication;
- b) A determination of the implications of a change in the benefit risk profile for the current REMS;
- c) *If the new indication for use introduces unexpected risks:* A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

- d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.
- e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.
- f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including:* Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications, provide a rationale for why the REMS does not need to be modified.*

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 19758 REMS ASSESSMENT METHODOLOGY

An authorized generic drug under this NDA must have an approved REMS prior to marketing.

If you should decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 301(f)(1) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 301(b)(2) or (j). A violation of this provision in 301(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 19758 REMS ASSESSMENT

or

**NEW SUPPLEMENT FOR N A 19758/S-
CHANGES BEING EFFECTE IN 30 AYS
PROPOSE MINOR REMS MO DIFICATION**

or

**NEW SUPPLEMENT FOR N A 19758/S-
PRIOR APPROVAL SUPPLEMENT
PROPOSE MAJOR REMS MO IFICATION**

or

**NEW SUPPLEMENT FOR N A 19758/S-
PRIOR APPROVAL SUPPLEMENT
PROPOSE REMS MO IFICATIONS UE TO SAFETY LABEL CHANGES D
SUBMITTE IN SUPPLEMENT XXX**

or

**NEW SUPPLEMENT (NEW IN ICATION FOR USE)
FOR N A 19758/S-
REMS ASSESSMENT
PROPOSE REMS MO IFICATION (if included)**

ould you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR N A 19758

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

SUBMISSION OF REMS OCUMENT IN SPL FORMAT

FDA can accept the REMS document in structured Product Labeling (PL) format. If you intend to submit the REMS document in PL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in PL format using the FDA automated drug registration and listing system (eLIT). D

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314. 0 and 314. 1).

If you have any questions, call Er as Zerislassie, Safety Regulatory Project Manager, at 301 796 2770.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Division Director Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research m

ENCLOSURE(): m
REMS

**This is a receipt for a National Record that was signed
electronically. Following this matter if said party shall
electronically sign for this National Record.**

/s/ N

TIFFA YR FARCHIO E
01/16/2019 12:15:13 PM
On behalf of Mitch Mathis

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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REMS

RI K EVALUATION ANM I TIGATION STRATEGY (RE)

INGLE HARED Y TE FOR CLOZAPINE

I. GOAL

The goal of the Clozapine REMS Program is to mitigate the risk of severe neutropenia associated with the use of clozapine by:

- A. Educating prescribers and pharmacists about the risk of severe neutropenia and appropriate monitoring requirements
- B. Informing patients about the risk of severe neutropenia and appropriate monitoring requirements
- C. Ensuring compliance with the monitoring schedule for absolute neutrophil count (ANC) prior M to dispensing clozapine
- D. Ensuring the prescriber documents a risk-benefit assessment when ANC falls below the acceptable range as described in the Prescribing Information
- E. Establishing long-term safety and safe use of clozapine by enrolling all patients who receive clozapine in the registry

II. RE EM E NT

A. E emen s To Assure fe Use

1. Cer n He hc re Prov ders who prescr be c oz p ne re cer f ed

- a. All Healthcare Providers who prescribe clozapine for outpatient use must be certified.
- b. All Healthcare Providers who prescribe clozapine to a patient who is not yet enrolled must be certified.
- c. To become certified to prescribe clozapine, Healthcare Providers must:
 - i. Review the Prescribing Information for clozapine,
 - ii. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and M successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*; and,

iii. In the C zapi e R MS P g am by c mp eti g the *Cl zapine REMS Prescriber Enrollment Form*.

d. As a c diti f ce tificati , p esc ibe s must:

i. each patie t i the C zapi e R MS P g am by:

1.) I f mi g the patie t ab ut the isks ass ciated with c zapi e i c udi g seve e eut pe ia a d the C zapi e R MS P g am equi eme ts by usi g *A Guide for Patients and Caregivers: What You Need to Know about Cl zapine and Neutr penia* a d p vidi g it t the patie t ca egive u ess c i ca judgme t i dicates that the patie t's adhe e ce t the t eatme t egime wi be egative y impacted by p vidi g *A Guide for Patients and Caregivers: What You Need to Know about Cl zapine and Neutr penia*

2.) C mp eti g the *Cl zapine REMS Patient Enrollment Form* f each patie t. Submit the c mp eted f m t the C zapi e R MS P g am

ii. Pe f m the f wi g equi eme ts a g i g basis f each patie t a d submit t the C zapi e R MS P g am via the i e system, by fax, by ca i g the C zapi e R MS P g am C tact Ce te :

1.) O de ANC acc di g t the m o it i g schedu e desc ibed i the P esc ibi g I f mati

2.) Submit ANC acc di g t the patie t's m o it i g f eque cy fie with the C zapi e R MS P g am as desc ibed i the M o it i g Schedu e f the P esc ibi g I f mati :

a) F week y m o it i g f eque cy, ANC must be submitted t the C zapi e R MS P g am withi 7 days f the ab d aw date

b) F eve y tw weeks m o it i g f eque cy, ANC must be submitted t the C zapi e R MS P g am withi 15 days f the ab d aw date

c) F m o th y m o it i g f eque cy, ANC must be submitted t the C zapi e R MS P g am withi 31 days f the ab d aw date

3.) P vidi auth izati f t eatme t f patie ts (i.e., T eatme t Rati a e) with a ANC that fa s be w the acceptab e a ge desc ibed i the P esc ibi g I f mati , whe the p esc ibe dete mi es the be efits utweigh the isks f deve pi g seve e eut pe ia

4.) Ve ify the patie t m o it i g f eque cy fie with the C zapi e R MS P g am is a ig ed with the patie t's m o it i g f eque cy as desc ibed i the P esc ibi g I f mati

e Clozapine Sp ns rs must:

- i Ensure that Healthcare Providers h prescribe Clozapine as described in II A 1 a-b are w certified in accordance ith the requirements described above
- ii Ensure that Healthcare Providers can complete the certification process, patient enrollment and management online r by fax t the Clozapine REMS Pr gram
- iii Ensure that Healthcare Providers h prescribe Clozapine as described in II A 1 a-b are notified hen they have been certified in the Clozapine REMS Pr gram
- iv Maintain a validated, secure database f Healthcare Providers h are certified t prescribe Clozapine in the Clozapine REMS Pr gram . Clozapine Sp ns rs must ensure that the prescriber's REMS requirements are met and may de-certify n nc mpliant prescribers if the requirements d n t continue t be met
- v Maintain a validated, secure database f patients enr ed in the Clozapine REMS Pr gram
- vi Ensure that certified prescribers are pr vided access t the database f certified pharmacies and enr ed patients
- vii Pr vide *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers t Healthcare Providers h* :

w

- 1) Attempt t prescribe Clozapine as described in II A 1 a-b and are n t yet certified, r
- 2) Inquire ab ut h t bec me certified

w

- viii Ensure that ithin 30 calendar days f REMS appr va , the REMS materials listed be are available n the Clozapine REMS Pr gram Website, Clozapinerems.com, and by calling the Clozapine REMS Pr gram ntact enter at 844-267-8678

The following materials are part f the REMS and are appended:

- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- *Clozapine REMS Prescriber Enrollment Form*
- *Clozapine REMS Prescriber Designee Enrollment Form*
- *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia*
- *Clozapine REMS Patient Enrollment Form*
- Clozapine REMS Pr gram Website w

2 Pharmacies that dispense clozapine are certified

Outpatient Pharmacies

a. To become certified to dispense clozapine, outpatient pharmacies must:

i. Designate an authorized representative to complete certification on behalf of the pharmacy using the appropriate form: o

1.) *Clozapine REMS Outpatient Pharmacy Enrollment Form*

2.) *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*

ii. Ensure the authorized representative will oversee implementation and compliance with the Clozapine REMS Program requirements by doing the following: o

1.) Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

2.) Ensure all relevant staff involved in the dispensing of clozapine are trained in the Clozapine REMS Program requirements as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and maintain records of staff training o

a.) For pharmacies that have a pharmacy management system that supports electronic telecommunication verification, each pharmacist must be trained utilizing established training protocols for their certified pharmacy

b.) For pharmacies that have a pharmacy management system that does not support electronic telecommunication verification, each pharmacist must be trained by reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and successfully completing the *Clozapine REMS Knowledge Assessment for Healthcare Providers* o

iii. Put processes and procedures in place to ensure the following requirements are completed:

1.) Obtain a Predispense Authorization each time from the Clozapine REMS Program by accessing the Clozapine REMS Program Website, Clozapine REMS Program Contact Center, or enabling the pharmacy management system to support communication with the Clozapine REMS Program system

2.) Maintain appropriate documentation that all processes and procedures are in place and are being followed for the Clozapine REMS Program and provide it upon request to the Clozapine Sponsors or a third party acting on behalf of the Clozapine Sponsors o

- 3 Verify in the Clozapin EMS Program every two years
- 4 Comply with audits by the Clozapin Sponsors or a third party acting on behalf of the Clozapin Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapin EMS Program

b. As a condition of certification:

i. Pharmacies that support telemedicine certification with the Clozapin EMS Program system:

m
mmu

1. Ensure the pharmacy maintains pharmacy management system to support telemedicine certification with the Clozapin EMS Program system using established telemedicine standards and runs validation test transaction(s) to validate the system changes.

2. Dispense clozapin to patients only after obtaining a Prescription Authorization authority by processing all clozapin prescriptions, including cash sales, through the telepharmacy management system to telemedicine:

m

a. Verify the prescriber is certified in the Clozapin EMS Program

b. Verify the patient is enrolled in the Clozapin EMS Program

Verify the ANC is current (within 7 days of the Prescription Authorization transaction date) for close monitoring, 15 days for every two weeks monitoring and 31 days for monthly monitoring

m

d. Verify the ANC is within the acceptable range as prescribed in the Prescribing Information, or that a certified prescriber has authorized clozapin treatment for patients with an ANC that falls below the acceptable range when the prescriber has determined that benefits outweigh the risks of developing serotonin toxicity

Report dosing information for each clozapin prescription/fill to the Clozapin EMS Program

ii. Pharmacies that do not support telemedicine certification with the Clozapin EMS Program system:

Dispense clozapin to patients only after obtaining a Prescription Authorization authority by accessing the Clozapin EMS Program Website or calling the Clozapin EMS Program Contact Center to:

1. Verify the prescriber is certified in the Clozapin EMS Program

2. Verify the patient is enrolled in the Clozapin EMS Program m

3. Verify the ANC is current (within 7 days of the dispensing Authorization P
Transaction date) with weekly monitoring, 15 days for every two weeks
monitoring, and 31 days for monthly monitoring
4. Verify the ANC is within the acceptable range described in the prescribing
Information, or that the prescriber has authorized clozapine treatment for
patients with an ANC that falls below the acceptable range when the prescriber
determines that benefit outweighs the risks of developing severe neutropenia
5. Report dosing information for each clozapine prescription/fill to the Clozapine
REMS program

Inpatient Pharmacies

c. To be certified to dispense clozapine, inpatient pharmacies must:

- i. Designate an authorized representative to complete the certification process on behalf
of the pharmacy using the *Clozapine REMS Inpatient Pharmacy Enrollment Form*
- ii. Ensure the authorized representative will oversee implementation and compliance with
the Clozapine REMS program requirements by doing the following:
 1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* P
and successfully complete the *Clozapine REMS Knowledge Assessment for
Healthcare Providers*
 2. Ensure all relevant staff involved in the dispensing of clozapine are trained on the
Clozapine REMS program requirements as described in *Clozapine and the Risk of
Neutropenia: A Guide for Healthcare Providers* and maintain records of staff
training. Each pharmacist must be trained by reviewing *Clozapine and the Risk of
Neutropenia: A Guide for Healthcare Providers* and successfully completing the
Clozapine REMS Knowledge Assessment for Healthcare Providers
- iii. Implement processes and procedures in place to ensure the following requirements are
completable prior to the initial inpatient dispensing of clozapine:
 1. Perform an Eligibility Check from the Clozapine REMS program by accessing the
Clozapine REMS program Website or contacting the Clozapine REMS program
Contact Center to verify the patient is enrolled in the Clozapine REMS program
 2. Obtain a current ANC by accessing the Clozapine REMS program Website,
contacting the Clozapine REMS program Contact Center, or by accessing the
inpatient medical record
 3. Verify that the ANC is within the acceptable range described in the prescribing
Information or that the prescriber has authorized clozapine treatment for patients P

w ANC falls below acceptable range we prescribe derivatives
effective our risks of developing severe eu rope

- v M appropriate documents of all processes and procedures replaced
being followed for the Clozapine REMS Program and provided upon request of
Clozapine Sponsors or their primary caregiver of the Clozapine Sponsors
- v Comply with audits by the Clozapine Sponsors or their primary caregiver of the
Clozapine Sponsors to ensure all processes and procedures replaced
being followed for the Clozapine REMS Program

d As codification process, parameters must:

Describe clozapine only for:

- 1) Performing Eligibility Check by accessing the Clozapine REMS Program
Website or the Clozapine REMS Program Co-ordinator to verify the
patient's enrolled in the Clozapine REMS Program;
- 2) Verifying patient's ANC obtained from the Clozapine REMS Program
Website, the Clozapine REMS Program Co-ordinator, or patient's
medical records currently;
- 3) Verifying the ANC is within acceptable range described in the Prescribing
Information or the prescriber's authorized clozapine regimen for patients
with ANC falls below acceptable range we prescribe derivatives
effective our risks of developing severe eu rope

Describe the 7-day temporary supply of clozapine or the rolled patient
upon discharge from the facility

e Clozapine Sponsors must:

Ensure parameters describe clozapine rechecked, accordance with the
requirements described above

Ensure authorized representatives complete the primary certification process
directly or by fax to the Clozapine REMS Program

Ensure parameters rechecked weekly verified the Clozapine
REMS Program

- v Ensure parameters rechecked for the Clozapine REMS Program every two
years

- v Verify every two years the authorized representative's medical contact
information corresponds to the current designated authorized representative for

to the following; and finally, you may also want to
authorize prescriptions

The following materials are part of the REMS and appendices:

- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- *Clozapine REMS Inpatient Pharmacy Enrollment Form*
- *Clozapine REMS Outpatient Pharmacy Enrollment Form*
- *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*
- Clozapine REMS Program Website

3. Clozapine will be dispensed with evidence or other documentation of safe-use conditions

a. To enroll a patient into the Clozapine REMS Program, a prescriber must complete a
Clozapine REMS Patient Enrollment Form and attach patient information as:

• Bring a copy of *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* unless already documented at the patient's admission to the treatment center will be automatically provided by the provider of *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia*

• Bring information by the prescriber of the risks of clozapine and the Clozapine REMS Program requirements, using *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*

b. Clozapine Sponsors must:

• Ensure that the prescriber can submit completed *Clozapine REMS Patient Enrollment Form* online or by fax to the Clozapine REMS Program

• Ensure that the prescriber can verify that the prescriber is a patient at the time of clozapine enrollment into the Clozapine REMS Program (see 'Section II.A.2 Program Standards for Dispensing Clozapine' for details)

The following materials are part of the REMS and appendices:

- *Clozapine REMS Patient Enrollment Form*

4. Each patient using clozapine is subject to certain monitoring

a. Clozapine Sponsors must ensure that before dispensing clozapine to a patient and verify ANC counts and,

• Without a patient's signed consent, Prescriber Information; or, g

- ii. Each patient using clozapine must be enrolled in the Clozapine Rational Use Registry (RUR) for patients with an A-Ct at falls below the acceptable range without the use of divalproex sodium

5. Each patient using clozapine is enrolled in a registry

- a. Clozapine Sponsors must ensure that each site enrolls all patients in the Clozapine NREMS Program using the *Clozapine REMS Patient Enrollment Form*
- b. Clozapine Sponsors must maintain the Clozapine REMS Program. The primary objective of the Clozapine REMS Program is to ensure patient safety and safety of clozapine through periodic monitoring of divalproex sodium
- c. Clozapine Sponsors must ensure that patient enrollment can be completed via the Clozapine REMS Program Website or by fax

B. Implementation System

- 1. Clozapine Sponsors must ensure that clozapine is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute clozapine comply with the program requirements for wholesalers/distributors. For a wholesaler/distributor to distribute clozapine, the wholesaler/distributor must:
 - i. Put processes and procedures in place to verify, prior to distributing clozapine, that the pharmacist is certified
 - ii. Train all relevant staff on the Clozapine REMS Program requirements
 - iii. Agree to be audited by the Clozapine Sponsor or a third party acting on behalf of the Clozapine Sponsor to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program
 - iv. Maintain a quality documentation and make it available for audits
 - v. Provide distribution data to the individual Clozapine Sponsors
 - b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of clozapine and provide that data to the individual Clozapine Sponsors
 - c. Monitoring distribution data and auditing the wholesalers/distributors within one year after the wholesaler/distributor is enrolled to ensure that all processes and procedures are in place and functioning to support the requirements of the Clozapine REMS Program. Clozapine Sponsors must institute corrective action if noncompliance is identified
- 2. Clozapine Sponsors must maintain a validated, secure database of pharmacist at a certified to NDCs clozapine in the Clozapine REMS Program

3. pine Sp ns rs must m ant in dequ te rec rds f c pine distributi n, dispensing, certified prescribers, ph rm aies, distribut rs/ h es ers, nd p tients t meet the pine REMS Pr gr m requirements
4. pine Sp ns rs must ensure th t ph rm aies' REMS requirements re met nd m ay decertify n nc mp i nt ph rm aies if the requirements d n t c ntinue t be met
5. pine Sp ns rs must m ant in v id ted, secure d t b se f p tients h re enr ed in the pine REMS Pr gr m
6. pine Sp ns rs must m ant in pine REMS Pr gr m nt ct enter t supp rt prescribers nd ph rm aies interf cing ith the pine REMS Pr gr m
7. pine Sp ns rs must ensure th t ithin 70 c end r d ys f ppr v f the 02/2019 REMS m odific ti n, the pine REMS Pr gr m Website is fu y per ti n nd m ateri s isted in r ppended t the pine REMS Pr gr m d cument re v i b e thr ugh the pine REMS Pr gr m Website (.c pinerems.c m) w by c ing the pine REMS Pr gr m nt ct enter t 844-267-8678
8. The pine REMS Pr gr m Website (.c pinerems.c m) must c ntinue f r the dur ti n w f the REMS. Additi n y,
 - a. The pine REMS Pr gr m Website must inc ude the f ing n ine c p bilities f r certified He thc re Pr vid ers, their designees, r ph rm ay st ff, s pp ic b e:
 - i. c mp eti n f prescriber nd ph rm ay certific ti n,
 - ii. enr ment nd m an gement f p tients,
 - iii. pr visi n f Predispose Auth ri ti ns; nd, w
 - iv. pr visi n f E igibi ity heck resu ts
 - b. The pine REMS Pr gr m Website must inc ude the pti n t print versi ns f the pine REMS Pr gr m materi s
 - c. The individu , pr duct-specific c pine ebsites f r He thc re Pr vid ers must inc ude pr minent REMS-specific ink t the pine REMS Pr gr m Website
9. pine Sp ns rs must c ntinu us y m nit r the certified ph rm aies t ensure the requirements f the pine REMS Pr gr m re being met. pine Sp ns rs must institute c rrective cti n if n nc mp i nce is identified
10. pine Sp ns rs must udit certified ph rm aies th t h ve rdered c pine t ensure th t pr cesses nd pr cedures re in p ce nd functi ning t supp rt the requirements f the pine w REMS Pr gr m n the f ing schedu e:

- a. a pharmacy audit must be implemented within 180 days following approval of the current Clozapine REMS modification;
- b. Subsequent audits will be administered every two years thereafter; and,
- c. Clozapine Sponsors must institute corrective action if noncompliance is identified

11. Clozapine Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Clozapine REMS Program based on monitoring and evaluation of the Clozapine REMS Program

III. Timetable for Submission of Assessments

Clozapine NDA Sponsors must submit REMS Assessments annually beginning February 28, 2020. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Clozapine Sponsors will submit each assessment so that it will be received by the FDA on or before the due date. v

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

This guide is intended to educate Healthcare Providers about clozapine and the Clozapine REMS Program. During the launch of the Clozapine REMS Program, there were challenges that required an extension of the phased implementation period. This guide is reflective of the full implementation of the Clozapine REMS Program, which is expected in [TBD]. For the current state of the Clozapine REMS Program, expected full implementation dates and important updates on the transition period, please see the *Clozapine REMS Frequently Asked Questions (FAQs)* on the Clozapine REMS Program Website at www.clozapinerems.com.

Clozapine and the Risk of Neutropenia:

A Guide for Healthcare Providers

This Guide discusses:

- What is the Clozapine REMS Program?
- Clozapine and the risk of severe neutropenia
- Treatment recommendations and patient absolute neutrophil count (ANC) monitoring
- Prescriber requirements for the Clozapine REMS Program
- Pharmacy requirements for the Clozapine REMS Program

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1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key program requirements:

Prescribers (who prescribe clozapine for outpatient use)

- Must certify in the Clozapine REMS Program to prescribe clozapine
- Must enroll all patients in the Clozapine REMS Program
- Must submit patients' ANCs to the Clozapine REMS Program for every prescription of clozapine according to the patient's monitoring frequency:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

Pharmacies

- Must certify in the Clozapine REMS Program to dispense clozapine
- Must verify the prescriber is certified and the patient is enrolled prior to dispensing clozapine
- Must verify the ANC is within the acceptable range described in the Prescribing Information, or that the prescriber has authorized the continuation of clozapine treatment by providing a "Treatment Rationale" for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia
- Prior to dispensing clozapine, verify ANC is current (within 7/15/31 days prior to the "Predispense Authorization"/"Eligibility Check" transaction date)

Patients

- Must be enrolled in the Clozapine REMS Program by the prescriber to receive clozapine
- Must comply with the ANC testing requirements

Important Terms Used in the Clozapine REMS Program:

- **Predispense Authorization (PDA):** An authorization given to outpatient pharmacies which reflects that the safe-use conditions for that patient have been met. The PDA is an electronic code provided by the Clozapine REMS Program verifying that the patient is enrolled, the prescriber and pharmacy are certified, and that the ANC is on file, current and within acceptable range. This PDA then permits dispensing of clozapine to the patient.
- **Treatment Rationale (TR):** A justification used by a prescriber to allow a patient having moderate neutropenia (ANC 500-999/ μL for the general population) or severe neutropenia (ANC < 500/ μL for general population and patients with documented BEN) to continue treatment. Only prescribers can confirm that benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia.
- **Dispense Rationale (DR):** The opportunity provided by the Clozapine REMS Program to certified outpatient pharmacies to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient's prescriber is not certified in the Clozapine REMS Program. The Clozapine REMS Program alerts the pharmacy if the prescriber is not certified in the Clozapine REMS Program, and prevents a PDA from being issued for a clozapine dispense unless the pharmacy provides a "Dispense Rationale" authorizing dispensing. The *Dispense Rationale* is valid for only 72 hours (3 calendar days) and can be provided a maximum of 3 times in a rolling six-month period.
- **Eligibility Check (EC):** The process inpatient pharmacies use to determine whether a patient can receive clozapine. Obtained by using the Clozapine REMS Program Website or Clozapine REMS Program Call Center, the EC verifies the patient is enrolled, the ANC is on file, current, and within acceptable range.
- **Inpatient pharmacy:** a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).
- **Outpatient pharmacy:** a pharmacy dispensing clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.
- **Absolute neutrophil count (ANC):** laboratory parameter for monitoring patients for clozapine-induced neutropenia.
- **Benign Ethnic Neutropenia (BEN):** a condition observed in certain ethnic groups whose average ANC is lower than "standard" laboratory ranges for neutrophils compared to the general population. Patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

2 Absolute Neutrophil Count (ANC), Neutropenia, and Patient ANC Monitoring

What is ANC?

Absolute neutrophil count (ANC) is the laboratory parameter for monitoring patients for clozapine-induced neutropenia. Prescribers must submit the ANC before starting and during clozapine treatment.

ANC is usually available as a component of the complete blood count (CBC), including differential:

- ANC is more relevant to drug-induced neutropenia than white blood cell (WBC) count
- ANC may also be calculated using the following formula:

$$\text{Absolute Neutrophil Count} \times \text{Total WBC count} = \text{Total percentage of neutrophils* obtained from the differential}$$

* neutrophils includes "segs" and "bands"

Other granulocytes (basophils and eosinophils) contribute minimally to neutropenia and their measurement is not necessary.

What is the risk of severe neutropenia associated with clozapine?

Clozapine can cause severe neutropenia, which can lead to serious infections and death. Severe neutropenia occurs in a small percentage of patients taking clozapine.

- Severe neutropenia is defined as ANC less than 500/ μL
- Severe neutropenia replaces the previous terms "severe leukopenia", "severe granulocytopenia", and "agranulocytosis"
- The risk appears greatest during the first 18 weeks of clozapine treatment
- The mechanism is not dose-dependent
- It is unclear if concurrent use of other drugs known to cause neutropenia increases the risk or severity of clozapine-induced neutropenia
- If clozapine is used concurrently with a medication(s) known to cause neutropenia:
 - Consider monitoring patients more closely than the treatment guidelines recommend, and
 - Consult with the treating oncologist in patients receiving concomitant chemotherapy

For a complete discussion of other risks, including other Boxed Warnings, please see the full Prescribing Information available at www.clozapinerems.com.

What is Benign Ethnic Neutropenia (BEN)?

BEN is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine.

When enrolling a patient in the Clozapine REMS Program, identify if the patient has documented BEN, so the patient is monitored according to the correct ANC monitoring algorithm.

A few important things to know about patients documented with BEN:

- It is most commonly observed in individuals of African descent (approximate prevalence of 25-50%), some Middle Eastern ethnic groups, and in other non-Caucasian ethnic groups with darker skin
- BEN is more common in men
- Patients with BEN have normal hematopoietic stem cell number and myeloid maturation, are healthy, and do not suffer from repeated or severe infections
- Patients with BEN **are not** at increased risk for developing clozapine-induced neutropenia

Additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Consider a hematology consultation before starting or during clozapine treatment as necessary.

What are the treatment recommendations and monitoring requirements for patients taking clozapine?

The recommended ANC monitoring frequency for patients in the general population as well as patients who have documented BEN is shown in [Table 1](#). The table also provides recommendations for monitoring patients who experience a decrease in ANC during the course of treatment.

Patients may transition to less frequent ANC monitoring based on the number of weeks of continuous clozapine therapy and the patient's ANC's. Weekly ANC monitoring is required for all patients during the first six months of treatment. If the ANC remains in the normal range (ANC greater than or equal to 1500/ μ L for the general population, ANC greater than or equal to 1000/ μ L for patients with BEN) for the first six months of therapy, monitoring frequency can be reduced to every two weeks. If the patient's ANC continues to remain in the normal range for the second six months of treatment, ANC monitoring may be reduced to monthly.

The Clozapine REMS Program will alert prescribers via their website dashboard when a patient qualifies for a change in ANC monitoring frequency.



Before starting treatment with clozapine, the baseline ANC must be:

- at least 1500/ μ L for the general population
- at least 1000/ μ L for patients diagnosed with BEN

During treatment, monitor ANC regularly as described in [Table 1](#) below.

Table 1: Recommended Monitoring Frequency and Clinical Decisions by ANC Level

ANC Level	Treatment Recommendation	ANC Monitoring
<p>Normal Range for a New Patient GENERAL POPULATION</p> <ul style="list-style-type: none"> • ANC \geq 1500/μL <p>BEN POPULATION</p> <ul style="list-style-type: none"> • ANC \geq 1000/μL • Obtain at least two baseline ANC levels before initiating treatment 	<ul style="list-style-type: none"> • Initiate treatment • If treatment interrupted: <ul style="list-style-type: none"> - < 30 days, continue monitoring as before - \geq 30 days, monitor as if new patient • Discontinuation for reasons other than neutropenia 	<ul style="list-style-type: none"> • Weekly from initiation to six months • Every two weeks from 6 to 12 months • Monthly after 12 months • See Section 2.4 of the full Prescribing Information
<p>Mild Neutropenia (1000 - 1499/μL)*</p>	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Continue treatment <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Mild neutropenia is normal range for BEN population, continue treatment • Obtain at least two baseline ANC levels before initiating treatment • If treatment interrupted <ul style="list-style-type: none"> - < 30 days, continue monitoring as before - \geq 30 days, monitor as if new patient • Discontinuation for reasons other than neutropenia 	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Three times weekly until ANC \geq 1500/μL • Once ANC \geq 1500/μL return to patient's last "Normal Range" ANC monitoring interval** <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Weekly from initiation to six months • Every two weeks from 6 to 12 months • Monthly after 12 months • See Section 2.4 of the full Prescribing Information
<p>Moderate Neutropenia (500 - 999/μL)*</p>	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Recommend hematology consultation • Interrupt treatment for suspected clozapine-induced neutropenia • Resume treatment once ANC normalizes to \geq 1000/μL <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Recommend hematology consultation • Continue treatment 	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 1000/μL, then • Three times weekly until ANC \geq 1500/μL • Once ANC \geq 1500/μL check ANC weekly for 4 weeks, then return to patient's last "Normal Range" ANC monitoring interval** <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Three times weekly until ANC \geq 1000/μL or \geq patient's known baseline. • Once ANC \geq 1000/μL or patient's known baseline, check ANC weekly for 4 weeks, then return to patient's last "Normal BEN Range" ANC monitoring interval**
<p>Severe Neutropenia (< 500/μL)*</p>	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Recommend hematology consultation • Interrupt treatment for suspected clozapine-induced neutropenia • Do not rechallenge unless prescriber determines benefits outweigh risks <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Recommend hematology consultation • Interrupt treatment for suspected clozapine-induced neutropenia • Do not rechallenge unless prescriber determines benefits outweigh risks 	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 1000/μL • Three times weekly until ANC \geq 1500/μL • If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC \geq 1500/μL <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 500/μL • Three times weekly until ANC \geq patient's established baseline • If patient rechallenged, resume treatment as a new patient under "Normal BEN Range" monitoring once ANC \geq 1000/μL or at patient's baseline

* Confirm all initial reports of ANC less than 1500/ μ L (ANC < 1000/ μ L for BEN patients) with a repeat ANC measurement within 24 hours

** If clinically appropriate

Can a patient continue clozapine treatment with an ANC less than 1000/ μ L?

For Patients in the General Population

Yes; prescribers may choose to continue clozapine treatment in patients with ANCs less than 1000/ μ L. However, prescribers should follow the treatment recommendations as noted in [Table 1](#) and carefully determine if the benefits of continuing clozapine treatment outweigh the risks.

The recommendations to interrupt treatment are provided to ensure patient safety. If monitoring ANC and symptoms of infection is not done appropriately, patients with ANCs less than 1000/ μ L are at risk of developing complications of severe neutropenia including serious infection and death.

Refer to [Section 3](#) of this document for more details on how to authorize a patient to continue treatment.

For Patients with documented BEN

Yes; the Prescribing Information for clozapine recommends interrupting clozapine treatment for patients with BEN only when the ANC is **less than 500/ μ L**. No interruption in treatment is recommended for ANC 500-999/ μ L, although a hematology consultation is recommended.

If a patient develops a fever, how is clozapine treatment managed?

Generally, clozapine treatment should be interrupted as a precautionary measure in any patient who develops a fever of 38.5°C (101.3°F) or greater, and an ANC should be obtained. Fever is often the first sign of a neutropenic infection.

If fever occurs in any patient with an ANC less than 1000/ μ L, initiate appropriate neutropenia work-up and treatment for infection. Refer to [Table 1](#) for ANC monitoring recommendations.

If any patient presents with evidence of fever and/or neutropenia, consider a hematology consultation.

How is clozapine discontinued for neutropenia?

The method of treatment discontinuation will vary depending on the patient's most recent ANC result. Abrupt treatment discontinuation is necessary for moderate to severe neutropenia that you suspect is caused by clozapine.



REMEMBER to submit the decision to discontinue clozapine for a patient to the Clozapine REMS Program. You can complete it one of three ways:



By signing into the Clozapine REMS Program Website at www.clozapinerems.com



By calling the Clozapine REMS Program Contact Center at 844-267-8678



By completing the “Patient Update – Change Treatment Status” section of the *Clozapine REMS ANC Lab Reporting Form* and faxing it to the Clozapine REMS Program at 844-404-8876

How is a patient monitored if clozapine treatment is discontinued for neutropenia?

After **discontinuing** clozapine, monitor ANC according to the recommendations in [Table 2](#) as shown below.

Table 2: Recommended monitoring frequency when clozapine treatment is discontinued

<p>Moderate Neutropenia (500 to 999/μL)*</p>	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 1000/μL, then • Three times weekly until ANC \geq 1500/μL
<p>Severe Neutropenia (less than 500/μL)*</p>	<p>GENERAL POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 1000/μL, then • Three times weekly until ANC \geq 1500/μL <p>BEN POPULATION</p> <ul style="list-style-type: none"> • Daily until ANC \geq 500/μL • Three times weekly until ANC \geq patient's established baseline

* Confirm all initial reports of ANC less than 1500/ μ L (ANC < 1000/ μ L for BEN patients) with a repeat ANC measurement within 24 hours

- Monitor ANC in any patient reporting a fever (temperature of 38.5°C or 101.3°F or greater) during the 2 weeks after discontinuation
- Monitor all patients carefully for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such as profuse sweating, headache, nausea, vomiting, and diarrhea
- For abrupt clozapine discontinuation for a reason unrelated to neutropenia, continuation of the existing ANC monitoring is recommended for general population patients until their ANC is greater than or equal to 1500/ μ L and for patients with documented BEN until their ANC is greater than or equal to 1000/ μ L or above their baseline

Refer to Section 2.4 of the clozapine Prescribing Information for further information.

Can a patient be rechallenged with clozapine?

Yes; for some patients who experience, or have experienced, moderate clozapine-related neutropenia (ANC less than 1000/ μL) or severe clozapine-related neutropenia (ANC less than 500/ μL), the risk of serious psychiatric illness from discontinuing clozapine may be greater than the risk of rechallenge. This may be relevant for patients with severe schizophrenic illness who have no treatment option other than clozapine.

In making the decision to rechallenge a patient, consider:

- A hematology consult
- The ANC ranges defined in the full Prescribing Information
- The patient's medical and psychiatric history
- A discussion with the patient and his or her caregiver about the benefits and risks of clozapine rechallenge
- The severity and characteristics of the neutropenic episode




Refer to Section 2.5 in the clozapine Prescribing Information for more information on how to restart clozapine in patients who have discontinued clozapine.

3 Clozapine REMS Program Requirements for Prescribers

What is the role of prescribers in the Clozapine REMS Program?

Step 1: Review the full Prescribing Information for clozapine

Step 2: Certify* in the Clozapine REMS Program by:

-  Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-  Passing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
-  Completing the *Clozapine REMS Prescriber Enrollment Form*

Step 3: Enroll every new patient in the Clozapine REMS Program

Step 4: Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death

Step 5: Check the ANC for each patient according to the monitoring requirement

Step 6: Submit each ANC for each patient to the Clozapine REMS Program within 7/15/31 days of the lab draw date according to the patient's monitoring frequency on the file with the Clozapine REMS Program

Step 7: Provide authorization to continue treatment, if necessary, through the Clozapine REMS Program when the patient's ANC results meet criteria for interruption of therapy and you decide to continue clozapine treatment.

Refer to the section titled "What is a *Treatment Rationale*?" on [page 14](#) for more details on how to authorize a patient to continue treatment.



Prescribers may designate other healthcare providers or office staff to enroll patients and enter ANC results on the prescriber's behalf.



Find more information about designees at www.clozapinerems.com.

*Prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) are not required to certify in the Clozapine REMS Program. Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, he/she must be enrolled by a certified prescriber before being allowed to receive clozapine.



What do I tell my patients about clozapine?

Use the patient counseling tool entitled, *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia*. Review this information with patients or their caregivers as often as needed to ensure they understand the risk of neutropenia associated with clozapine and the importance of ANC monitoring. Refer to Section 17 (Patient Counseling Information) of the clozapine Prescribing Information for additional important counseling messages for your clozapine patients.

You may choose not to provide *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* to the patient or caregiver if you determine that the patient's adherence to clozapine treatment will be negatively impacted by providing it.

How do I enroll a patient?

You can enroll a patient in one of two ways:

-  By signing in to the Clozapine REMS Program Website at www.clozapinerems.com and enrolling the patient online
-  By downloading a *Clozapine REMS Patient Enrollment Form* from the Clozapine REMS Program Website at www.clozapinerems.com, and faxing the completed form to 844-404-8876

Complete a *Clozapine REMS Patient Enrollment Form* if:

- The patient has never been treated with clozapine before, or
- If you have never treated this patient with clozapine, regardless of the patient's history of clozapine treatment

What if my patient has been treated with clozapine before?

If you have treated the patient with clozapine after **October 1, 2012** and that patient was registered in any of the individual clozapine patient registries, the patient is listed in the Clozapine REMS Program where you can access the patient's profile.

Patient information before **October 1, 2012** was not transferred into the Clozapine REMS Program, unless the patient was listed in the National Non-Rechallenge Master File (NNRMF).

If another prescriber has previously treated the patient with clozapine, you must enroll the patient by completing and submitting the *Clozapine REMS Patient Enrollment Form* to the Clozapine REMS Program (online or by fax) to be able to access the patient's ANC history.

If you cannot find the patient, contact the Clozapine REMS Program Contact Center at 844-267-8678 for assistance or re-enroll the patient.

If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

How do I find out if my patient was listed in the National Non-Rechallenge Master File (NNRMF)?

Patients were listed in the NNRMF if a patient had a WBC less than 2,000/ μ L or an ANC less than 1,000/ μ L.



All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program. These patients are identified with a red flag in the Clozapine REMS Program at www.clozapinerems.com.

To access patient information through the Clozapine REMS Program, you must enroll the patient. If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

How do I report ANC results for my patients?

For patients in an outpatient setting:

Prescribers or their designees are responsible for submitting ANC for each prescription to the Clozapine REMS Program before clozapine can be dispensed by a pharmacy to patients treated on an outpatient or chronic basis, including but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

For patients in an inpatient setting:

Pharmacists must verify the patient is enrolled in the Clozapine REMS Program before clozapine can be dispensed by a pharmacy within a facility that dispenses clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).




While you are not required to submit ANCs to the Clozapine REMS Program before clozapine can be dispensed to a patient in an inpatient setting, you (or the certified pharmacy responsible for the patient in the hospital) are encouraged to submit ANCs to the Clozapine REMS Program with a blood draw date within the patient's monitoring frequency on file with the Clozapine REMS Program.



While the patient is hospitalized, remember to monitor ANC according to the patient's ANC monitoring frequency on file with the Clozapine REMS Program.

For Prescribers in an Outpatient setting:

Prescribers or their designees must report the ANC one of three ways:

-  By signing in to the Clozapine REMS Program Website at www.clozapinerems.com
-  By calling the Clozapine REMS Program Contact Center at 844-267-8678
-  By faxing the ANC results to the Clozapine REMS Program at 844-404-8876

* When using the *Clozapine REMS ANC Lab Reporting Form* to submit patient ANC to the Clozapine REMS Program, prescribers can enter the Patient ID number found on the prescriber dashboard on the website. This is also known as the Patient Enrollment ID.

When should I submit a patient's ANC to the Clozapine REMS Program?

Patient ANC information should be submitted to the Clozapine REMS Program as soon as possible after the patient blood draw occurs; but, must be submitted according to the table below, which is consistent with a patient's monitoring frequency.

Monitoring Frequency	ANC Blood Draw Date
Weekly	Labs must be within 7 days of the lab draw* date
Every two weeks	Labs must be within 15 days of the lab draw* date
Monthly after 12 months	Labs must be within 31 days of the lab draw* date

*Assumes the lab draw date is day 0.

Prescribers must ensure their patients are on the appropriate monitoring frequency and adhere to the corresponding blood draw dates in order for their patient to receive clozapine.

How do I authorize continuation of clozapine when my patient's ANC is less than 1000/ μ L (general population) or less than 500/ μ L (patients with BEN)?

When a patient's ANC is less than 1000/ μ L (general population) or less than 500/ μ L (patients with documented BEN), a prescriber may provide a *Treatment Rationale* to authorize clozapine treatment to continue.

What is a Treatment Rationale?



An authorization called a *Treatment Rationale* requires the prescriber to confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia.

How can I provide a Treatment Rationale?

- The Clozapine REMS Program will alert the prescriber if an ANC is submitted that is below the recommended thresholds for a patient; clozapine will not be dispensed to the patient unless the prescriber provides a *Treatment Rationale* to authorize continuation of treatment.
- The Clozapine REMS Program will change the treatment status automatically of a patient with a low ANC to "interrupted" or "discontinued", according to the recommendations in the Prescribing Information, found in [Table 1](#) above.

- If the prescriber wishes to continue clozapine treatment, the prescriber must change the patient's treatment status to "active", and confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia (i.e., by providing a *Treatment Rationale*).

Prescribers must confirm treatment continuation one of two ways:

-  By signing in to the Clozapine REMS Program Website at www.clozapinerems.com and providing a *Treatment Rationale* online
 -  By faxing a signed *Clozapine REMS ANC Lab Reporting Form* to 844-404-8876 with a completed *Treatment Rationale* section
- After the prescriber provides the *Treatment Rationale*, the Clozapine REMS Program will issue a PDA which allows the outpatient pharmacy to dispense clozapine.
 - Information provided in the Clozapine REMS Program is not a substitute for appropriate documentation in the patient's medical record regarding the prescriber's decision to continue, interrupt, or discontinue clozapine treatment.

What if my clozapine patient is under hospice care?

For hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every six months, after a discussion with the patient and his/her caregiver. Individual treatment decisions should weigh the importance of monitoring ANC in the context of the need to control psychiatric symptoms and the patient's terminal illness.

4 Clozapine REMS Program Requirements for Pharmacies

What types of pharmacies must be certified?

All inpatient and outpatient pharmacies must certify in the Clozapine REMS Program to purchase and dispense clozapine. The requirements for outpatient pharmacies are different from the requirements for inpatient pharmacies. The different requirements are explained in the section, "[How do I verify the patient is authorized to receive clozapine?](#)"

An **inpatient pharmacy** is a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

An **outpatient pharmacy** is a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

The designated authorized representative for the pharmacy will complete the *Clozapine REMS Inpatient Pharmacy Enrollment Form* and/or the *Clozapine REMS Outpatient Pharmacy Enrollment Form*. This form is to certify a single inpatient or a single outpatient pharmacy location.

- **For outpatient pharmacies**, the authorized representative must confirm if your pharmacy management system can or cannot support electronic communication with the Clozapine REMS Program to verify the Clozapine REMS Program safe-use requirements
- **For inpatient pharmacies**, a pharmacy management system that supports electronic communication with the Clozapine REMS Program is not needed

The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax. Certifying multiple pharmacy locations must be completed online.

Who is an Authorized Representative?

In general, an authorized representative for a pharmacy:

- Coordinates the activities required in the Clozapine REMS Program
- Establishes and implements processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program

Specific duties of an authorized representative are noted in the section, "[What is the role of the pharmacy authorized representative in the Clozapine REMS Program?](#)"

For a pharmacy with a single location, the authorized representative may be a:

- Pharmacy Manager, or
- Staff Pharmacist

If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the authorized representative may be a:

- Director of Pharmacy Services, or
- Corporate Executive overseeing Pharmacy Services

What is a Predispense Authorization (PDA)?




Before clozapine can be dispensed to a patient by a pharmacy dispensing clozapine to patients treated on an **outpatient or chronic basis**, including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, the pharmacy must obtain a PDA each time from the Clozapine REMS Program. A PDA is an electronic code that indicates the Clozapine REMS Program has verified:

- Patient is enrolled in the Clozapine REMS Program
- Prescriber is certified in the Clozapine REMS Program
- Pharmacy is certified in the Clozapine REMS Program
- ANC is within acceptable range described in the Prescribing Information, or the prescriber has provided a *Treatment Rationale*
- ANC is current (i.e., submitted within 7/15/31 days prior to the PDA transaction date according to the patient's monitoring frequency on file with the Clozapine REMS Program)



Once a PDA is obtained, the outpatient pharmacy can dispense clozapine to the patient.

Obtain a PDA in one of three ways:

-  By enabling your pharmacy management system to support electronic communication with the Clozapine REMS Program
-  By using the Clozapine REMS Program Website at www.clozapinerems.com
-  By calling the Clozapine REMS Program Contact Center at 844-267-8678







Note: Inpatient pharmacies are not required to obtain a PDA. Inpatient pharmacies must complete an *Eligibility Check* for each patient before dispensing clozapine. For additional details about the *Eligibility Check*, please refer to the *Clozapine REMS Eligibility Check Fact Sheet*, or visit the Clozapine REMS Program Website at www.clozapinerems.com.

What is the role of the pharmacy authorized representative in the Clozapine REMS Program?

Designate an authorized representative for your pharmacy. The authorized representative for every pharmacy must:

Step 1: Review the Prescribing Information for clozapine

Step 2: Certify in the Clozapine REMS Program by:

-   Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-   Passing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
-   Completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form and/or the Clozapine REMS Outpatient Pharmacy Enrollment Form*

Step 3: Ensure training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements

Step 4: Put processes and procedures in place to ensure pharmacy staff obtain a PDA (for outpatient pharmacies) or conduct an *Eligibility Check* (for inpatient pharmacies) to verify that it is safe to dispense clozapine

Step 5: Renew certification in the Clozapine REMS Program every two years from initial enrollment to maintain certification to order and dispense clozapine

In addition, the authorized representative of a pharmacy that uses electronic telecommunication verification must:

- Ensure the pharmacy enables its pharmacy management system to support electronic communication with the Clozapine REMS Program
- Run the verification test transactions to ensure system connectivity

How do I verify the patient is authorized to receive clozapine?

How you verify the patient is authorized to receive clozapine depends on your pharmacy type (outpatient or inpatient) and your pharmacy's telecommunication capabilities.



Dispensing Information for All Outpatient Pharmacies

- The amount of clozapine that can be dispensed depends on when the patient's next blood draw is scheduled to occur according to the monitoring frequency requirements.
- Pharmacies should dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber.
- If you do not receive a PDA, you will receive a message explaining why you are not authorized to dispense clozapine to the patient.
- If a PDA is not received because a patient's prescriber is not certified in the Clozapine REMS Program, certified pharmacies can apply clinical judgment and provide a *Dispense Rationale* to dispense clozapine.

Outpatient Pharmacies WITH Electronic Telecommunication Verification

Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements, which include how your pharmacy will ensure a PDA is obtained each time a clozapine prescription is dispensed.

Dispensing

Before you dispense clozapine to each patient, you must:

Step 1: Obtain a PDA using the pharmacy management system



All prescriptions require a PDA prior to dispensing, including those paid for in cash and/or not using insurance for reimbursement.

Step 2: Before issuing the PDA, the Clozapine REMS Program will verify the following:

- The **prescriber is certified** in the Clozapine REMS Program
- The **patient is enrolled** in the Clozapine REMS Program
- The **outpatient pharmacy is certified** in the Clozapine REMS Program
- The **ANC is current** according to the patient's monitoring frequency on file (i.e., the most recent ANC submitted is within 7/15/31 days prior to the PDA transaction date) with the Clozapine REMS Program
- The **ANC is within an acceptable range** described in the Prescribing Information, or the prescriber has provided a *Treatment Rationale*

Step 3: Once a PDA is obtained, dispense clozapine to the patient.

- You do not need to document the PDA on the prescription or in your pharmacy management system
- If you do not receive a PDA, the Clozapine REMS Program will provide a message to explain why you are not authorized to dispense clozapine to the patient
- The pharmacist is encouraged to submit the patient's ANC to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency, or if you have an ANC more current than the one reported in the PDA result, submit it to the Clozapine REMS Program by:



By signing in to the Clozapine REMS Program Website at www.clozapinerems.com



By calling the Clozapine REMS Program Contact Center at 844-267-8678



By faxing the ANC results to the Clozapine REMS Program at 844-404-8876

Outpatient Pharmacies *WITHOUT* Electronic Telecommunication Verification

Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements, which include how your pharmacy will ensure a PDA is obtained each time a clozapine prescription is dispensed.

Dispensing

Before you dispense clozapine to each patient, you must obtain a PDA by:

Step 1: Access the Clozapine REMS Program in one of two ways:



Sign in to the Clozapine REMS Program Website at www.clozapinerems.com, or



Call the Clozapine REMS Program Contact Center at 844-267-8678

Step 2: Provide the following information:

- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days' Supply
- Quantity

Step 3: Before issuing the PDA, the Clozapine REMS Program will verify the following for you:

- The **prescriber is certified** in the Clozapine REMS Program
- The **patient is enrolled** in the Clozapine REMS Program
- The **outpatient pharmacy is certified** in the Clozapine REMS Program
- The **ANC is current** according to the patient's monitoring frequency on file (i.e., the most recent ANC submitted is within 7/15/31 days prior to the PDA transaction date) with the Clozapine REMS Program
- The **ANC is within an acceptable range** described in the Prescribing Information, or the prescriber has provided a *Treatment Rationale*

Step 4: Once a PDA is obtained, you can dispense clozapine to the patient.

- You do not need to document the PDA on the prescription or in your pharmacy management system
- If you do not receive a PDA, the Clozapine REMS Program will provide a message to explain why you are not authorized to dispense clozapine to the patient
- The pharmacist is encouraged to submit the patient's ANC to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency.

Inpatient Pharmacies

Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements.

Obtaining a PDA is not required in an inpatient setting.

Dispensing

Before you dispense the first inpatient dose of clozapine to each patient, the inpatient pharmacist must complete an *Eligibility Check* as follows:

Step 1: Access the Clozapine REMS Program by:

-  Signing in to the website at www.clozapinerems.com, or
-  Calling the Clozapine REMS Program Contact Center at 844-267-8678



Step 2: Obtain an *Eligibility Check* to verify the patient is enrolled in the Clozapine REMS Program. To obtain an *Eligibility Check*, you must provide the following information:

- Pharmacy Location Information
- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC

Step 3: Verify the ANC is within acceptable range as described in the Prescribing Information, or the prescriber has authorized the continuation of clozapine treatment by either (a) completing an *Eligibility Check* or (b) reviewing the patient's medical record in their hospital's medical record system.

Step 4: Verify the ANC is current according to the patient's ANC monitoring frequency on file (i.e., submitted within 7/15/31 days prior to the *Eligibility Check* transaction date) with the Clozapine REMS Program by either (a) completing an *Eligibility Check* or (b) reviewing the patient's medical record in their hospital's medical record system.

The pharmacist is encouraged to submit the patient's ANC obtained at the inpatient facility to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency. ANC results may be submitted:

-  By calling the Clozapine REMS Program Contact Center at 844-267-8678
-  By faxing the ANC results to the Clozapine REMS Program at 844-404-8876

How does an outpatient pharmacy authorize continuation of clozapine when the patient's physician is not certified in the Clozapine REMS Program?

Outpatient pharmacies may provide a *Dispense Rationale* to dispense clozapine to a patient.

What is a Dispense Rationale?

The Clozapine REMS Program provides certified outpatient pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient's prescriber is not certified in the Clozapine REMS Program. In order to dispense to a patient who does not have an associated certified prescriber, the pharmacist must provide a *Dispense Rationale*.

- The Clozapine REMS Program will alert the pharmacy if the prescriber is not certified in the Clozapine REMS Program when a PDA is requested. A PDA will not be issued for a clozapine dispense unless the pharmacy provides a *Dispense Rationale* to authorize a dispense.
- In order for a patient to be eligible for a *Dispense Rationale*, that patient must:
 - Be enrolled in the Clozapine REMS Program
 - Have an acceptable ANC value on file or, if the ANC on file is low indicating moderate or severe neutropenia, a *Treatment Rationale* must be on file
- The *Dispense Rationale* is valid for 72 hours (3 calendar days).
- The *Dispense Rationale* will be limited to no more than three (3) *Dispense Rationales* for an individual patient within a rolling six (6) month period.
- Pharmacies must fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.

How can I provide a Dispense Rationale?

Certified authorized representatives and enrolled pharmacy staff for certified pharmacies provide the *Dispense Rationale* electronically via one of two available processes, depending on whether your pharmacy requests a *Predispense Authorization* by using the Clozapine REMS Program Website (see section A. below) or by using the pharmacy network system, i.e., "switch" (see section B. below).

A. Pharmacies using the Clozapine REMS Program Website to request a *Predispense Authorization* should:

- Step 1:** Log in to the Clozapine REMS Program Website at www.clozapinerems.com.
- Step 2:** Access the dashboard.
- Step 3:** Select '*Predispense Authorization*' from the drop-down menu and click the **Go** button.
- Step 4:** Enter the patient information on the '*Predispense Authorization*' screen and click **Submit**. The '*Predispense Authorization Result*' screen will appear with a reject message.
- Step 5:** Click the '*Provide a Dispense Rationale for this patient*' check box at the bottom of the '*Predispense Authorization Result*' screen and click the **Submit** button.
- Step 6:** If the *Dispense Rationale* was provided successfully, a success screen will appear.

B. Pharmacies using the using the pharmacy network system (i.e., “switch”) to request a *Predispense Authorization* should:

- Step 1:** Log in to the Clozapine REMS Program Website at www.clozapinerems.com.
- Step 2:** Access the dashboard.
- Step 3:** Select '*Dispense Rationale*' from the drop-down menu and click the **Go** button.
- Step 4:** Enter the patient information on the *Dispense Rationale* screen and click **Submit**.
- Step 5:** The '*Dispense Rationale Result*' screen will appear with a reject message similar to the switch reject message.
- Step 6:** Click on the '*Provide a Dispense Rationale for this patient*' check box at the bottom of the '*Dispense Rationale Result*' screen and click **Submit**.
- Step 7:** If the *Dispense Rationale* is provided successfully, a **success** screen will appear.
- Step 8:** Reprocess the claim transaction through the pharmacy switch system.
- Note: Please wait approximately 2 minutes before going back to the switch to reprocess the claim transaction.

If you experience any issues, please call the Clozapine REMS Program Contact Center at 844-267-8678.

5 Reporting Adverse Events Associated with Clozapine

Report suspected adverse events directly to the Clozapine REMS Program Contact Center at 844-267-8678. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088 or by mail using Form 3500A, available at www.fda.gov/medwatch.

6 Clozapine REMS Program Information and Resources

Additional Clozapine REMS Program information and resources are available online at www.clozapinerems.com or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

Please select the best answer for each of the following questions. All questions must be answered correctly to become certified:

Question 1

All clozapine products are only available under the single shared Clozapine REMS Program.

- A. True
- B. False

Question 2

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- A. True
- B. False

Question 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L
- C. An absolute neutrophil count (ANC) less than 500/ μ L
- D. None of the above

Question 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ μ L for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ μ L for a patient who is part of the general population (i.e., the patient does not have documented BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

Please fax this *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below to ensure it is associated with your program record.

Name: _____ NPI: _____ Fax: _____

Question 5

Before clozapine is dispensed to a patient, a certified prescriber must:

- A. Determine if the patient has documented BEN
- B. Enroll the patient in the Clozapine REMS Program
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and submit it to the Clozapine REMS Program
- F. All of the above

Question 6

In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

Question 7

Before clozapine can be dispensed, a pharmacist in an outpatient pharmacy must:

- A. Verify the patient is enrolled in the single shared Clozapine REMS Program
- B. Verify the prescriber is certified in the single shared Clozapine REMS Program
- C. Verify the ANC is acceptable or verify the prescriber has authorized continuing treatment if the ANC is abnormal
- D. Obtain a "Predispose Authorization" each time from the Clozapine REMS Program
- E. All of the above

Question 8

How much clozapine can be dispensed?

- A. A 30-day supply
- B. A 90-day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

Please fax this *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below to ensure it is associated with your program record.

Name: _____ NPI: _____ Fax: _____

Question 9

Regarding patients with documented BEN, which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

Question 10

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

Question 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC $\geq 1500/\mu\text{L}$ if the patient is part of the general population (i.e., if the patient does not have documented BEN)
- B. Mild neutropenia is within the normal range for a patient with documented BEN
- C. If the patient has documented BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

Please fax this *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below to ensure it is associated with your program record.

Name: _____ NPI: _____ Fax: _____

Question 12

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
- D. None of the above

Question 13

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

Please fax this *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below to ensure it is associated with your program record.

Name: _____ NPI: _____ Fax: _____

Instructions

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference you list below.

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to become certified and prescribe clozapine, you must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
3. Complete and submit this one-time *Clozapine REMS Prescriber Enrollment Form*¹ along with the completed *Clozapine REMS Knowledge Assessment for Healthcare Providers*

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

Prescriber Responsibilities

By signing this form, I attest that:

1. I understand that clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements to prescribe clozapine.
2. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, reviewed the clozapine Prescribing Information, and successfully completed the *Clozapine REMS Knowledge Assessment for Healthcare Providers*.
3. I understand the risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
4. Prior to initiating treatment, I agree to provide *A Guide for Patients and Caregivers: What You Need to Know about Clozapine* to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing *A Guide for Patients and Caregivers: What You Need to Know about Clozapine*.
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program.
6. I understand the absolute neutrophil count (ANC) testing and monitoring requirements as described in the clozapine Prescribing Information.
7. I understand there is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN).
8. I will order ANC testing for each patient according to the clozapine Prescribing Information.
9. I will submit and verify the ANC according to each patient's monitoring frequency on file with the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed.
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0
10. I will verify the patient's monitoring frequency on file with the Clozapine REMS Program is aligned with the patient's monitoring frequency as described in the Prescribing Information.
11. I understand that, as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed.
12. I agree that personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
13. I understand that clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
14. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

Prescriber Information (All Fields Required Unless Otherwise Indicated)

First Name:	MI (opt):	Last Name:
NPI:	DEA:	
Email:	Credentials (MD, DO, NP, PA):	
Clinic/Practice Name:		
Address:		
City:	State:	Zip Code:
Phone:	Ext (opt):	Fax:
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax		
Prescriber's Signature: _____		Date (MM/DD/YYYY): _____

¹Prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) are not required to be certified in the Clozapine REMS Program. Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine.

Instructions

For immediate online absolute neutrophil count (ANC) reporting, please go to www.clozapinerems.com.

Use this form to submit ANC monitoring information or update patient information.

Prescribers must:

- Order ANC according to the monitoring frequency described in the Prescribing Information.
- Submit ANC according to the patient's monitoring frequency on file with the Clozapine REMS Program:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of the lab draw* date

*Assumes the lab draw date is day 0

Section 1: ANC Lab Reporting and Prescriber Information (All Fields Required)

Name:		NPI or DEA:	
Phone:	Email:	Fax:	
Submitter:	<input type="checkbox"/> Prescriber	<input type="checkbox"/> Prescriber Designee	<input type="checkbox"/> Pharmacy

Patient Information (All Fields Required Unless Otherwise Indicated)

Name:		REMS Patient ID (optional):	
Date of Birth (MM/DD/YYYY):	Zip Code:	Gender:	

ANC Monitoring (All Fields Required)

Blood Draw Date (MM/DD/YYYY):	ANC (per μ L):
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Section 2: Patient Treatment Status Update (If Applicable)

Complete this section to change this patient's treatment status. If this section is left blank, no changes will be made.

I want to change this patient's treatment status to: (check one)

- Active* Interrupted Discontinued

*Restarting or continuing clozapine requires a "Treatment Rationale" for patients with moderate or severe neutropenia. Please refer to *Treatment Rationale* section below.

Section 3: Prescriber or Designee Authorization: Patient Monitoring Frequency Update (If Applicable)

Complete this section to change the patient's monitoring frequency. If this section is left blank, no changes will be made.

Based on the clozapine Prescribing Information, my patient is eligible for a change in ANC monitoring frequency. By selecting 'monthly,' I attest that this patient: is eligible for monthly monitoring, has been on clozapine therapy continuously for one year, and all ANC results in the past 12 months have been within normal limits according to the Prescribing Information.

- Weekly Every 2 weeks Monthly

Prescriber or Designee Name:

Prescriber or Designee Signature:

Date (MM/DD/YYYY):

Section 4: Prescriber Authorization: Treatment Rationale or Hospice Care (If Applicable)

Complete this section to continue treatment if the patient has moderate neutropenia (ANC 500-999/ μ L for the general population) or severe neutropenia (ANC < 500/ μ L for general population and patients with benign ethnic neutropenia).

To provide a *Treatment Rationale*, check one and sign below:

- Benefits of continuing clozapine treatment outweigh the risk of neutropenia
- Until next ANC Lab
- Until (MM/DD/YYYY) _____ (not to exceed 6 months)
- This is a patient with documented benign ethnic neutropenia (no expiration)

For hospice patients (i.e., terminally-ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every 6 months after a discussion with the patient and his/her caregiver.

To change the monitoring frequency to once every 6 months for a hospice patient, check the box and sign below:

- This is a hospice patient

Prescriber Name:

NPI or DEA#:

Prescriber Signature:

Date (MM/DD/YYYY):

General Information

Certified prescribers may identify and associate designees to their Clozapine REMS Program certification record. This allows prescribers to approve responsible individual(s) to act on behalf of the certified prescriber for patients being treated with clozapine. Prescriber designees can submit absolute neutrophil count (ANC) test results, enroll, and manage patients with the following exceptions:

- Designees cannot categorize a patient as having benign ethnic neutropenia (BEN)
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate to severe neutropenia (general population) or severe neutropenia (patients with documented BEN)
- Designees cannot categorize a patient as a hospice patient

Prescriber Designee Responsibilities

To be a designee for a certified prescriber in the Clozapine REMS Program, you must understand that you are acting on behalf of the certified prescriber, and that you understand:

- Clozapine is only available through the Clozapine REMS Program and I must comply with the program requirements
- There is a risk of severe neutropenia associated with clozapine, which can lead to serious infection and death
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **Outpatient Settings**¹: An ANC must be submitted to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed and per the Monitoring Schedule described in the Prescribing Information:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0
- A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
- Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
- I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine only via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

Instructions

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference listed below.

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to access the Clozapine REMS Program as a prescriber designee, you must complete this form.

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Designee Requirements

By signing this form, I acknowledge that I will act on behalf of the certified prescriber identified below to comply with the Clozapine REMS Program requirements.

I understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
- There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
- Outpatient¹ Settings:** An absolute neutrophil count (ANC) must be submitted to the Clozapine REMS Program for each patient according to the following monitoring frequency, and I understand these results must be provided before clozapine can be dispensed:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date
- *Assumes the lab draw date is day 0
- A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient.
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
- Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
- I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

Designee Information (All Fields Required Unless Otherwise Indicated)

First Name:		Last Name:	
Email:			
Phone:		Ext (opt):	Fax:
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Prescriber Designee Signature:			Date (MM/DD/YYYY):

Prescriber Information (All Fields Required Unless Otherwise Indicated)

First Name:		Last Name:	
REMS Certification ID (opt):	DEA:	NPI:	
Prescriber's Signature:			Date (MM/DD/YYYY):

Please select the **best** answer for the following question. This question must be answered correctly to become certified:

Question 1

I have reviewed the requirements of the Clozapine REMS Program.

- A. Yes
- B. No

Please fax this *Clozapine REMS Knowledge Assessment for Prescriber Designees* to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below so we can correctly associate your progress with your program record.

Name: _____ NPI: _____ Fax: _____

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

A Guide for Patients and Caregivers:

What You Need to Know about Clozapine
and Neutropenia

What is clozapine?

Clozapine is a prescription medicine to treat people with schizophrenia who have not responded to other medicines. Clozapine may also reduce the risk of suicidal behavior.

What is the most serious risk information about clozapine treatment?

Clozapine can cause severe neutropenia, which can lead to serious infections and death. Neutropenia is a blood disorder that occurs when a certain type of white blood cells called neutrophils are not made or not enough of them are made. This makes it harder for your body to fight infections.

Before you can start clozapine and during treatment, you must have regular blood tests to measure the number of neutrophils you have in your blood. This test is called absolute neutrophil count (ANC). If the number of neutrophils, or ANC, is too low, you may have to stop clozapine. Your doctor will decide if or when it is safe to restart clozapine.

This is not the only serious risk associated with clozapine treatment. Talk to your doctor about the other serious risks.

What are the symptoms of neutropenia?

You might not have any symptoms at all. Getting your blood tested to measure the number of neutrophils is the only way to check for neutropenia. This helps your doctor know if you are more likely to get an infection.



If you have any of these symptoms, talk to your doctor right away

- Infection, including skin, throat, urinary tract, vaginal, pneumonia, or any other infection
- Fever or chills
- Sores or ulcers inside your mouth, gums, or on your skin
- Wounds that take a long time to heal
- Feel like you have the flu
- Pain or burning while urinating
- Unusual vaginal discharge or itching
- Abdominal pain
- Sores or pain in or around your rectal area
- Feel extremely weak or tired

What can I do to help reduce the risk of developing neutropenia?

Three important things you can do:

1. Have your blood tested as instructed by your doctor.
2. Tell your doctor about all the medicines you are taking (prescription and over-the-counter) and if you start a new medicine.
3. Tell your doctor right away if you get a fever or feel sick.

What is the Clozapine **R**isk **E**valuation and **M**itigation **S**trategy (REMS) Program?

Because of the risk of developing severe neutropenia, the Food and Drug Administration (FDA) has required a special program called a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) for clozapine. The purpose of the Clozapine REMS Program is to make sure that the benefits of clozapine treatment outweigh the risks.

What are the Clozapine REMS Program requirements for me?

To receive Clozapine:

1. **Review this Guide** with your doctor, pharmacist, or nurse.
2. Ask questions! **Make sure you understand** what you need to do to take part in the Clozapine REMS Program.
3. **Get your blood tested** as directed by your doctor. You must get your blood tested before you can receive clozapine from your pharmacy.
4. **Pick up your clozapine prescription** from a pharmacy that is part of the Clozapine REMS Program. Your doctor will help you find a pharmacy that participates in the Clozapine REMS Program.
5. **Tell your doctor right away** if you suffer any flu-like illness or fever while taking clozapine.

What are blood testing requirements for clozapine?

Get your Blood Tested

- Your doctor will give you an order to have blood tests done.
- You will need to get your blood tested on the following schedule or as directed by your doctor:
 - Weekly blood tests for the first 6 months you are taking clozapine
 - Every 2 weeks for the next 6 months if your ANC stays normal
 - Monthly after the first year if your ANC stays normal

Monitoring Results

- If your ANC is too low, your doctor will schedule blood tests more frequently.

Stay on Clozapine

- The Clozapine REMS Program will keep track of your blood test results so your doctor and pharmacist know if it is safe to fill your clozapine prescription.

No Blood No Drug

- *Remember: You must get your blood tested before you can receive clozapine from your pharmacy!*

Where can I get more information about clozapine?

If you would like more information, talk to your doctor or visit www.clozapinerems.com.

Report any side effects directly to the Clozapine REMS Program at [844-267-8678](tel:844-267-8678).

You can also report negative side effects to the FDA at www.fda.gov/medwatch, or call [800-FDA-1088](tel:800-FDA-1088).

Instructions for Prescribers

For immediate enrollment, please go to www.clozapinerems.com.

For enrollment via fax, please complete all required fields below and fax to 844-404-8876. For enrollment via the Clozapine REMS Program Contact Center, please call 844-267-8678. Enrollment confirmation will be sent via the contact preference specified on the prescriber's *Clozapine REMS Prescriber Enrollment Form*.

Complete this form for a patient if:

- The patient has never been treated with clozapine previously, or
- If you have never treated this patient with clozapine (regardless of the patient's history of clozapine treatment)

Clozapine is only available through the single shared Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to treat a patient with clozapine, the patient MUST be enrolled in the Clozapine REMS Program. To enroll a patient, you must:

1. Provide the patient or caregiver with *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia*
2. Inform the patient or caregiver about the risk of severe neutropenia with clozapine and the Clozapine REMS Program requirements unless you determine that the patient's adherence to the treatment regimen will be negatively impacted by providing the *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* and informing them about this risk
3. Complete and submit this *Clozapine REMS Patient Enrollment Form*

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Patient Information (All Fields Required)

First Name:		Last Name:	
Gender:	<input type="checkbox"/> Male	<input type="checkbox"/> Female	
Race:	<input type="checkbox"/> Caucasian	<input type="checkbox"/> African American	<input type="checkbox"/> Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other
Date of Birth (MM/DD/YYYY):		Zip Code:	
Is this patient actively on clozapine therapy?		<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown

Lab Information (Not Required for Enrollment, Required for Dispense)

Blood Draw Date (MM/DD/YYYY):	ANC (per µL):
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Prescriber Information (All Fields Required)

Name:		
NPI or DEA:		
Phone:	Email:	Fax:
Submitter:	<input type="checkbox"/> Prescriber	<input type="checkbox"/> Prescriber Designee

Benign Ethnic Neutropenia (BEN) Patient Attestation* (Signature required only for attestation of BEN diagnosis)

By signing below, I attest that the above is a patient with documented benign ethnic neutropenia.

Prescriber Signature: _____	Date (MM/DD/YYYY): _____
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*Enrollment for patients with documented BEN must be completed by faxing this signed document to 844-404-8876 or by accessing the Clozapine REMS Program Website at www.clozapinerems.com.

Instructions

Complete this form if your pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

If your pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, please complete the Clozapine REMS Outpatient Pharmacy Enrollment Form.

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. A confirmation will be sent via the contact preference chosen below.

Use this form to enroll a SINGLE pharmacy location. To enroll MULTIPLE pharmacy locations, you must go to www.clozapinerems.com.

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense clozapine, the pharmacy must designate an authorized representative.

The authorized representative for the pharmacy must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
3. Complete and submit this *Clozapine REMS Inpatient Pharmacy Enrollment Form* along with the completed *Clozapine REMS Knowledge Assessment for Healthcare Providers*
4. Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

Inpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. Establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the patient is enrolled in the Clozapine REMS Program by:
 - Signing in to the Clozapine REMS Program Website at www.clozapinerems.com to complete an "Eligibility Check", or
 - Calling the Clozapine REMS Program Contact Center at 844-267-8678
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the *Eligibility Check* date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine

Continued on Page 2

Inpatient Pharmacy Authorized Representative Responsibilities (continued)

4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Inpatient pharmacies must complete an *Eligibility Check* and verify ANC/prescriber authorization before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
7. Provide dispensing location information to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
9. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

Note: Inpatient pharmacies are not required to obtain a "Predispense Authorization" (PDA) prior to dispensing clozapine.

Inpatient Pharmacy Information (All Fields Required)

Pharmacy Name:

Address:

City:

State:

Zip Code:

Inpatient Pharmacy Identifiers (At Least One Required)

NCPDP:

NPI:

DEA:

Authorized Representative Information (All Fields Required)

First Name:

Last Name:

 Credentials: RPh PharmD BCPS Other

Phone:

Fax:

Email:

 Contact Preference (please select one): Email Fax
Authorized Representative Signature:**Date:**

Instructions

Complete this form if your pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

If your pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition), please complete the Clozapine REMS Inpatient Pharmacy Enrollment Form.

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. A confirmation will be sent via the contact preference chosen below.

Use this form to enroll a SINGLE pharmacy location. To enroll MULTIPLE pharmacy locations, you must go to www.clozapinerems.com.

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense clozapine, the pharmacy must designate an authorized representative.

The authorized representative for the pharmacy must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
3. Complete and submit this *Clozapine REMS Outpatient Pharmacy Enrollment Form* along with the completed *Clozapine REMS Knowledge Assessment for Healthcare Providers*
4. Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the

Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Outpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the "Predispense Authorization" (PDA) transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for continuing clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Provide dispensing location information to the Clozapine REMS Program
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
8. Outpatient pharmacies must obtain a PDA each time before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
9. Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program

Outpatient Pharmacy Authorized Representative Responsibilities (continued)

10. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

Can your outpatient pharmacy management system adjudicate claims online?

<input type="checkbox"/> Yes	By selecting "Yes", you are confirming that your pharmacy management system CAN support electronic communication with the Clozapine REMS Program using established telecommunications standards. Clozapine will be dispensed only after obtaining electronic authorization for all clozapine prescriptions, including cash claims, through your pharmacy management system. After submitting this form, you will receive instructions through the contact preference indicated in the authorized representative information section below on how to submit test transactions to the Clozapine REMS Program. This is to ensure that your pharmacy management system has been successfully configured to allow for communication with the Clozapine REMS Program.
<input type="checkbox"/> No	By selecting "No", you are confirming that your pharmacy management system CANNOT support electronic communication with the Clozapine REMS Program and you will access the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center to confirm safe-use conditions (as outlined in attestation #8) before dispensing each clozapine prescription. A complete PDA request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

Outpatient Pharmacy Information (All Fields Required)

Pharmacy Name:		
Address:		
City:	State:	Zip Code:

Outpatient Pharmacy Identifiers (NCPDP and NPI Required)

NCPDP:	NPI:	DEA:
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AUTHORIZED REPRESENTATIVE INFORMATION (All Fields Required)

First Name:		Last Name:	
Credentials: <input type="checkbox"/> RPh <input type="checkbox"/> PharmD <input type="checkbox"/> BCPS <input type="checkbox"/> Other			
Phone:	Fax:	Email:	
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Authorized Representative Signature:			Date:

Instructions

Contact your Pharmacy Network Account Manager to submit this form to the Clozapine REMS Program.

Please complete all required fields below. You will receive a confirmation via the contact preference you select below.

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to become certified and dispense clozapine, you must:

1. Select an authorized representative
2. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
3. Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
4. Complete and submit this *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form* along with the completed *Clozapine REMS Knowledge Assessment for Healthcare Providers*
5. Implement the necessary staff training and processes at both a headquarter level and at each dispensing location to comply with the Clozapine REMS Program requirements

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, the Prescribing Information, and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to contact them via phone, mail, or email to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the chain headquarters pharmacy, I agree to comply with the following program requirements:

1. My chain headquarters pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the Clozapine REMS Program, including the following, before dispensing clozapine:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained.
 - Through electronic communication with the Clozapine REMS Program using established telecommunications standards, my pharmacy will dispense clozapine to each patient only after obtaining authorization by electronically verifying documentation of the following:
 - Prescriber is certified in the Clozapine REMS Program
 - Pharmacy is certified in the Clozapine REMS Program
 - Patient is enrolled in the Clozapine REMS Program
 - The ANC is current based on the patient's monitoring frequency (within 7 days prior to the PDA transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - The last ANC is acceptable or the certified prescriber has authorized clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - This information will be verified each time by processing all clozapine prescriptions, including cash claims, through the pharmacy management system.
 - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit.
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine.
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program.
5. Clozapine REMS Program personnel may contact pharmacists in my pharmacies to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
6. For each trained dispensing location, provide the following information: Pharmacy Name, NCPDP or NPI or DEA, Address, Phone, Fax, Email, Store Number, and Responsible Pharmacist name.
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

Chain Headquarters Pharmacy Information (All Fields Required)

Name:		
Chain ID:		
Address:		
City:	State:	Zip Code:
Phone:	Fax:	

Authorized Representative Information (All Fields Required)

First Name:	Last Name:		
Credentials:	<input type="checkbox"/> RPh	<input type="checkbox"/> PharmD	<input type="checkbox"/> BCPS <input type="checkbox"/> Other
Phone:	Fax:	Email:	
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Authorized Representative Signature:			Date (MM/DD/YYYY):

Next Steps

1. Once this form is processed, you will receive instructions about submitting test transaction(s) to the Clozapine REMS Program to ensure that your pharmacy management system is successfully configured/updated to communicate with the Clozapine REMS Program.
2. After successful completion of the test transactions, you will receive a pharmacy certification confirmation. Upon receipt, your corporate pharmacy is certified and your dispensing locations are now eligible to complete training.
3. Once each dispensing location is trained, it is your responsibility to report documentation of training to the Clozapine REMS Program online via www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center to obtain instructions on providing a list of certified pharmacy locations. Once the Clozapine REMS Program confirms the required dispensing location information, the dispensing location will be certified and permitted to purchase, receive, and dispense clozapine.

Pharmacy Staff Enrollment Attestation Language – Web Only

Pharmacy staff can access the Clozapine REMS Program online at www.clozapinerems.com to complete the following:

- Enter an absolute neutrophil count (ANC) result for a patient
- Verify a patient is enrolled in the Clozapine REMS Program
- In an outpatient pharmacy:
 - Obtain a “Predispense Authorization” (PDA)^{1,2} or
 - Provide a “Dispense Rationale”
- In an inpatient pharmacy:
 - Complete an “Eligibility Check”

For online access to perform the above tasks, you must enroll by creating an account.

¹Inpatient pharmacies do not need to obtain a PDA.

²Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunications standards do not obtain a PDA via the Clozapine REMS Program Website.

By enrolling, you agree not to share your credentials for the Clozapine REMS Program Website or allow others to sign in to the website using your credentials.

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense clozapine. It is your responsibility to update this information as necessary.

Clozapine REMS Program

Frequently Asked Questions

General Section

1. What is a REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is an FDA required risk management plan that uses risk minimization strategies beyond the prescribing label to ensure that the benefits of prescription drugs outweigh their risks.

2. What is the Clozapine REMS Program?

The Clozapine REMS Program is an FDA-mandated program implemented by the manufacturers of clozapine. It is intended to help Healthcare Providers (HCPs) ensure the safety of patients taking clozapine. The Clozapine REMS Program is a single shared patient registry with requirements for prescribers, pharmacists, patients, and distributors, and reduces the multiple individual clozapine patient registries.

3. What are the goals of the Clozapine REMS Program?

The goals of the Clozapine REMS Program are to mitigate the risk of severe neutropenia associated with the use of clozapine by:

- Educating prescribers and pharmacists about the risk of severe neutropenia and appropriate monitoring requirements
- Informing patients about the risk of severe neutropenia and appropriate monitoring requirements
- Ensuring compliance with the monitoring frequency for absolute neutrophil count (ANC) prior to dispensing clozapine
- Ensuring the prescriber documents risk-benefit assessment when the patient's ANC is below the acceptable ranges described in the Prescribing Information
- Establishing long-term safety and safe-use of clozapine by enrolling patients who receive clozapine in the registry

Download program enrollment forms [here](#)

4. Where can I obtain the Prescribing Information for clozapine?

For current Prescribing Information for clozapine, visit the Resources page on the Clozapine REMS Program Website at www.clozapinerems.com.

5. What are the different roles of healthcare staff in the Clozapine REMS Program?

There are 4 different roles in the Clozapine REMS Program:

- Prescriber
- Prescriber Designee
- Pharmacy Staff
- Pharmacy Authorized Representative

Please refer to the description of each of these roles and determine which one best describes your duties in the Clozapine REMS Program. There are instances where a Healthcare Provider can serve in more than one role in the Clozapine REMS Program (click [here](#) for details). The high-level enrollment and/or certification requirements for each role are presented in the table below.

<u>Role</u>	<u>Certify or Enroll?</u>	<u>Description</u>
Prescriber	Certify	<p><u>Prescriber Certification Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center
Prescriber Designee	Enroll	<p><u>Prescriber Designee Enrollment Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Designee Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Become associated in the system with a certified prescriber • Be approved by a certified prescriber

<u>Role</u>	<u>Certify or Enroll?</u>	<u>Description</u>
Authorized Representative (Non-chain Pharmacy)	Certify	<p><u>Authorized Representative Certification Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Outpatient Pharmacy Enrollment Form</i> or the <i>Clozapine REMS Inpatient Pharmacy Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center • Renew certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment
Authorized Representative (Chain Pharmacy)	Certify	<p><u>Chain Pharmacy Authorized Representative Certification Process</u></p> <ul style="list-style-type: none"> • Work with an account manager from your pharmacy network system (i.e., the “switch”) provider to complete the certification process • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Renew certification of their pharmacies in the Clozapine REMS Program every two years from initial enrollment
Pharmacy Staff	Enroll	<p><u>Pharmacy Staff Enrollment Process</u></p> <ul style="list-style-type: none"> • Enroll online as pharmacy staff at www.clozapinerems.com • Become associated in the system with a pharmacy

Prescriber

<u>Definition</u>	<u>Responsibilities</u>
<p>A prescriber is any healthcare professional who prescribes clozapine to a patient</p> <p>**An inpatient pharmacy operates within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> • A prescriber must certify in the Clozapine REMS Program: <ul style="list-style-type: none"> ○ Review the Prescribing Information for clozapine ○ Review <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> ○ Complete the <i>Clozapine REMS Prescriber Enrollment Form</i> ○ Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> • Prescribers who order clozapine to be dispensed from an inpatient pharmacy** <u>are not required</u> to become certified in the Clozapine REMS Program <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • Prescribers who order clozapine to be dispensed from an outpatient pharmacy are required to become certified in the Clozapine REMS Program and must adhere to the following requirements: <ul style="list-style-type: none"> ○ Enroll every new patient in the Clozapine REMS Program ○ Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death ○ Check the ANC for each patient according to the monitoring requirements ○ Submit and verify ANC according to the patient's monitoring frequency on file with the Clozapine REMS Program: <ul style="list-style-type: none"> ▪ For weekly monitoring frequency, ANC must be submitted within 7 days of the lab draw* date ▪ For every two weeks monitoring frequency, ANC must be submitted within 15 days of the lab draw* date ▪ For monthly monitoring frequency, ANC must be submitted within 31 days of the lab draw* date <p>*Assumes the lab draw date is day 0</p> <p>In the future¹, a lab that is not current according to the patient's monitoring frequency will prevent a patient from receiving clozapine. The Clozapine REMS Program will then require the ANC to be aligned with the patient's monitoring frequency. In the interim, warning messages will alert the pharmacy if the ANC is overdue.</p>

<u>Definition</u>	<u>Responsibilities</u>
	<ul style="list-style-type: none"> • Provide a “Treatment Rationale” to authorize the continuation of clozapine therapy for patients with moderate or severe neutropenia if it is determined that: <ul style="list-style-type: none"> ○ The benefits of clozapine therapy outweigh the risks ○ The patient has documented benign ethnic neutropenia (BEN) <p>¹Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and will also be available on the Clozapine REMS Program Website.</p>

Prescriber Designee

<u>Definition</u>	<u>Responsibilities</u>
<p>A Healthcare Provider, office staff member, or pharmacist designated by a certified prescriber to act on their behalf</p>	<p><u>Enrollment Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Designee Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Become associated in the system with a certified prescriber • Be approved by the associated prescriber <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • A prescriber designee can: <ul style="list-style-type: none"> ○ Enroll general population patients ○ Counsel patients ○ Check ANCs ○ Submit ANCs on the prescriber’s behalf ○ Change a patient’s monitoring frequency • A prescriber designee cannot: <ul style="list-style-type: none"> ○ Enroll a patient with benign ethnic neutropenia (BEN) ○ Provide a <i>Treatment Rationale</i> for a patient ○ Designate a patient as a hospice patient

Authorized Representative for Outpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For outpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> • Pharmacy Manager, or • Staff Pharmacist <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> • Director of Pharmacy Services, or • Corporate Executive over-seeing Pharmacy Service <p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS Program requirements</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> • An authorized representative for an outpatient pharmacy must certify in the Clozapine REMS Program by: <ul style="list-style-type: none"> ○ Reviewing the Prescribing Information for clozapine ○ Certifying their pharmacy in the Clozapine REMS Program by: <ul style="list-style-type: none"> • Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> • Completing the <i>Clozapine REMS Outpatient Pharmacy Enrollment Form</i> • Passing the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> ○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements ○ Putting processes and procedures in place to verify: <ul style="list-style-type: none"> • The prescriber is certified in the Clozapine REMS Program prior to dispensing clozapine • The patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine • The ANC result is current according to the patient’s monitoring frequency: <ul style="list-style-type: none"> ▪ For weekly monitoring frequency, the submitted ANC result must have been drawn* within 7 days prior to the “Predispense Authorization” (PDA) transaction date ▪ For every two weeks monitoring frequency, the submitted ANC result must have been drawn* within 15 days prior to the PDA transaction date ▪ For monthly monitoring frequency, the submitted ANC result must have been drawn* within 31 days prior to the PDA transaction date • The submitted ANC is within acceptable range or a certified prescriber has provided a <i>Treatment Rationale</i> to authorize the continuation of clozapine treatment <p>*Assumes the lab draw date is day 0</p>

<u>Definition</u>	<u>Responsibilities</u>
	<ul style="list-style-type: none"> ○ Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> ● Coordinate the activities required in the Clozapine REMS Program ● Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program

Authorized Representative for Inpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For inpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> ● Pharmacy Manager, or ● Staff Pharmacist <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement process for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> ● Director of Pharmacy Services, or ● Corporate Executive overseeing Pharmacy Service <p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> ● An authorized representative for a pharmacy must certify in the Clozapine REMS Program by: <ul style="list-style-type: none"> ○ Reviewing the Prescribing Information for clozapine ○ Certifying their pharmacy in the Clozapine REMS Program by: <ul style="list-style-type: none"> ● Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> ● Completing the <i>Clozapine REMS Inpatient Pharmacy Enrollment Form</i> ● Passing the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> ○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements ○ Putting processes and procedures in place to verify the patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine ○ Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> ● Coordinate the activities required in the Clozapine REMS Program ● Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program ● Verify every patient receiving clozapine is enrolled in the Clozapine REMS Program prior to dispensing

<u>Definition</u>	<u>Responsibilities</u>
REMS Program requirements	<ul style="list-style-type: none"> • Before dispensing clozapine, inpatient pharmacies can: <ul style="list-style-type: none"> ○ Verify the ANC is current (within 7 days of the “Eligibility Check” date for weekly monitoring, 15 days for every 2 weeks monitoring, and 31 days for monthly monitoring) ○ Verify ANC is within the acceptable range or a certified prescriber has provided a <i>Treatment Rationale</i> to authorize the continuation of clozapine treatment ○ Inpatient pharmacists are encouraged to submit the patient's ANC to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency.

Pharmacy Staff

<u>Definition</u>	<u>Responsibilities</u>
Any pharmacist or pharmacy employee may assume the role of pharmacy staff member associated with a pharmacy to conduct basic program functions	<p><u>Enrollment Process</u></p> <ul style="list-style-type: none"> • Enroll online as pharmacy staff • Associate with a pharmacy <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • Outpatient pharmacy staff must: <ul style="list-style-type: none"> ○ Verify a prescriber is certified in the Clozapine REMS Program ○ Verify the pharmacy is certified ○ Verify a patient is enrolled in the Clozapine REMS Program ○ Obtain a PDA before dispensing clozapine to a patient ○ May submit an ANC for a patient • Inpatient pharmacy staff must: <ul style="list-style-type: none"> ○ Verify a patient is enrolled in the Clozapine REMS Program using the <i>Eligibility Check</i> ○ Verify patient has an ANC on file and the ANC is current and within acceptable range via an <i>Eligibility Check</i> and/or review of the patient’s medical record ○ Dispense clozapine to patients only after verifying safe-use conditions have been met ○ May submit an ANC for a patient

6 **Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS Program?**

Yes; the Clozapine REMS Program allows Healthcare Providers with multiple roles in the Clozapine REMS Program to create multiple website user accounts using the same email address.

One example of multiple roles a Healthcare Provider might have in the Clozapine REMS Program includes being a pharmacy authorized representative and a prescriber designee.

If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

7 **How does a Healthcare Provider certify in more than one role in the Clozapine REMS Program (i.e., pharmacist and prescriber designee)? Can the same email address be used for multiple roles in the Clozapine REMS Program?**

Yes; to certify in more than one role in the Clozapine REMS Program, you must create a Clozapine REMS Program Website user account for each role. The same email address can be used for each role. If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

8 **Why are white blood cell (WBC) counts no longer being collected?**

FDA has determined that the absolute neutrophil count (ANC) is more relevant to drug-induced neutropenia than is the white blood cell (WBC) count. Therefore, WBC counts are no longer required. An [ANC calculator](#) is available on the Clozapine REMS Program Website.

9 **How frequently should a patient's ANC be monitored?**

A patient's monitoring frequency depends on the patient's ANC and the amount of time a patient has been on treatment. For details regarding what monitoring frequency a patient should be on, refer to the Prescribing Information.

The [ANC Monitoring Table](#) can be found on the Clozapine REMS Program Website:

- Home Page → Resources → Program Materials → Prescriber Tab → ANC Monitoring Table

10 **When should I submit a patient's ANC to the Clozapine REMS Program?**

Patient ANC information should be submitted to the Clozapine REMS Program as soon as possible after the patient blood draw occurs but must be submitted according to the table below, which is consistent with patient monitoring frequency.

The monitoring frequency and corresponding blood draw dates can be found in the table below:

<u>Monitoring Frequency</u>	<u>ANC Blood Draw Date</u>
Weekly	ANC must be submitted within 7 days of the lab draw* date
Every two weeks	ANC must be submitted within 15 days of the lab draw* date
Monthly	ANC must be submitted within 31 days of the lab draw* date

*Assumes the lab draw date is day 0

Presently, although the 'Lab Not Current' will not prevent a patient from receiving medication, i.e., will not prevent a PDA from being provided; a warning message will be sent to the pharmacy advising that the lab is not current and to contact the prescriber for a current ANC. In the future when the Clozapine REMS Program is fully implemented, a lab that is not current with the patient's monitoring frequency will prevent the patient from receiving clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and will be available on the Clozapine REMS Program Website.) In the interim, warning messages will be provided if the ANC is overdue.

A prescriber must ensure patients are on the appropriate monitoring frequency and adhere to the appropriate corresponding blood draw dates in order for the patient to receive clozapine.

11. How do I contact the Clozapine REMS Program?

For additional information about the Clozapine REMS Program, please call 844-267-8678. For additional contact methods, please see the [Contact Us](#) page.

12. How does a Healthcare Provider report an adverse event, product complaint, or obtain medical information about clozapine?

Promptly report suspected adverse events associated with the use of a clozapine directly to the Clozapine REMS Program Contact Center at 844-267-8678. You should also report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088, by mail using Form 3500, or online. Downloadable reporting forms and online reporting forms are available at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.

To report a product complaint, or if you require medical information, you may also call the Clozapine REMS Program Contact Center at 844-267-8678.

1 What is the new certification deadline for prescribers and outpatient pharmacies?

The decision to extend the deadlines was made in consultation with the FDA to minimize treatment disruption for patients while allowing more time for pharmacies and prescribers to complete certification. Please refer to the categories below for specific dates.

Pharmacies

All pharmacies are required to become certified in the Clozapine REMS Program by February 28, 2019.

Outpatient Prescribers

All prescribers who prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems must be certified in the Clozapine REMS Program by February 28, 2019.

Inpatient Prescribers

In February 2019, prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program. However, in order to initiate clozapine therapy in an inpatient setting, a certified prescriber must enroll the patient in the Clozapine REMS Program before the first dose can be dispensed.

For more information on this program change for prescribers who prescribe clozapine in an inpatient setting, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

14 How is monitoring frequency determined in the Clozapine REMS Program?

Monitoring frequency is calculated by the Clozapine REMS Program automatically, based on the patient's history of consistently acceptable ANC values submitted to the program. The guidelines for determining monitoring frequency are described in the Prescribing Information.

If a patient's monitoring frequency is incorrect, the prescriber can modify a patient's monitoring frequency by attesting in the patient's profile via the Clozapine REMS Program Website. Prescribers and prescriber designees can also modify a patient's monitoring frequency by calling the Clozapine REMS Program Contact Center at 844-267-8678 or by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the Clozapine REMS Program Contact Center for processing.

Note: A pharmacy cannot update a patient's monitoring frequency. Pharmacies should work with the patient's prescriber to update a patient's monitoring frequency.

The [Monitoring Table](#) can be found on the Clozapine REMS Program Website:

- Home Page → Resources → Program Materials → Prescriber Tab → Monitoring Table

15. Why did established patients with monthly monitoring frequency get converted to weekly monitoring frequency?

The Clozapine REMS Program made every effort to consolidate data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. Patients with complete profile information in the individual manufacturer registries were migrated to the Clozapine REMS Program successfully, but may have had different monitoring frequencies across multiple individual manufacturer registries and/or had a significant gap in C data when patient data was consolidated from the multiple individual manufacturer registries.

In accordance with the approved Clozapine Prescribing Information, if the patient had consistent results submitted over the previous 12-month period, the patient was migrated with a monthly monitoring frequency.

If a patient's results were inconsistently submitted to the registries in the previous 12-month period and/or there was a time-frame longer than 56 days between blood draw dates, the patient was migrated with a weekly monitoring frequency.

The guidelines outlined above for assigning a new monitoring frequency are consistent with the Clozapine [Prescribing Information](#).

If a prescriber needs to change a patient's monitoring frequency, the prescriber can do so on the prescriber dashboard on the Clozapine REMS Program Website. The prescriber or a prescriber designee may also update a patient's monitoring frequency by calling the Clozapine REMS Program contact center at 844-267-8678.

16. My existing clozapine patient was not migrated from the individual manufacturer registries and therefore the Clozapine REMS Program identifies this patient as new and has aligned this patient to a weekly monitoring frequency. How can I update the system so my patient is correctly returned to monthly monitoring frequency?

The Clozapine REMS Program made every effort to consolidate data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. In some instances, data was incomplete, creating gaps in the history. These gaps resulted in some patients who were previously on a monthly monitoring frequency in an individual manufacturer registry to revert to a weekly monitoring frequency in the Clozapine REMS Program.

If a prescriber needs to change a patient's monitoring frequency, the prescriber can do so on the prescriber dashboard on the Clozapine REMS Program Website. The prescriber or the prescriber designee can also update a patient's monitoring frequency by calling the S

pine REMS Program contact center at 844-267-8678 or by faxing the update via the ,
Clozapine REMS ANC Lab Reporting Form to the pine REMS Program contact
center for processing.

ib

17. How can a prescriber become certified in the inpatient clozapine REMS program?

Any prescriber who wants to initiate clozapine therapy in a patient must be certified in order for the patient to be enrolled in the Clozapine REMS Program.

Prescribers who prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems must certify in the Clozapine REMS Program and adhere to the Clozapine REMS Program requirements. Prescribers may certify online through the Clozapine REMS Program Website or by submitting the *Clozapine REMS Prescriber Enrollment Form* and *Clozapine REMS Knowledge Assessment for Healthcare Providers* via fax to the Clozapine REMS Program Contact Center at 844-404-8876. **C**

To complete certification on the Clozapine REMS Program Website:

- From the Home Page, use the “Start Prescriber Certification” button. You will be taken to the Prescriber Certification page, which will explain what is expected and required in the Clozapine REMS Program.
- From that certification page, use the “Begin Now!” button to begin certification in the Clozapine REMS Program.

Prescribers who have completed the Clozapine REMS Program certification requirements will receive notification that they are certified in the program.

During the February 2019 Clozapine REMS Program Modification, prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program. Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine.

For further information, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678. For a faxed copy of the certification forms, call the Clozapine REMS Program Contact Center at 844-267-8678.

18. When do I need to complete certification?

The new deadline for prescriber certification is February 28, 2019. If you are not certified by this date your patient may not be eligible to receive clozapine. Prescribers are highly encouraged to certify in the Clozapine REMS Program as soon as possible. **C**

the information in this change prescribes when prescribing clozapine in an inpatient setting, please visit the Clozapine EMS Program Website at www.clozapineems.com call the Clozapine EMS Program Contact Center at 844-267-8678.

19. What are the changes for prescribers in an inpatient setting with the February 2019 Clozapine REMS Program Modification?

During the February 2019 Clozapine EMS Program Modification, prescribes when prescribing clozapine only to patients receiving inpatient medical care and the related services singly, acute medical conditions injuries (usually a short-term illness condition) will not be eligible to become certified in the Clozapine EMS Program.

Patients in this setting are eligible to be enrolled in the Clozapine EMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine. R

the information in prescribing when prescribing clozapine in an inpatient setting, please call the Clozapine EMS Program Contact Center at 844-267-8678.

20. If a prescriber is going to be out of the office for an extended period of time, can another prescriber cover during the absence?

Yes; however, the covering prescriber must be certified in the Clozapine EMS Program and it may be beneficial if the new prescriber associates themselves with these patients in the program call the Clozapine EMS Program Contact Center at 844-267-8678 to have the patient assigned to that covering prescriber.

21. If a prescriber is going to be out of the office for a short period of time, can another prescriber write a prescription for the patient during the absence?

Yes; the covering prescriber can write a prescription on the prescriber's patient as long as the covering prescriber is certified in the Clozapine EMS Program. When the eligibility of the patient to receive clozapine is checked, it does not look at an established relationship between the prescriber and patient.

22. Can a nurse practitioner, physician assistant, resident, or intern certify as a certified prescriber in the Clozapine REMS Program?

Yes; any medical professional with prescribing privileges can become certified in the Clozapine EMS Program.

23. Can a member of the prescriber's office staff help manage patients in the Clozapine REMS Program?

Yes; the Clozapine EMS Program allows a certified prescriber to identify a prescriber designee to perform medical duties on behalf of the prescriber. The prescriber's designee(s) will need to be enrolled in the Clozapine EMS Program and become certified

they can perform many duties and functions that are associated with prescriptions. A prescriber may have more than one prescriber designation.

Anticipation will result in the prescriber having the designation. Because a designation can act in a similar manner to a prescriber, the prescriber will not be approved for prescribing new prescriptions. Once the designation has been approved by the state prescriber, they will be able to engage in patient management through the Clozapine REMS Program Website.

24. How can a prescriber find a list of pharmacies that are certified in the Clozapine REMS Program?

A prescriber can obtain a list of participating pharmacies by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If a prescriber knows the pharmacy's DEA, NPI, NCPDP number, the prescriber can also confirm that a pharmacy is certified by using the state "Certification Lookup" on the Resources tab of the Clozapine REMS Program Website at [.clozapine.ms.c m](https://www.clozapine.ms.c m).

25. Where can I find the Patient ID for the Clozapine REMS ANC Lab Reporting Form?

The Patient ID can be found in the Prescriber Dashboard in the patient tab. The Patient ID will also be known as the Patient Enrollment ID.

Note: The Patient ID is an optional identifier in the Clozapine REMS ANC Lab Reporting Form.

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26. What a tion an a p ib d ign p fo m in th C ozapin REMS og am? I

A prescriber designee can perform the following actions on behalf of the prescriber:

- Enroll general population patients
- Counsel patients
- Submit ANCs on the prescriber's behalf
- View patient lists and patient ANC history
- Change monitoring frequency

A prescriber designee **annot p fo m** the following actions on behalf of a prescriber: I

- Enroll patients with documented benign ethnic neutropenia
- Provide a *Treatment Rationale* for a patient
- Designate a patient as a hospice patient

To download the *Clozapine REMS Prescriber Designee Enrollment Form* or *Clozapine I REMS Patient Enrollment Form*, visit the Clozapine REMS Program Website.

Download program enrollment forms [here](#)

n Management

27. Do patients enrolled in the Clozapine REMS Program need to be enrolled in the Clozapine REMS Program?

Yes; any patient prescribed clozapine, whether in an inpatient or outpatient setting must be enrolled in the Clozapine REMS Program by the patient's prescriber or the prescriber designee. To enroll a patient, please visit www.clozapinerems.com or fax the completed *Clozapine REMS Patient Enrollment Form* to the Clozapine REMS Program Contact Center at 844-404-8876.

Note: An acceptable ANC or *Treatment Rationale* must also be on file with the Clozapine REMS Program for patients to receive clozapine in an outpatient setting

28. How are patients enrolled in the Clozapine REMS Program?

Prescribers and prescriber designees can enroll patients into the Clozapine REMS Program. General population patients can be enrolled by both prescribers and prescriber designees online, by phone, or by faxing the *Clozapine REMS Patient Enrollment Form*.

Only a prescriber can enroll patients with benign ethnic neutropenia (BEN). The prescriber must indicate BEN status as part of the enrollment process on the Clozapine REMS Program Website or on the *Clozapine REMS Patient Enrollment Form* to be faxed; patients with BEN cannot be enrolled by phone. Phone enrollment is only available for general population patients.

For assistance in enrolling your patient, please call the Clozapine REMS Program Contact Center at 844-267-8678.

To download the *Clozapine REMS Patient Enrollment Form*, visit the Clozapine REMS Program Website.

Download program enrollment forms [here](#).

29. Can Healthcare Providers who are not certified in the Clozapine REMS Program submit an ANC?

If you are a Healthcare Provider directly involved in the treatment of a clozapine patient, you can call the Clozapine REMS Program Contact Center at 844-267-8678 and submit an ANC over the phone even if you aren't certified in the Clozapine REMS Program. You may be required to provide specific identifying patient information when you submit the ANC results.

An ANC can also be faxed to the Clozapine REMS Program Contact Center at 844-404-8876 for data entry.

For organizations with high laboratory volumes, a simple automated interface can be implemented to electronically send ANC data for entry into the Clozapine REMS Program.

Part of the Coz pin REMS Program Contract 844-26-868 for more information on this program.

30. Will the program send notices if the patient experiences a low ANC or substantial drop?

The Coz pin REMS Program automatically will notify the patient of a drop in hemoglobin if the patient experiences a mild, moderate, or severe neutropenia defined in the approved Coz pin Prescribing Information for both patients in the general population and for patients with documented benign thrombocytopenia.

Substantive drops are not defined in the Coz pin Prescribing Information, so if you notice a drop in hemoglobin if the patient experiences a low drop. A notice will be sent if the ANC meets criteria for mild, moderate, or severe neutropenia.

31. What is a Treatment Status?

A patient's *Treatment Status* describes the patient's status in the Coz pin treatment program.

There are four Treatment Statuses in the Coz pin REMS Program:

- *Pre-Treatment*: new patient with no baseline ANC submitted who has not started Coz pin
- *Active*: receiving Coz pin treatment and on site with their monitoring frequency
- *Interrupted*: Coz pin usage has temporarily stopped pending next transition before resuming therapy or being permanently discontinued
- *Discontinued*: Coz pin usage has stopped

Treatment Status is automatically updated based on the ANC values entered into the system.

- For general population patients:
 - An ANC between 500 and 999/ μ L (moderate neutropenia) will update Treatment Status to *Interrupted*
 - An ANC below 500/ μ L (severe neutropenia) will update Treatment Status to *Discontinued*
- For patients with documented benign thrombocytopenia (BEN):
 - An ANC below 500/ μ L (severe neutropenia) will update Treatment Status to *Interrupted*

A Treatment Status of *Interrupted* or *Discontinued* will prevent PDA from being provided and could result in discontinuation of patient's Coz pin therapy. If prescribed treatment is not suitable for continuing Coz pin outweighs the risk when patient's Treatment Status is changed to *Interrupted*, the prescriber should provide *Treatment Rationale* into the system and change the patient's Treatment Status back to *Active* therapy following 7 Coz pin toxicology.

If a patient's Treatment Status was changed to *Discontinued* because of low ANC value, the Treatment Status will automatically return to *Active* only when a new/current lab is submitted with the patient's ANC value within acceptable range.

32. What is a *Treatment Rationale*?

A *Treatment Rationale* is required from a prescriber when he or she determines that a patient should continue clozapine treatment despite low ANC.

To authorize the continuation of clozapine therapy or any patient with Treatment Status of *Interrupted* or *Discontinued* because of low ANC indicating severe neutropenia, the prescriber must take a t i o n by providing *Treatment Rationale* outside the patient's Treatment Status block of *Active* or low PDA request be provided.

The Clozapine REMS Program will alert the prescriber via the Clozapine REMS Program Web site should a submitted ANC is below the recommended thresholds or a patient's Clozapine will not be dispensed to the patient unless the prescriber then provides *Treatment Rationale* to authorize continued treatment. There are two *Treatment Rationale* options in the Clozapine REMS Program:

1. "Benefit outweighs risks" → In the prescriber's clinical judgment; the benefit of continuing clozapine treatment outweighs the risk of neutropenia
2. "Patient with documented BEN" → The ANC is within a range where treatment can continue or a patient with benign hematologic neutropenia (BEN)

In addition, provided in the Clozapine REMS Program is no substitute or other documented condition in the patient's medical record regarding the prescriber's decision to continue, interrupt, or discontinue clozapine treatment.

33. How can I provide a *Treatment Rationale*?

Providing *Treatment Rationale* confirms that the benefit of continuing clozapine treatment outweighs the risks of developing severe neutropenia when the prescriber wishes to continue clozapine treatment in a patient whose ANC value is low. The *Treatment Rationale* returns the patient's Treatment Status in the Clozapine REMS Program to *Active* and allows the Clozapine REMS Program to provide PDA which permits the pharmacy to dispense clozapine.

Prescribers may continue treatment continuation with *Treatment Rationale* in the Clozapine REMS Program by:

1. Faxing signed *Clozapine REMS ANC Lab Reporting Form* to 844-404-8876 containing completed *Treatment Rationale* section, or
2. Accessing the Clozapine REMS Program Web site to provide *Treatment Rationale* online. To do so, users must follow these steps:
 - a. **Log in to** the Clozapine REMS Program Web site www.clozapinerems.com.
 - b. **Access** the Web site.

- c Click the **Change Treatment Rationale** from the drop-down menu and click the **GO** button
- d Enter the lab information on the 'Lab Information' screen and click **Next**. The user will be redirected back to the Dashboard after this step is complete

34. What happened to patients previously on the National Non-Restarting Master File (NNRMF)?

The NNRMF was developed by the Novartis Pharmaceuticals Corporation to ensure that patients at risk of developing severe neutropenia (previously referred to as agranulocytosis) while on clozapine, regardless of the manufacturer, could not be restarted on clozapine. Due to updates to the clozapine Prescribing Information, the NNRMF is no longer applicable. Patients who were previously identified in the NNRMF will be identified in the Clozapine REMS Program with a flag on the Prescriber Dashboard.

Patients who were previously identified in the NNRMF may restart clozapine in certain circumstances as defined in the Prescribing Information. Monitoring requirements for patients previously identified in the NNRMF are the same as for patients new to clozapine.

35. How are patient ANC's submitted to the Clozapine REMS Program?

Patient ANC's can be submitted to the Clozapine REMS Program in a variety of ways:

- Prescribers and prescriber designees can log in to the Clozapine REMS Program Website and enter ANC's for a patient using their dashboard
- Pharmacy staff and pharmacy authorized representatives can submit an ANC via their dashboard on the Clozapine REMS Program Website
- All program roles can call the Clozapine REMS Program Contact Center at 844-267-8678
- All program roles can fax ANC's to the Clozapine REMS Program Contact Center at 844-404-8876

Download [Clozapine REMS ANC Lab Reporting Form](#)

36. Does the Clozapine REMS Program need to be advised when a patient is admitted to or discharged from an acute or long-term health care setting?

No; the Clozapine REMS Program does not track when patients are admitted or discharged. Patient association to a prescriber is updated automatically when a new prescriber enrolls a patient. There is no action required on the part of the previous prescriber.

If a prescriber wishes to remove a patient from their list, they can deactivate the patient via their dashboard.

38 When discontinuing treatment, do most patients' ANC need to be monitored for 4 weeks?

No; the duration and frequency of all patient ANC monitoring after discontinuation is dependent on that patient's ANC and clinical status (see Section 2.4 in the clozapine [Prescribing Information](#) for more details).

39 If a patient is eligible to reduce their monitoring frequency do most Clozapine REMS Program need to be notified?

No; the monitoring frequency recommendations are described in the Prescribing Information. In the Clozapine REMS Program, monitoring frequency is a calculated value, based on the patient's ANC history. Thus, if the patient is eligible to reduce their monitoring frequency, the system will automatically adjust their monitoring frequency.

If a patient's monitoring frequency is incorrect, the prescriber can modify the patient's monitoring frequency to monthly by performing an attestation in the patient's profile via the Clozapine REMS Program Website. Prescribers and prescriber designees can modify a patient's monitoring frequency to monthly by calling the Clozapine REMS Program Contact Center at 844-267-8678.

A prescriber can move a patient from monthly or every two weeks monitoring frequency to bi-weekly by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the bi-weekly Clozapine REMS Program Contact Center for processing.

40 If a patient or caregiver will not provide the required information needed to complete Patient Enrollment (i.e., Name, Date of Birth) can they still receive clozapine?

This information is needed in order for prescribers and pharmacies to identify the patient in the Clozapine REMS Program to submit ANCs and provide authorization to receive clozapine. If a patient and/or their caregiver will not provide the required information, the patient will not be able to receive clozapine therapy.

41 How does a patient in an inpatient setting become enrolled if prescribers in that setting are not required to be certified in the Clozapine REMS Program?

All patients are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine. bi-weekly

Pharmacy Management

41. What are the different pharmacy certification types in the Clozapine REMS Program?

All pharmacies must certify in the Clozapine REMS Program to purchase and dispense clozapine.

Pharmacies participating in the Clozapine REMS Program must determine their pharmacy type based on the definitions below. The [certification requirements](#) are different for different pharmacy types.

<u>Pharmacy Type</u>	<u>Definition</u>
Chain Pharmacy	<ul style="list-style-type: none"> • A chain of retail pharmacies has an authorized representative located at a chain headquarters who is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain. • A chain pharmacy is contracted to participate with a pharmacy network provider. • Chain pharmacies must adjudicate claims through their Pharmacy Benefit Management System (PBMS) via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”).
Outpatient Pharmacy	<ul style="list-style-type: none"> • Pharmacies are considered outpatient if the pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. • An outpatient pharmacy is an individual location or multiple stores with an authorized representative associated to the independent stores. The authorized representative is responsible for ensuring certification and training in the Clozapine REMS Program within the individual or multiple stores. • Even if a pharmacy has multiple locations, it is not considered a chain for the purposes of the REMS unless it has a single authorized representative at a corporate headquarters that is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain. • An outpatient pharmacy <u>may</u> be able to adjudicate claims via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”). • Outpatient pharmacies that cannot adjudicate claims via the switch must obtain a PDA via the Clozapine

<u>Pharmacy Type</u>	<u>Definition</u>
	REMS Program Website, or by calling the Clozapine REMS Program Contact Center.
Inpatient Pharmacy	<ul style="list-style-type: none"> • Pharmacies are considered inpatient if the pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition). • Inpatient pharmacies are required to perform an <i>Eligibility Check</i> to verify a patient is eligible to receive clozapine before dispensing. If the patient is found to not yet have been enrolled in the Clozapine REMS Program, he/she must be enrolled by a <u>certified prescriber</u> before being allowed to receive clozapine.

42. What is a *Predispense Authorization (PDA)*?

A *Predispense Authorization (PDA)* determines if a patient is eligible to receive clozapine and provides authorization for an outpatient pharmacy to dispense.

The PDA currently evaluates that the:

- Prescriber is certified; and,
- Pharmacy is certified; and,
- Patient is enrolled; and,
- Patient has an ANC on file; and,
- Patient's ANC is within acceptable range according to the Prescribing Information, or has a valid *Treatment Rationale* on file from the prescriber.

In addition, PDA responses provide the dispensing pharmacy with the following information:

- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

If the ANC is not current (i.e., within 7/15/31 days of the ANC draw date) based on the patient's monitoring frequency (either weekly, every 2 weeks or monthly), this **will not** prevent a PDA.

Upon full implementation of the Clozapine REMS Program, pharmacies will be required to verify the patient ANC is current. At that time, if the ANC is not current based on the patient's monitoring frequency, a PDA will not be provided and the patient will not be allowed to receive clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and available on the Clozapine REMS Program Website.)

Click [here](#) to access the *Clozapine REMS PDA Fact Sheet*.

What is an *Eligibility Check*?

The *Eligibility Check* (EC) determines if a patient is eligible to receive clozapine and provides an authorization for an inpatient pharmacy to dispense.

The EC evaluates the criteria of patient enrollment in the Clozapine REMS Program to determine if it is safe to dispense clozapine to the patient. Patients who are not enrolled in the Clozapine REMS Program are not “eligible” to receive clozapine and must be enrolled by a certified prescriber prior to their first dose of clozapine.

In addition, the EC will provide a warning message informing the pharmacy if the patient’s ANC is not on file, is not within acceptable ranges according to the Prescribing Information; or, when the ANC on file indicates moderate or severe neutropenia there is no valid *Treatment Rationale* on file from the prescriber. This warning message will not prevent a dispense for a patient as long as the patient is enrolled in the Clozapine REMS Program.

All EC responses will provide the following information:

- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

Pharmacy authorized representatives and pharmacy staff in an inpatient pharmacy can perform an EC from their dashboard. To perform an EC, the user enters the following data:

- Patient data: First Name, Last Name, Date of Birth, Zip Code (Required)
- Prescriber identifier: DEA or NPI (at least one identifier is required)
- Patient ANC data: ANC, Blood Draw Date (Optional)
- Dispense data: Date of Service, NDC, Days’ Supply, Quantity (Optional)

Click [here](#) to access a *Clozapine REMS Eligibility Check Fact Sheet*.

How is an *Eligibility Check* different from a *Predispense Authorization*?

The *Eligibility Check* is primarily used by inpatient pharmacies, whereas the PDA is used by outpatient pharmacies. Further specifics about the use of each and the steps required to perform each one can be obtained from the Clozapine REMS Program Website at www.clozapinerems.com by downloading and reviewing the *Clozapine REMS PDA Fact Sheet* and/or *Clozapine REMS Eligibility Check Fact Sheet*.

5 What is a “Dispense Rationale”?

The Clozapine REMS Program provides certified outpatient pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient’s prescriber is not certified in the Clozapine REMS Program. In order to dispense to a patient who does not have an associated certified prescriber, the pharmacist must provide a *Dispense Rationale*.

The Clozapine REMS Program will alert the pharmacy if the prescriber is not certified in the Clozapine REMS Program when a PDA is requested. A PDA will not be provided for a clozapine dispense unless the pharmacy provides a *Dispense Rationale* to authorize a dispense.

For a patient to be eligible for a *Dispense Rationale*, that patient must:

- Be enrolled in the Clozapine REMS Program; and,
- Have an acceptable ANC value on file; and,
- Have a *Treatment Rationale* on file if the ANC on file is low indicating more than seven consecutive days.

The *Dispense Rationale* is valid for 72 hours (3 calendar days).

The *Dispense Rationale* will be limited to more than three (3) *Dispense Rationales* for an individual patient within a rolling six (6) month period.

Pharmacists must fill a prescription more than the amount of clozapine necessary to treat the patient until the next low/ANC assessment is dictated by the prescriber.

46. How can I provide a *Dispense Rationale*?

Certified authorize representatives are able to pharmacy staff certified pharmacists can provide a *Dispense Rationale* through the Clozapine REMS Program Website. The process varies slightly for providing a *Dispense Rationale* depending on whether you pharmacy requests a *Predispense Authorization* (PDA) by using the Clozapine REMS Program Website (see Section A below) or by using the pharmacy network system, i.e., a "switch" (see Section B below). Alternatively, a *Dispense Rationale* may be provided via calling the Clozapine REMS Program Contact Center at 844-267-8678.

A. A Pharmacy using the Clozapine REMS Program Website to request a PDA, should:

1. **Log in to** the Clozapine REMS Program Website.
Note: You must be enrolled as a pharmacy staff certified pharmacist as an authorize representative for the pharmacy.
2. **Access** the dashboard.
3. **Select 'Predispense Authorization'** from the dropdown menu and **click the Go** button.
4. **Enter the patient information** in the '*Predispense Authorization*' screen and **click Submit** (see screenshot below.) The '*Predispense Authorization Result*' screen will appear with a reject message.

Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the Predispense Authorization information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the Predispense Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5. Click on the 'Provide a *Dispense Rationale* for this patient' check box at the bottom of the '*Predispense Authorization Result*' screen and **click** the **Submit** button. (see screenshot below)

Patient's Lab History

Provide *Dispense Rationale* for this patient.

Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6. If the *Dispense Rationale* was provided successfully, you will be taken to a **success screen**. (see screenshot below)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

<p>Name Summer H</p> <p>DOB</p> <p>Authorization Number</p>	<p>▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>▲ Current ANC is not on file.</p> <p>A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
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Patient's Lab History

For additional information about the Clozapine REMS Program, please call 844-267-8678.

B Pharmacy using the pharmacy network system (i.e., “switch ” to request PD s ould:

1. **Log in** to the Clozapine REMS Program Website.
 Note: You must be enrolled as a pharmacy staff or certified as an authorized representative for the switch pharmacy.)
2. **ccess** the dashboard.
3. **Select ‘Dispense Rationale’** from the drop-down menu and **click the Go** button. (see screenshot below)

Alerts Notifications **Pharmacies** Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Add Pharmacy

Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- <input type="button" value="Go"/>
TestPharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- <input type="button" value="Go"/>
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- <input type="button" value="Go"/>
JC Penney	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- <input type="button" value="Go"/>
 Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	<div style="border: 1px solid black; padding: 2px;"> -- Please Select -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Predispose Authorization Dispense Rationale Recertify Pharmacy </div> <input type="button" value="Go"/>
 Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- <input type="button" value="Go"/>
 Inpatient	Address, SCOTTSDALE, Arizona 85260	Inpatient	FAC5414782350	Incomplete	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 7 of 7 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

4. Enter the patient information on the *Dispense Rationale* screen and click **Submit**. (see screenshot below)

5. The "*Dispense Rationale Result*" screen will appear with a reject message similar to the switch reject message.

- Click on the 'Provide a *Dispense Rationale* for this patient' check box at the bottom of the '*Dispense Rationale* Result' screen and click the **Submit** button (see screenshot below).

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

✖ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

Cancel
Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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- If the *Dispense Rationale* is provided successfully, you will be taken to a success screen. (see screenshot below)

Dispense Rationale Result

✔ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

<p>Name Summer H</p> <p>DOB</p> <p>Authorization Number</p>	<p>▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>▲ Current ANC is not on file.</p> <p>A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
--	--

Patient's Lab History

For additional information about the Clozapine REMS Program, please call 844-267-8678.

roc ss th claim transaction throu h the harmacy sw tch syste
Note: I as wait a roximat I 2 minut s before on back to the sw tch to
re rocess the cla transact on

If you ex erience any issues, lease call the Cloza ine REMS Program Contact Center at
44-267- 67

47. How do s a harmacy c rtify in th Cloza in EMS Program?

To certify in the Cloza ine REMS Program, the authorized re resentative of a harmacy
must:

- Com lete the *Clozapine REMS Inpatient Pharmacy Enrollment Form* or the *Clozapine
REMS Outpatient Pharmacy Enrollment Form*

in Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
Completion of the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

Non-chain pharmacies can also certify online through the Clozapine REMS Program Website at www.clozapinere.ms.com, or by submitting the completed *Clozapine REMS Inpatient Pharmacy Enrollment Form* or the *Clozapine REMS Outpatient Pharmacy Enrollment Form* via fax to the Clozapine REMS Program Contact Center at 800-8876. N

Chain pharmacies should work with their account managers from their pharmacy N management system (i.e., “switch”) provider to become certified.

For additional information, call the Clozapine REMS Program Contact Center at 800-267-8678.

48. How often must pharmacies recertify?

Pharmacists are required to recertify in the Clozapine REMS Program every two (2) years N from the date of the pharmacy’s original certification to maintain ability to order and dispense clozapine.

49. How does a pharmacy recertify in the Clozapine REMS Program?

Certification requires that the authorized representative of the pharmacy has (or) certified by reviewing of the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, (or) attesting to the program requirements on the appropriate *Clozapine REMS Enrollment Form* for the pharmacy type, and successful completion of the *Clozapine REMS Knowledge Assessment for Healthcare Providers*. Pharmacy recertification may then be completed after the authorized representative is (or) certified. Certification tasks may be completed on the Clozapine REMS Program Website at www.clozapinere.ms.com; or, by downloading and completing the appropriate type of *Clozapine REMS Pharmacy Enrollment Form (Inpatient, Outpatient, or Chain Headquarters)* and the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and faxing the completed/sign forms to 800-8876. N

Note: Chain Headquarters Pharmacists may recertify only by completing and faxing the *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form* and *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program Contact Center N at 800-8876.

Additional assistance for questions or problem resolution may be obtained by calling the Clozapine REMS Contact Center at 800-267-8678.

50. What happens if a pharmacy does not recertify every 2 years?

Pharmacists that do not recertify every two years from the date of their original certification in the Clozapine REMS Program will be deactivated and will be unable to N order or dispense clozapine.

51. What happens if a pharmacy is deactivated?

Deactivated pharmacies will be unable to order or dispense clozapine. Previously certified pharmacies will be unable to obtain *Predispense Authorization* from the Clozapine REMS Program until recertified.

52. If my pharmacy is “deactivated,” what must be done?

If our pharmacy has been deactivated from the Clozapine REMS Program due to failure to recertify over 2 years, the pharmacy authorized representative should immediately log on to the recertification website www.clozapinere.ms.com; or, download and complete the appropriate copy of *Clozapine REMS Pharmacy Enrollment Form (Inpatient, Outpatient, or Chain Headquarters)* and the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and fax the completed/sign forms to 844-404-8876.

Additional assistance for questions or problem resolution may be obtained by calling the Clozapine REMS Program Contact Center at 844-267-8678.

Pharmacy Authorized Representative

53 What is a pharmacy authorized representative?

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the [General Section](#) of the FAQs.

54 Who should contact a pharmacy authorized representative in the pharmacy?

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the [General Section](#) of the FAQs.

55 When does certification need to be completed?

The new deadline for pharmacy certification is February 28, 2019. If you are not certified by this date your patient may not be eligible to receive clozapine from a pharmacy.

Pharmacies are required to verify and/or update their pharmacy classification upon recertification in the program. This pharmacy reclassification may change prescriber certification and patient safety requirements.

For more information, visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-278-7878.

56 What is the difference between an inpatient pharmacy and an outpatient pharmacy?

- A pharmacy that dispenses clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition), the pharmacy will be classified as an “inpatient pharmacy.”
- A pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, the pharmacy will be classified as an “outpatient pharmacy.”

If you feel your pharmacy is incorrectly classified or if your pharmacy dispenses to both patient groups, please call the Clozapine REMS Program Contact Center for further instructions at 844-278-7878.

57 What if I am in a pharmacy that dispenses clozapine for both inpatient and outpatient use?

The authorized representative will need to complete both the inpatient pharmacy enrollment and outpatient pharmacy enrollment. The authorized representative can complete enrollment through the Clozapine REMS Program Website or by completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form* and the *Clozapine REMS Outpatient*

armacy Enrollment Form and faxing them to the Clozapine REMS Program at 844-404-8866.

For additional questions, please call the Clozapine REMS Program Contact Center at 844-268-8688.

58. What is “the switch”?

The term “the switch” refers to a technical solution that allows pharmacies to adjudicate prescription information simultaneously through both the Clozapine REMS Program to obtain the PDA and their Pharmacy Management System (PMS) to obtain insurance claim payments via electronic communication using established telecommunications standards. [h](#)

59. What happens to patients who try to fill a prescription at a pharmacy that is not certified?

Beginning on February 28, 2019, if a pharmacy is not certified in the Clozapine REMS Program, a patient presenting a clozapine prescription at that pharmacy location will not receive clozapine regardless if the patient meets other program element requirements as defined by the Clozapine REMS Program (patient is enrolled and has ANC on file with acceptable values per the Prescribing Information).

Pharmacies must become certified in the Clozapine REMS Program by February 28, 2019 [h](#) in order to obtain clozapine from a wholesaler.

60. Will pharmacies that are not certified be able to order and receive clozapine?

Starting on February 28, 2019, if a pharmacy is not certified in the Clozapine REMS Program, the pharmacy will not be able to order and receive clozapine, regardless if they were in any of the previous individual manufacturer registries.

Access the pharmacy certification procedure [here](#)

61. The pharmacy has been certified but the system is reporting that the pharmacy is not certified. What are the next steps?

Please ensure you have completed the steps listed on the certification page. If you are still experiencing issues, please call the Clozapine REMS Program Contact Center at 844-268-8688 for assistance.

62. Will patients still need to have blood draws?

Yes; blood draws for ANC monitoring are required prior to dispensing. Monitoring frequency [h](#) (i.e., weekly, every 2 weeks, or monthly) is determined by the patient's prescriber based on criteria in the clozapine Prescribing Information.

an clozapine be dispensed to a patient without bloodwork

No; patients must have ANC's that are current according to their monitoring frequency and in the acceptable range. If there is no ANC on file in the patient's lab history, an ANC will be required before a PDA is provided. After the Clozapine REMS Program is fully implemented, if the ANC on file is not current based on the patient's monitoring frequency, a more recent ANC will be required before dispensing clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and available on the Clozapine REMS Program Website.)

If the ANC meets the criteria for moderate or severe neutropenia, a patient must have an appropriate *Treatment Rationale* provided to the Clozapine REMS Program prior to ? dispensing clozapine.

4 What actions are required if the prescribing physician isn't certified

Prescribers who prescribe clozapine for outpatient use must be certified in the Clozapine REMS Program by February 2 , 2019.

Prescribing clozapine for patients receiving inpatient care does not require prescriber certification in the Clozapine REMS Program if the patient is already enrolled in the program. If the patient is to be initiated on clozapine while admitted to an inpatient setting, a certified prescriber must enroll the patient in the Clozapine REMS Program prior to receiving the first dose of clozapine.

We encourage you to contact the prescriber to advise him or her of the need to certify in the Clozapine REMS Program. The Clozapine REMS Program *Dispense Rationale* provides certified outpatient pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient's prescriber is not certified in the Clozapine REMS Program.

5 What should a pharmacist do with the patient's ANC Lab Reporting Form

The pharmacist should enter the patient's ANC via the Clozapine REMS Program Website or fax it to the Clozapine REMS Program Contact Center at 44-404- 76. Once the information has been entered, the pharmacist may keep the form for his or her records, if desired. The length of time these records are kept is based on the policies implemented by each individual pharmacy or organization.

The pharmacy just certified and needs to order clozapine today What are the next steps

The Pharmacy should contact its wholesaler/distributor to inform them that the pharmacy just certified in the Clozapine REMS Program. If the wholesaler needs to verify certification, they can access the Certification Look-up on the Clozapine REMS Program Website or call the Clozapine REMS Program Contact Center at 44-267- 67 to verify the pharmacy's certification in the program. ?

What if the authorized representative leaves the pharmacy

If the authorized representative leaves the pharmacy, the new authorized representative must notify the Clozapine REMS Program of the change in the authorized representative by ? certifying in the Clozapine REMS Program as soon as possible.

8 If the patient's prescription is denied or the *Eligibility Check* indicates "do not dispense," will the Clozapine REMS Program system explain the reason

Yes; when a prescription is denied (i.e., a PDA is not generated), an appropriate message will be displayed to the pharmacy staff member.

There are several rejection reasons that could be provided for a patient. The following are examples of the most common rejection messages (actual messages may vary):

Outpatient Pharmacy using the pharmacy management system:

"*REMS* - ANC results out of range. Results Last ANC: 400 01/12/16; MF=7d

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient."

"*REMS* - ANC results not on file. Contact prescriber"

Outpatient Pharmacy using web-based PDA:

"*REMS* - ANC results out of acceptable range"

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient."

"*REMS* - ANC results not on file. Contact prescriber"

Inpatient Pharmacy:

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient." ?

sa r/Distribut r

69. D s a distribut r av t nr in t C zapin EMS Pr gram?

Yes; clozapine is only available through the Clozapine REMS Program. As part of a restricted distribution REMS program, distributors will need to enroll in the Clozapine REMS Program in order to be able to purchase and distribute clozapine.

70. H w can a distribut r nr in t C zapin EMS Pr gram?

To enroll in the Clozapine REMS Program, a distributor should contact info@clozapinedistributor.com to have a *Clozapine REMS Distributor Enrollment Form* sent to via email.

A Customer Manager will help the distributor to complete a *Clozapine REMS Distributor Enrollment Form*. In completing the enrollment form, the distributor is required to indicate that they understand that clozapine is available only through the Clozapine REMS Program and they will comply with the program requirements.

71. H w can nr d distribut rs acc ss a ist f p armaci s t at participat in t C zapin EMS Pr gram?

After enrollment, distributors can access the current list of certified pharmacies by:

- Downloading a current list of certified pharmacies from a secure FTP site
- Using the “Certification Look-up” feature on the Resources tab of the Clozapine REMS Program Website at www.clozapinerems.com to verify a pharmacy
- Calling the Clozapine REMS Program Contact Center at 844-267-8678

72. A p armacy as r qu st d c zapin , but t yar n ty t c rtifi d in t C zapin EMS Pr gram. Can my c mpany sti distribut c zapin t t m?

Starting February 28, 2019, a pharmacy is only eligible to receive clozapine if the pharmacy has certified in the Clozapine REMS Program. If the pharmacy is not on the current list of R certified pharmacies, you must not ship clozapine to that pharmacy.

73. If a p armacy as r qu st d c zapin but is n t igib t r c iv c zapin , w d l n tify t m?

If a Pharmacy orders clozapine, but is not certified in the Clozapine REMS Program, distributors should reject the order per their standard procedures. At that point, the pharmacy can contact the Clozapine REMS Program and start the certification process. R

Technical Support

74. What if I need help using the Clozapine REMS Program Website ?

Call the Clozapine REMS Program Contact Center for assistance at 844-267-8678. **C**

75. What browsers and versions do you support on the Clozapine REMS Program Website?

We support the latest and previous releases of all major browsers on a rolling basis. Each time a new version is released; we begin supporting that version and typically stop supporting the third most recent version. Major browsers include Internet Explorer, Chrome, Firefox, and Safari.

76. How do we use cookies on the Clozapine REMS Program Website?

Our technical cookies are used to display the correct alerts and notifications on your dashboard that assist you in complying with the Clozapine REMS Program requirements.

We never store your unencrypted sensitive information in a cookie. Refer to our privacy policy to find more information about how we use cookies.

77. What do I do if I am unable to view a document on the Clozapine REMS Program Website ?

If you are attempting to open a document but nothing appears, you may have a pop-up blocker installed on your browser or, if you're unable to open a .pdf file, you may not have the Adobe Reader software installed. To rectify this, disable the feature in your browser for pop-up blockers. To install Adobe Reader, visit the Adobe site [here](#).

78. How do I report a problem with the Clozapine REMS Program Website ?

If you experience an outage or need to report a problem with the Clozapine REMS Program Website, please call the Clozapine REMS Program Contact Center at 844-267-8678.

79. Why do we use Captcha on the Clozapine REMS Program Website?

The Captcha on the Create Account page is used to ensure that only humans obtain accounts on the Clozapine REMS Program Website. The Captcha has been implemented to prevent abuse by automated scripts. To complete the Captcha, the user must type the letters of a distorted image that appears on the screen. If the Captcha image is difficult to read, the user can reload the Captcha image.

80. How do I obtain a username and password for the Clozapine REMS Program Website ?

You can create a user account for the Clozapine REMS Program Website. You will be asked to provide your contact information and create a username and password. Once the information is submitted online, you will be sent an email with a link to use in order to verify your account. **C**

What if I do not receive the verification email after I created my account?

If you did not receive the email with the verification link, please check your junk mail folder or call the Clozapine REMS Program Contact Center at 844-267-8678.

2 What do I do if I forgot my password?

If you forgot your password, you can use the “Forgot Password?” option in the upper right-hand corner of the page in the sign in section. Fill in the requested information and submit it online. A temporary password will be sent to your email address online.

3 What do I do if I forgot my username?

If you forgot your username, you can use the “Forgot Username?” option in the upper right-hand corner of the page in the sign in section. Fill in the requested information and submit it online. Your username will be sent to your email address online.

4 What do I do if my user account is locked?

If your user account is locked, please call the Clozapine REMS Program Contact Center at 844-267-8678 so a Clozapine REMS Program support agent can assist you in unlocking it.

5 How do I change my username and/or password?

To change your username and/or password select the drop-down arrow displayed next to your name in the upper right corner and select “My Profile.” Select the appropriate tab and enter the information in the fields and submit the information online. You will be sent either your username or a temporary password.

6 How does a Health Care Provider create multiple accounts with the same email address?

If you are a health care provider with multiple roles in the Clozapine REMS Program, you may create multiple accounts by following this procedure:

- In the Create an Account screen, you may enter the same email address in the My Information section for each account being set up. (see screenshot below)


Create Account

Please complete the form below and press **Submit**. The information you provide for your Username must be unique within the Clozapine REMS Program Website. Once you have submitted this form you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. All fields below are required.

My Information

Sign in

 Use Email Address as Username Suggest Username

 I'm not a robot 
reCAPTCHA
Privacy Terms

For additional information about the Clozapine REMS Program, please call 844-267-8678.

When you sign in to the system, do not use your email address as your username or select the checkbox to use email address as username. Please create a unique username for each account you create.

- You will need to log in to each account separately in order to access applicable role functionality.
 - For example, if you have an account as a prescriber designee and an account as a pharmacy staff, you would have to log out of one in order to access the other.

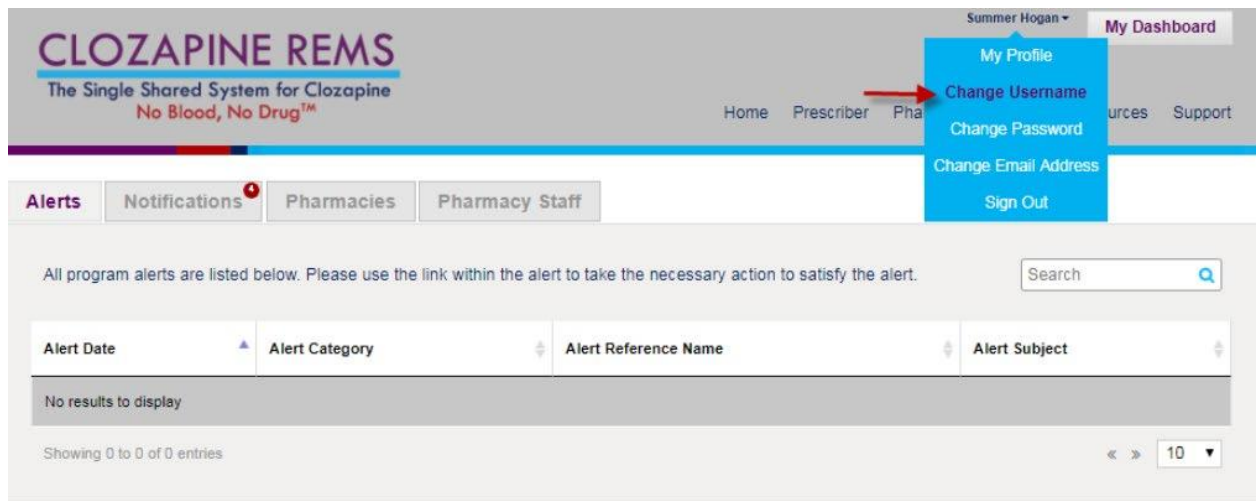
single log in for multiple roles is not available at this time.

- You will receive Clozapine REMS Program communication to a single email address if the steps are followed.

If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

87. How does a Healthcare Provider change a website username if they wish to create multiple accounts and have already used their email address as the username previously?

You may change your username by logging to your account on the Clozapine REMS Program Website and selecting the Change Username option from the link below your account link in the upper right corner of the website. (See screenshot below)



For additional information about the Clozapine REMS Program, please call 844-267-8678.

Would a healthcare Provider change the email address on their REPSfile if they previously created an account with an email address they no longer wish to use?

You may change your email address by signing in to your account on the Clozapine REMS Program Website and selecting the Change Email Address option from the links below your account link in the upper right corner of the website. **M**

The screenshot shows the user interface of the Clozapine REMS Program Website. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". The user is logged in as "Summer Hogan" and is viewing their "My Dashboard". A dropdown menu is open under the user name, showing options: "My Profile", "Change Username", "Change Password", "Change Email Address" (highlighted with a red arrow), and "Sign Out". Below the dashboard, there are tabs for "Alerts", "Notifications" (with a red notification icon), "Pharmacies", and "Pharmacy Staff". A search bar is present, and a table of alerts is shown with the message "No results to display". The table has columns for "Alert Date", "Alert Category", "Alert Reference Name", and "Alert Subject". At the bottom of the page, there is a footer with links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

For additional information about the Clozapine REMS Program, please call 844-267-8678.

en

89. I'm taking clozapine pills. How do I know if I'm enrolled in the Clozapine REMS program? If I'm not enrolled, how do I become enrolled in the Clozapine REMS program?

Please contact your Healthcare Provider for information on whether you are currently enrolled or how to become enrolled in the Clozapine REMS Program.

90. Where do I find lists of local pharmacies participating in the Clozapine REMS program?

Your Healthcare Provider can help you find a participating pharmacy. Please contact your Healthcare Provider for additional information about the Clozapine REMS Program. r

- The “**Eligibility Check**” (EC) evaluates criteria established by the Clozapine REMS Program to determine if it is safe to dispense clozapine to patients receiving inpatient medical care. This includes absolute neutrophil count (ANC) values.
- **An EC must be completed before dispensing an inpatient’s first dose of clozapine by using the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.**
- **An EC requires an ANC value which may be obtained through the Clozapine REMS Program, or by checking the patient’s medical records.**
- Inpatient pharmacies are encouraged to submit the patient’s ANC via the Clozapine REMS Program Website, by phone, or by fax according to the patient’s monitoring frequency (i.e., within 7 days of the EC date for weekly monitoring, within 15 days for every two weeks monitoring and within 31 days for monthly monitoring).

HOW CAN I PERFORM AN ELIGIBILITY CHECK?

Option 1: Use the Clozapine REMS Program Website:

- **Log in to your account at www.clozapinerems.com**
- **Access** the dashboard
- **Select ‘Eligibility Check’** from the drop-down menu and **click** the **GO** button
- **Enter the patient information** on the ‘Eligibility Check’ screen and **click Submit**
- A success message will appear or you will receive a warning message that will inform you of next steps to take. Refer to page 2 of this *Clozapine REMS Eligibility Check Fact Sheet* for further guidance.

Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I SUBMIT ANC VALUES?

Pharmacies are encouraged to submit ANC values to the Clozapine REMS Program according to the patient’s monitoring frequency by utilizing one of the following methods:

Option 1: Submit via the Clozapine REMS Program Website:

- **Log in to your account at www.clozapinerems.com**
- **Access** the dashboard
- **Select ‘Add Lab’** from the drop-down menu and **click** the **GO** button
- **Enter the patient information and ANC results** on the ‘Add Lab’ screen and **click Submit**
- User will be returned to the dashboard when complete

Option 2: Fax to the Clozapine REMS Program:

- **Visit www.clozapinerems.com**
- **Choose the Resources** tab
- **Click on Program Materials**
- **Select ‘Clozapine REMS ANC Lab Reporting Form’** from the list
- **Print and complete the form**
- **Fax the completed form to 844-404-8876**

Note: ANC values will be available immediately if submitted on the Clozapine REMS Program Website, but may be delayed up to 48 hours for processing of the paper form.

Option 3: Call the Clozapine REMS Program Contact Center at 844-267-8678.

ELIGIBILITY CHECK FACT SHEET

For INPATIENT PHARMACIES

Phone: 844-267-8678

Fax: 844-404-8876

www.clozapinerems.com

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

REMS PROGRAM ELEMENT EVALUATED BY THE <i>ELIGIBILITY CHECK</i>	POSSIBLE OUTCOMES	ELIGIBILITY TO RECEIVE CLOZAPINE	ACTION BY PHARMACY
Patient enrollment in the Clozapine REMS Program	Patient is enrolled.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	Patient is not enrolled.	<i>Eligibility Check Unsuccessful.</i>	Do not dispense. Contact a <u>certified</u> prescriber (or his designee) to enroll new patient.
Patient absolute neutrophil count (ANC) is on file	ANC on file.	<i>Eligibility Check Successful.</i>	Check if ANC is acceptable. Dispense.
	No ANC on file.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Check inpatient's medical record to verify ANC. Apply clinical judgement whether to dispense. ² Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency. ¹
Last ANC value on file is acceptable	ANC is acceptable.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a "Treatment Rationale" ³ is on file.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a <i>Treatment Rationale</i> ³ is not on file.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Check patient's inpatient medical record to verify ANC is acceptable. Apply clinical judgement whether to dispense. ²
ANC is current according to the patient's monitoring frequency ¹	ANC is current.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC is not current.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency. ¹ Apply clinical judgement whether to dispense. ²

¹Monitoring frequency:


- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
- For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
- For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

²Apply clinical judgement to determine if the benefits of clozapine outweigh its risks if a patient has an ANC indicating moderate or severe neutropenia.

³*Treatment Rationale*: a justification provided by a certified prescriber which allows a patient having moderate or severe neutropenia to continue treatment with clozapine.

BEFORE STARTING CLOZAPINE TREATMENT

- > Before starting treatment with clozapine, the baseline absolute neutrophil count (ANC) must be:
 - At least 1500/ μ L for the general population, or
 - At least 1000/ μ L for patients with documented benign neutropenia (BEN)
- > It is no longer necessary to check the National Non-Rechallenge Master File (NNRMF) before starting treatment.
- The NNRMF is no longer available. All patients who were listed in the NNRMF were transferred into the Clozapine REMS Program. These patients are identified with a red flag  in the Clozapine REMS Program.

MONITORING AND DURING TREATMENT

- > Prescribers must submit ANC according to the patient's monitoring frequency (MF) on file with the Clozapine REMS Program:
 - For weekly MF, ANC must be submitted within 7 days of the lab draw* date
 - For every two weeks MF, ANC must be submitted within 15 days of the lab draw* date
 - For monthly MF, ANC must be submitted within 31 days of the lab draw* date
- *Assumes the lab draw date is day 0
- > White blood cell (WBC) counts are not accepted. If you have a WBC count and differential, you may use the ANC calculator on the Clozapine REMS Program Website at www.clozapinere.ms.com to determine the ANC.
- > An ANC is normal if it is greater than or equal to 1500/ μ L for the general population, or greater than or equal to 1000/ μ L for patients with BEN.

LABS

- > Patients may transition to less frequent ANC monitoring based on their history of continuous clozapine therapy and normal ANCs.
 - Weekly ANC monitoring is required for all patients during the first six months of treatment.
 - If the patient's ANC remains in the normal range for the first six months of therapy, MF may be reduced to once every two weeks.
 - If the patient's ANC continues to remain in the normal range for the second six months of treatment, ANC MF may be reduced to once monthly.
- > Monitoring frequency is calculated based on the patient's lab history in the Clozapine REMS Program. It is critical that all labs be submitted to the Clozapine REMS Program according to the patient's MF to ensure that the patient's monitoring frequency does not revert to a more frequent schedule.
- The Clozapine REMS Program made every effort to consolidate ANC data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. Patients with complete profile information in the individual manufacturer registries were migrated to the Clozapine REMS Program successfully, but may have had different monitoring frequencies across multiple individual manufacturer registries and/or had a significant gap in ANC data when patient data was consolidated from the multiple individual manufacturer registries.
 - In accordance with the clozapine Prescribing Information, if the patient had consistent ANCs submitted over the previous 12-month period, the patient was migrated with a monthly MF.
 - If a patient's ANCs were inconsistently submitted to the registries in the previous 12-month period and there was a timeframe longer than 56 days between blood draw dates, the patient was migrated with a weekly MF.
- The guidelines outlined above for assigning a new MF are consistent with the Prescribing Information.
- If a prescriber needs to change a patient's MF, the prescriber may do so via the Prescriber Dashboard on the Clozapine REMS Program Website. The prescriber or prescriber designee may also update a patient's MF by calling the Clozapine REMS Program Contact Center at 844-267-8678.
- During the phased implementation period, the Clozapine REMS Program will not deny clozapine dispensing based on MF data. However, once the REMS Program is fully implemented, the MF is utilized to determine if a patient's ANC is current. Therefore, accuracy of the MF is important as a factor in determining if a pharmacy will be authorized to dispense clozapine to the patient.

MONITORING FREQUENCY

- > Treatment interruptions are now recommended at lower ANC thresholds than in previous versions of the Prescribing Information.
 - For general population patients, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 1000/ μ L.
 - For patients with documented BEN, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 500/ μ L.
 - See Table 1 in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or Tables 2 and 3 in the clozapine Prescribing Information for more detailed treatment guidance.
- > Prescribers may use clinical judgment to continue treatment with clozapine for patients with moderate or severe neutropenia if they determine that the benefits of clozapine therapy outweigh the risks. The prescriber must provide a "Treatment Rationale" in the Clozapine REMS Program to avoid treatment interruptions.
 - A prescriber can provide a *Treatment Rationale* via the Prescriber Dashboard on the Clozapine REMS Program Website or by calling the Clozapine REMS Program Contact Center at 844-267-8678.
- > Patients with documented BEN have specific treatment guidelines in the clozapine Prescribing Information (see Table 1 in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or Table 3 in the clozapine Prescribing Information for details).

TREATMENT

INTERRUPTIONS

BEN PATIENTS

HOSPICE PATIENTS

- > Patients in hospice may be excluded from certain program requirements (see Section 8.8 of the clozapine Prescribing Information).
- > Four weeks of weekly monitoring for patients who are discontinuing clozapine treatment is no longer required.
- > The duration and frequency of ANC monitoring is dependent on that patient's last ANC and clinical status (see Section 2.4 in the clozapine Prescribing Information for more details).

DISCONTINUING CLOZAPINE TREATMENT

A “**Predispose Authorization**” (PDA) determines if a patient is eligible to receive clozapine and provides an authorization for an **outpatient pharmacy** to dispense. An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis, including but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

Outpatient pharmacies must obtain a PDA each time before dispensing clozapine. PDAs may be obtained through the pharmacy management system (via the switch network), via the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

CLOZAPINE REMS PROGRAM ELEMENT EVALUATED BY THE PREDISPOSE AUTHORIZATION	POSSIBLE OUTCOMES	ELIGIBILITY TO RECEIVE CLOZAPINE	ACTION BY PHARMACY
		All PDA responses will provide the dispensing pharmacy with the most recent absolute neutrophil count (ANC) value, the associated blood draw date, and the patient's monitoring frequency ¹	Pharmacies are encouraged to submit the patient's ANCs through the Clozapine REMS Program Website, by phone, or by fax according to the patient's monitoring frequency ¹
Patient enrollment in the Clozapine REMS Program	Patient is enrolled	PDA Successful	No action necessary. Dispense.
	Patient is not enrolled	PDA Unsuccessful	Contact a certified prescriber (or his designee) to enroll new patient. Do not dispense.
Prescriber Certification	Prescriber is certified	PDA Successful	No action necessary. Dispense.
	Prescriber is not certified	PDA Unsuccessful	Contact prescriber to inform them they must be certified. Pharmacy can provide a “Dispense Rationale” and reattempt PDA. ²
Pharmacy Certification	Pharmacy is certified	PDA Successful	No action necessary. Dispense.
	Pharmacy is not certified	PDA Unsuccessful	Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine. Do not dispense.
Patient ANC is on file	ANC on file	PDA Successful	No action necessary. Dispense.
	No ANC on file	PDA Unsuccessful: A warning message will be displayed, reattempt PDA ² after ANC is obtained	If the pharmacist is in possession of an ANC, they are encouraged to submit the ANC to the Clozapine REMS Program; if not, contact the patient's certified prescriber. Reattempt PDA ² after ANC is obtained.
Last ANC value on file is acceptable	ANC is acceptable	PDA Successful	No action necessary. Dispense.
	ANC indicates moderate or severe neutropenia; and a “Treatment Rationale” is on file	PDA Successful	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a <i>Treatment Rationale</i> is not on file	PDA Unsuccessful: A warning message will be displayed	Do not dispense , unless one of these two possible follow-up actions are successful: <ul style="list-style-type: none"> If the pharmacist is in possession of an ANC that is more current and acceptable, the pharmacist is encouraged to submit the ANC to the Clozapine REMS Program and reattempt PDA.² Contact the prescriber to provide a <i>Treatment Rationale</i> or current acceptable ANC, reattempt the PDA.²
ANC is current according to the patient's monitoring frequency: ¹	ANC is current	PDA Successful	No action necessary. Dispense.
	ANC is not current	PDA Successful: a warning message will be displayed	Dispense clozapine; and: <ul style="list-style-type: none"> Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency.¹ Contact Prescriber to inform them that the ANC is not current according to the patient's monitoring frequency.¹

¹Monitoring frequency:

- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the PDA date.
- For every two weeks monitoring frequency, the last ANC result submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the PDA date.
- For monthly monitoring frequency, the last reported ANC result submitted to the Clozapine REMS must be drawn* within 31 days prior to the PDA date.

*Assumes lab draw date is day 0

²Wait approximately 2 minutes to reprocess the claim transaction through the pharmacy switch system.

HOW DO I REQUEST A PREDISPENSE AUTHORIZATION?

Pharmacies using a pharmacy management system (via the switch network):

1. Process all clozapine claims, including cash claims, through the pharmacy management system.
2. Responses:
 - a. A **success** message will appear; **displaying the PDA and recent ANC information, or**
 - b. A **warning** message will inform you of next steps to take. Refer to page 1 of this *Fact Sheet* for further guidance.

Pharmacies **that do not** use an electronic pharmacy management system (without switch network access):

Option 1: Use the Clozapine REMS Program Website to:

1. **Log in** to your account at www.clozapinerems.com
2. **Access the dashboard**
3. **Select 'Predispense Authorization'** from the drop-down menu and click the **GO** button
4. **Enter the patient information on the 'Predispense Authorization' screen and click Submit**
5. The *'Predispense Authorization Result'* screen will appear with a success or warning message. Refer to page 1 of this *Fact Sheet* for further guidance.

Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I PROVIDE A DISPENSE RATIONALE?

When a PDA is denied with the warning message: "Prescriber not certified in the Clozapine REMS Program" for an enrolled patient, a certified authorized representative or enrolled pharmacy staff in a certified pharmacy may exercise clinical judgment and continue to dispense clozapine by providing a *Dispense Rationale* electronically via one of two processes below:

Option 1: Pharmacies using the Clozapine REMS Program Website to request a PDA should:

1. Continue from Step 2b above at the PDA Result reject message screen.
2. **Click the 'Provide a Dispense Rationale for this patient' check box** at the bottom of the 'PDA Result' screen and **click the Submit** button.
3. If the *Dispense Rationale* was provided successfully, a success screen will appear.

Option 2: Pharmacies using the pharmacy network system (i.e., "switch") to request a PDA should:

1. **Log in** to the Clozapine REMS Program Website at www.clozapinerems.com.
2. **Access** the dashboard.
3. **Select 'Dispense Rationale'** from the drop-down menu and click the **Go** button. **Enter the patient information** on the *Dispense Rationale* screen and **click Submit**.
4. The *'Dispense Rationale Result'* screen will appear with a reject message similar to the switch reject message.
5. **Click on the 'Provide a Dispense Rationale for this patient' check box at the bottom** of the *'Dispense Rationale Result'* screen and **click Submit**.
6. If the *Dispense Rationale* is provided successfully, a **success screen** will appear.
7. **Wait approximately 2 minutes to reprocess the claim transaction** through the pharmacy switch system.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678

HOW DO I SUBMIT ANC VALUES?

Pharmacies are encouraged to submit the patient's ANC according to the patient's monitoring frequency by utilizing one of the following methods:

Option 1: Submit via the Clozapine REMS Program Website by:

1. **Logging in** at www.clozapinerems.com
2. **Accessing** the dashboard
3. **Selecting 'Add Lab'** from the drop-down menu and **click** the **GO** button
4. **Entering the patient information and ANC results** on the 'Add Lab' screen and **click Submit**
5. User will be returned to the dashboard when completed.

Option 2: Fax to the Clozapine REMS Program by:

1. **Logging in to your account** at www.clozapinerems.com
2. **Choosing** the *Resources* tab
3. **Clicking** on *Program Materials*
4. **Selecting 'Clozapine REMS ANC Lab Reporting Form'** from the list
5. **Printing and completing** the form
6. **Faxing the completed form to 844-404-8876.**

NOTE: ANC values will be available immediately when submitted via the Clozapine REMS Program Website, but are delayed up to 48 hours for processing of the paper form.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678

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Website Supplement 02/2019 REMS Modification

Clozapine REMS Program

November 2018

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1. Static Pages f 1.1 Home Page

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Prescriber

All prescribers of clozapine products must certify in the Clozapine REMS Program. Certification requires prescribers to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers

The 02/2019 Clozapine REMS Program Modification went live on 02/28/2019. Prescribers are required to certify in the Clozapine REMS Program as soon as possible to continue patient therapy. If prescribers are not certified at the time of the 02/2019 Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the Important Program Update (IPU) button for more information.

[Start Prescriber Certification](#)

Pharmacy

All pharmacies dispensing clozapine products must certify in the Clozapine REMS Program. Certification requires pharmacies to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
- **Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

The 02/2019 Clozapine REMS Program Modification went live on 02/28/2019. Pharmacies are required to certify in the Clozapine REMS Program. If pharmacies are not certified at the time of the 02/2019 Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the Important Program Update (IPU) button for more information.

[Start Pharmacy Certification](#)

*****Important Program Update (as of 02/28/2019)*****

[Please click to open the IPU](#)

What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L), which can lead to serious and fatal infections. The requirements to prescribe, dispense, and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.2 Site Guide – Prescriber Tab f



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.

Prescriber	Pharmacy	Patient	Designee	Pharmacy Staff
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Prescribers will begin the certification process by using the **Learn More** button below, which will navigate the prescriber to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber** page provides specific steps that must be completed to prescribe clozapine. From the **Prescriber** page, prescribers can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling new patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.3 Site Guide – Pharmacy Tab

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Home Prescriber Pharmacy Patient Resources **Support**

Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.

Prescriber **Pharmacy** Patient Designee Pharmacy Staff


Authorized representatives for a pharmacy will begin the certification process by using the **Learn More** button below, which will navigate the authorized representative to the certification landing page or by visiting the **Pharmacy** link at the top of the page.

The Pharmacy page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy** page, authorized representatives can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting predispose authorizations. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)



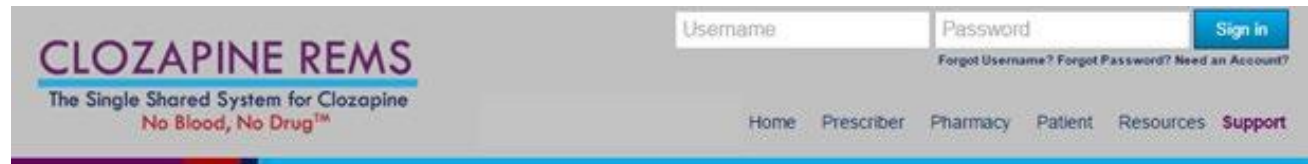
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.4 Site Guide – Patient Tab 3



Site Guide


This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy **Patient** Designee Pharmacy Staff

This site is for prescribers and pharmacists with patients on clozapine therapy. Patients must be enrolled in the program by a certified prescriber. If you believe you should be enrolled in the Clozapine REMS Program, please talk to your prescriber.

Additional information is available to patients by using the **Learn More** button below, which will navigate the patient to the patient information page or by visiting the **Patient** link at the top of the page.



[Learn More](#)

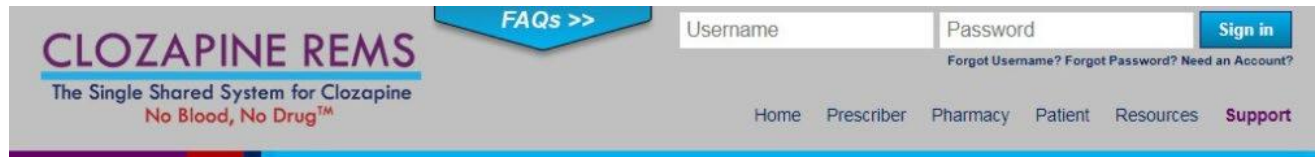
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.5 Site Guide – Designee Tab 4



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.



Prescriber designees can learn more about the certification process by using the **Learn More** button below, which will navigate the prescriber designee to the to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber Designee Certification** page provides specific steps that must be completed to become certified to prescribe clozapine. From the **Prescriber Designee** page, prescriber designees can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

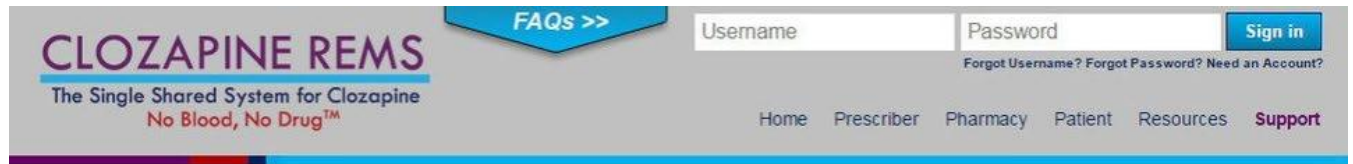
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For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.6 Site Guide – Pharmacy Staff Tab 5



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy Patient Designee **Pharmacy Staff**

Pharmacy staff can learn more about the enrollment process by using the **Learn More** button below, which will navigate the pharmacy staff to the enrollment landing page or by visiting the **Pharmacy** link at the top of the page.

The **Pharmacy Staff** page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy Staff Enrollment** page, pharmacy staff members can use the **Begin Now** button to start their enrollment process.

Once signed in to the site and your enrollment is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting *Predispense Authorizations*. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.7 Prescriber Certification 6

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Prescriber Certification

Steps for Prescriber Certification

Prescribers must be certified in the Clozapine REMS Program to prescribe clozapine.

If you choose to allow designees to act on your behalf, each designee must be certified in the Clozapine REMS Program. For more information on the designee certification process, please go to [Prescriber Designee Certification](#).

Certification in the Clozapine REMS Program includes the following three steps:

- 1. Enroll:** Complete the Enrollment Form (name, address, NPI, DEA)
- 2. Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- 3. Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Prescriber Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia](#)
- [Clozapine REMS How to Start Clozapine and Monitor Patients Fact Sheet](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.8 Prescriber Designee Certification 7

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Prescriber Designee Certification

Steps for Prescriber Designee Certification

The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a certified prescriber. Designees must be certified and approved in the Clozapine REMS Program before they can perform any duties or functions for their prescriber.

If you want to associate yourself to a pharmacy and have selected the Prescriber Designee Certification by accident, please go to [Pharmacy Staff Enrollment](#).

Prescriber Designee Certification in the Clozapine REMS Program includes the following three steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Educate: Review the REMS requirements

3. Confirm: Understanding of the requirements of the REMS

If the browser closes during certification, you can come back to the same point in the process

Please use the **Begin Now** button to start your certification today.

Begin Now!

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Designee Education Program](#)
-  [Clozapine REMS Prescriber Designee Enrollment Form](#)
-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
-  [Clozapine REMS Eligibility Check Fact Sheet](#)
-  [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.9 Pharmacy Certification f

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Pharmacy Certification

Steps for Pharmacy Certification

All inpatient and outpatient pharmacies must be certified in the Clozapine REMS Program in order to purchase and dispense clozapine. Certification requires the identification of an authorized representative for the pharmacy to complete the certification process. The authorized representative must ensure all pharmacists with privileges to dispense understand that clozapine is only available to certified pharmacies through the Clozapine REMS Program.

Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a *Predispense Authorization (PDA)* from the Clozapine REMS Program Website, to enter absolute neutrophil count (ANC), verify the prescriber is certified, or verify the patient is enrolled. If the pharmacy is a non-switch pharmacy to comply with the REMS, the pharmacy staff will either need to obtain a PDA by calling the program or by signing in to the website. For more information on the Pharmacy Staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Certification in the Clozapine REMS Program includes the following four steps:

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)

2. Educate: Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*

3. Assess: Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Chain Headquarters Pharmacy Enrollment Form](#)
- [Clozapine REMS Inpatient Pharmacy Enrollment Form](#)
- [Clozapine REMS Outpatient Pharmacy Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.10 Pharmacy Staff Enrollment 9

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Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense clozapine, pharmacy staff can enroll in the Clozapine REMS Program to have access to the Clozapine REMS Program Website. Pharmacy staff can link to multiple REMS-certified pharmacy locations.

Pharmacy staff enroll by creating an online account. Education is not required for enrollment but will be available after your enrollment is complete through your authorized representative.

For Outpatient Pharmacies: Pharmacy staff must enroll in the Clozapine REMS Program to obtain a *Predispose Authorization* (PDA) before dispensing each clozapine prescription. Pharmacy staff who are enrolled can obtain a PDA by calling the Clozapine REMS Program Contact Center or through electronic claim adjudication if your pharmacy has set up that process. Talk to your authorized representative if you are not sure how your pharmacy must obtain a PDA. Pharmacy staff must enroll to obtain a PDA through the Clozapine REMS Program Website.

For Inpatient Pharmacies: Pharmacy Staff must enroll to perform *Eligibility Checks* through the Clozapine REMS Program Website or the Clozapine REMS Program Contact Center.

Pharmacy staff enrollment in the Clozapine REMS Program includes the following two steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Attest: Complete and sign the Pharmacy Staff Attestation

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.11 Patient Information – Home Page

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Patient Information

Because of the risk of developing severe neutropenia, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for clozapine.

The purpose of the Clozapine REMS Program is to make sure that the benefits of clozapine treatment outweigh the risks.

Prescribers must talk to their patients about the Clozapine REMS Program requirements and the risks of using clozapine. Patients should review the *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* program material and talk with their prescriber if they have any questions or concerns about using clozapine.

Program Materials

-  **A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia**

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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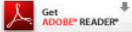
1.12 Program Materials f

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
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Program Materials



Forms | Patient | Pharmacy | Prescriber | Wholesaler/Distributor | Fact Sheets and Demos

-  Clozapine REMS ANC Lab Reporting Form
-  Clozapine REMS Chain Headquarters Pharmacy Enrollment Form
-  Clozapine REMS Patient Enrollment Form
-  Clozapine REMS Inpatient Pharmacy Enrollment Form
-  Clozapine REMS Outpatient Pharmacy Enrollment Form
-  Clozapine REMS Prescriber Designee Enrollment Form
-  Clozapine REMS Prescriber Enrollment Form

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Not : source s i clud d u d r th oth r tabs ar list d b low: f

- Patient
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
- Pharmacy
 - *Clozapine REMS Eligibility Fact Check Sheet*
 - *Clozapine REMS PDA Fact Sheet*
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
 - *Dear Inpatient Pharmacy Letter*
 - *Dear Outpatient Pharmacy Using Web PDA Letter*
 - *Dear Outpatient Pharmacy Using Switch Letter*
 - *Clozapine REMS Inpatient Pharmacy Enrollment Form*
 - *Clozapine REMS Outpatient Pharmacy Enrollment Form*
 - *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*

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- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers (Education Program and Knowledge Assessment)*
- *Clozapine REMS Patient Enrollment Form*
- *Clozapine REMS ANC Lab Reporting Form*
- *ANC Calculator*
- *ANC Monitoring Table*

- **Prescriber**
 - *Clozapine REMS Prescriber Enrollment Form*
 - *Clozapine REMS Prescriber Designee Enrollment Form*
 - *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers (Education Program and Knowledge Assessment)*
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
 - *Clozapine REMS How to Start Clozapine & Monitor Patients Fact Sheet*
 - *Clozapine REMS Patient Enrollment Form*
 - *Clozapine REMS ANC Lab Reporting Form*
 - *ANC Calculator*
 - *ANC Monitoring Table*
 - *Prescriber Designee Education Program*
 - *Prescriber Designee Acknowledgment Form*
 - *Dear Prescriber Letter*

- **Wholesaler/Distributor**
 - *Contact the ClozapMS Program by sending a mail to info@clozapine_distributor.com*

- **Fact Sheets and Demos**
 - *Clozapine REMS PDA Fact Sheet*
 - *Clozapine REMS Eligibility Check Fact Sheet*
 - *Clozapine REMS How to Start Clozapine & Monitor Patients Fact Sheet*
 - *Prescriber Certification*
 - *Prescriber Designee Certification*
 - *Pharmacy Authorized prescriber Certification and Pharmacy Certification*
 - *Pharmacy Staff Enrollment*
 - *How to View Prescriber Alerts and Notifications*
 - *How to Use the Prescriber Dashboard*
 - *How to Treat a *Treatment Rationale**
 - *How Prescribers Treat ANC's and *at Risk* Patients*
 - *How Prescribers Contact Labs*
 - *How Outpatient Pharmacists Obtain a Web *Predispense Authorization (PDA)**
 - *How Outpatient Pharmacists Treat ANC's*
 - *How Inpatient Pharmacists Check Eligibility and Treat ANC's*
 - *How to Obtain a *Dispense Rationale**

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1.13 Prescribing Information 3

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Prescribing Information

Products covered under the Clozapine REMS Program

Brand Name Products			
Trade Name	Generic Name	Company	Link
Clozaril®	Clozapine	HLS Therapeutics (USA), Inc.	Full Prescribing Information
FazaClo®	Clozapine, USP	Jazz Pharmaceuticals Inc.	Full Prescribing Information
Versacloz®	Clozapine, USP	Jazz Pharmaceuticals Inc.	Full Prescribing Information

Generic Products			
Trade Name	Generic Name	Company	Link
Clozapine	Clozapine Tablets, USP	Accord Healthcare Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Aurobindo Pharma USA Inc.	Full Prescribing Information
Clozapine	Clozapine, USP ODT	Jazz Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mayne Pharma Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mayne Pharma Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Orally Disintegrating Tablets	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Orally Disintegrating Tablets	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Sun Pharmaceutical Industries Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Teva Pharmaceuticals USA Inc.	Full Prescribing Information
Clozapine	Clozapine, USP ODT	Teva Pharmaceuticals USA Inc.	Full Prescribing Information

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Certification Lookup

To search for a pharmacy, please complete at least one field below and press **Search**. If an identifier is used for searching, no other fields need to be entered. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or or and

and

or or

[Search](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.15 Certification Lookup Results 5

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Certification Lookup

To search for a pharmacy, please complete at least one field below and press **Search**. If an identifier is used for searching, no other fields need to be entered. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required)

or or and

and

or or

[Search](#)

Pharmacy Name	Certification Id	Pharmacy Address	Pharmacy Phone	Pharmacy Type
Ikea Inc	FAC5413637605	4343 n scottsdale rd, PHOENIX, Arizona 85054	123-465-4687	Outpatient

Showing 1 to 1 of 1 entries

[1](#) [10](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Site Map

<u>Prescriber</u>	<u>Designee</u>	<u>Account</u>
Prescriber Certification Prescriber FAQs Prescriber Resources Prescriber Support	Prescriber Designee Certification Designee Support	Forgot Password Forgot Username Need an Account
<u>Pharmacy</u>	<u>Pharmacy Staff</u>	
Pharmacy Certification Pharmacy FAQs Pharmacy Resources Pharmacy Support	Pharmacy Staff Enrollment Pharmacy Staff Support	
<u>Patient</u>	<u>General</u>	
Patient FAQs Patient Information Patient Resources Patient Support	Contact Us General FAQs Prescribing Information Privacy Professional Societies Resources Technical Support FAQs Terms of Use Wholesaler/Distributor FAQs Wholesaler/Distributor Resources	

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Username: Password: [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Frequently Asked Questions (FAQs)

General	Prescriber	Prescriber Designee	Patient Mgmt	Pharmacy Mgmt	Pharmacy Auth Rep	Wholesaler/Distributor	Technical Support	Patient
<ul style="list-style-type: none">+ What is a REMS?+ What is the Clozapine REMS Program?+ What are the goals of the Clozapine REMS Program?+ Where can I obtain the Prescribing Information for clozapine?+ What are the different roles of healthcare staff in the Clozapine REMS Program?+ Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS Program?+ How does a Healthcare Provider certify in more than one role in the Clozapine REMS Program (e.g., as a pharmacy staff and a prescriber designee)? Can the same email address be used for multiple roles in the Clozapine REMS Program?+ Why are white blood cell (WBC) counts no longer being collected?+ How frequently should a patient's ANC be monitored?+ When should I submit a patient's ANC to the Clozapine REMS Program?+ How do I contact the Clozapine REMS Program?+ How does a Healthcare Provider report an adverse event, product complaint, or obtain medical information about clozapine?+ What is the new certification deadline for prescribers and outpatient pharmacies?+ How is monitoring frequency determined in the Clozapine REMS Program?+ Why did established patients with monthly monitoring frequency get converted to weekly monitoring frequency?+ My existing clozapine patient was not migrated from the individual manufacturer registries and therefore the Clozapine REMS Program identifies this patient as new and has aligned this patient to a weekly monitoring frequency. How can I update the system so my patient is correctly returned to monthly monitoring frequency?								

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source included with other tabs are listed below

- Prescriber
 - How can a prescriber become certified with the single shared Clozapine 7 Program?

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- When do I need to complete certification?
- What are the changes or prescriptions in a patient's setting with the <M /YYYY> Clozapine Program indication?
- If a prescriber is going to be out of the office or a extended period of time, can another prescriber cover during the absence?
- If a prescriber is going to be out of the office or a short period of time, can another prescriber write a prescription or the patient during the absence?
- If a nurse practitioner, physician assistant, resident, or other certified as a prescriber in the Clozapine Program?
- Can a member of the prescriber's office staff help manage patients in the Clozapine MS Program?
- How can a prescriber identify a list of pharmacies that are certified in the Clozapine Program?
- Where can I find the Patient ID or the Clozapine ANC Lab reporting Form?
- Prescriber Design
 - What actions can a prescriber design perform in the Clozapine Program?
- Patient Agreement
 - Do patients need to be enrolled in the Clozapine Program in order to receive clozapine?
 - How are patients enrolled in the Clozapine Program?
 - Can a health care provider certify in the Clozapine Program submit an ANC?
 - Will the program send out notices to patients experiencing a low ANC or substantial drop?
 - What is a Treatment Status?
 - What is a "Treatment Interval"?
 - How can a provider find the *Treatment Rationale*?
 - What happened to patients previously on the National No-Challenge Master File (NNCF)?
 - How are patient ANCs submitted to the Clozapine Program?
 - Does the Clozapine Program need to be advised when a patient is admitted to or discharged from an acute or long-term health care setting?
 - When discontinuing treatment, does the patient's ANC need to be monitored for 4 weeks?
 - If a patient is eligible to receive their monitoring requirements for the Clozapine Program, do they need to be notified?
 - If the patient or caregiver will not provide the required information needed to complete Patient Enrollment (e.g., Name, Date of Birth) can they still receive clozapine?
 - How do some patients in a patient's setting become enrolled in the Clozapine Program?
- Pharmacy Agreement
 - What are the direct pharmacy certification types in the Clozapine Program?
 - What is a *Predispense Authorization (PDA)*?
 - What is a *Eligibility Check*?

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- How is a *Eligibility Check* different from a *Predispense Authorization* (PDA)?
- What is a "Dispensation?"
- How can a pharmacy provide a *Dispense Rationale*?
- How does a pharmacy certify in the Clozapine Program?
- How often must a pharmacy recertify?
- How does a pharmacy recertify in the Clozapine Program?
- What happens if a pharmacy does not recertify every 2 years?
- What happens if a pharmacy is deactivated?
- If my pharmacy is "deactivated," what must be done?

- Wholesale/Distributor
 - Does a distributor have to enroll in the Clozapine Program?
 - How can a distributor enroll in the Clozapine Program?
 - How can enrolled distributors access a list of pharmacies that participate in the Clozapine Program?
 - A pharmacy has requested clozapine, but they are not yet certified in the Clozapine Program. Can my company still distribute clozapine to them?
 - If a pharmacy has requested clozapine but is not eligible to receive clozapine, how do I notify them?

- Technical Support
 - What if I'd help using the Clozapine Program website?
 - What browser types and versions does the Clozapine Program Website support?
 - How do I set the Clozapine Program Website cookies?
 - What do I do if I can't view a document on the Clozapine Program Website?
 - How do I report a problem with the Clozapine Program Website?
 - Why do I see the Clozapine Program Website Captcha?
 - How do I obtain a username and password for the Clozapine Program Website?
 - What if I do not receive the verification email after I created my account?
 - What do I do if I forgot my password?
 - What do I do if I forgot my username?
 - What do I do if my user account is locked?
 - How do I change my username and/or password?
 - How does a healthcare provider create multiple accounts with the same email address?
 - How does a healthcare provider change a website username if they wish to create multiple accounts and have already used their email address as their username previously?
 - How does a healthcare provider change their email address on their profile if they previously created an account with a different email address they no longer wish to use?

- Patient
 - I am a clozapine patient. How do I know if I'm enrolled in the Clozapine Program? If I'm not enrolled, how do I become enrolled in the Clozapine Program?
 - Where do I find a list of local pharmacies that participate in the Clozapine Program? S 9

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1.18 FAQ – Pharmacy Authorized Representative 3

The screenshot shows the top navigation bar of the Clozapine REMS website. It includes the logo, a tagline, and a navigation menu with links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. Below the navigation is a 'Frequently Asked Questions (FAQs)' section with a tabbed interface. The 'Pharmacy Auth Rep' tab is selected, displaying a list of 15 questions related to pharmacy certification and dispensing. At the bottom of the page, there is a contact information line and a footer with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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Username Password [Sign In](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Frequently Asked Questions (FAQs)

General	Prescriber	Prescriber Designee	Patient Mgmt	Pharmacy Mgmt	Pharmacy Auth Rep	Wholesaler/Distributor	Technical Support	Patient
---------	------------	---------------------	--------------	---------------	--------------------------	------------------------	-------------------	---------

- + What is an authorized representative?
- + Who should act as the authorized representative in the pharmacy?
- + When does certification need to be completed?
- + What is the difference between an inpatient pharmacy and an outpatient pharmacy?
- + What if I am in a pharmacy that dispenses clozapine for both inpatient and outpatient use?
- + What is "the switch"?
- + What happens to patients who try to fill a prescription at a pharmacy that is not certified?
- + Will pharmacies that are not certified be able to order and receive clozapine?
- + The pharmacy has been certified but the system is reporting that the pharmacy is not certified. What are the next steps?
- + Will patients still need to have blood draws?
- + Can clozapine be dispensed to a patient without bloodwork?
- + What actions are required if the prescribing physician isn't certified?
- + What should a pharmacist do with the patient's *ANC Lab Reporting Form*?
- + The pharmacy just certified and needs to order clozapine today. What are the next steps?
- + What if the authorized representative leaves the pharmacy?
- + If the patient's prescription is denied or the *Eligibility Check* indicates "do not dispense", will the Clozapine REMS Program system explain the reason?

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.19 Contact Us 3



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Contact Us

If you have any questions or require additional information, please contact the Clozapine REMS Program utilizing the information provided below.

Phone Number

844-267-8678

Fax Number

844-404-8876

Mailing Address

Clozapine REMS Program

PO BOX 29058

Phoenix, AZ 85038-9058

Program Manufacturers

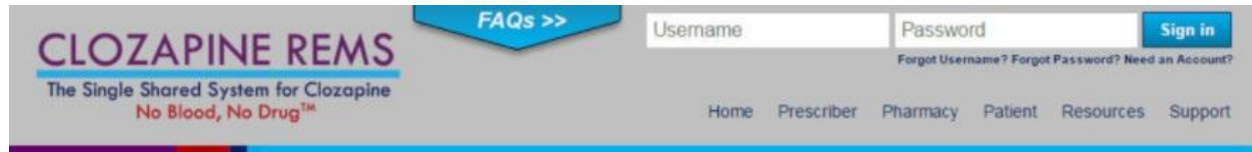
Company	Phone Number
Accord Healthcare Inc.	919-941-7878
Aurobindo Pharma USA Inc.	732-839-9400
HLS Therapeutics (USA) Inc.	844-457-8721
Jazz Pharmaceuticals Inc.	800-520-5568
Mayne Pharma Inc.	844-825-8500
Mylan Pharmaceuticals Inc.	800-796-9526
Sun Pharmaceuticals Industries Inc.	800-818-4555
Tasman Pharmaceuticals	257-317-4104
Teva Pharmaceuticals USA Inc.	800-292-4283

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2. User Identification and Record Search 3

2.1 User Identification



User Identification

Please select the option below that **best** describes you and press **Next**.

What type of user are you? 

-- Please Select --
-- Please Select --
New User
Phone/Fax User
-- Please Select --

Program role

New User - Users who are new to clozapine and have not previously submitted an enrollment form to the Clozapine REMS Program Contact Center.

Phone/Fax User - Users who submitted an enrollment form through the Clozapine REMS Program Contact Center via fax and have received an enrollment or certified ID.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Not :

Upon starting the enrollment or certification process, the users are asked to identify what type of user they are and what their role is.

– The options for type of user are New User and Phone/Fax User. The tool-tip next to the field will include a definition of each for the user which are also below (Previous Registry User is removed).

- New User – Users who are new to clozapine and have not previously submitted an enrollment form to the contact center for clozapine registry
- Phone/Fax User – Users who submitted an enrollment form through the contact center via fax and have received an enrollment or certification ID.
 - When the system locates the user's record and creates a web account, the user's web account and their enrollment or certification record are linked.

2 – The options for role are Prescriber, authorized representative for pharmacy, Prescriber 3 Designated, and Pharmacy Staff.

2.2 Phone/Fax User Prescriber Search 3

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. To the right are input fields for 'Username' and 'Password', followed by a 'Sign in' button and links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. Below these are navigation links: 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'.

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

The form is titled 'At least one identifier is required:'. It contains several input fields: 'DEA (opt)' and 'NPI' are grouped together with an 'or' separator; 'First Name', 'Last Name', and 'Certification ID (opt)'; 'Phone (opt)', 'Fax (opt)', and 'Email (opt)'. A blue 'Search' button is located at the bottom right of the form.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.3 Phone/Fax User Prescriber Search with Results 3

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Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

At least one identifier below is required:

<input type="text" value="AB1234567"/>	<input type="text" value="NPI"/>	
<input type="text" value="Summer"/>	<input type="text" value="Hogan"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

[New User](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.4 Phone/Fax User Prescriber Designee Search 3

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there are input fields for 'Username' and 'Password', a 'Sign in' button, and links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. Below these are navigation links: 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'.


Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

The search form is titled 'At least one identifier is required:'. It contains several input fields: 'DEA (opt)' and 'NPI' are grouped together with an 'or' separator; 'First Name', 'Last Name', and 'Certification ID (opt)'; 'Phone (opt)', 'Fax (opt)', and 'Email (opt)'. A blue 'Search' button is located at the bottom right of the form.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.5 Phone/Fax User Prescriber Designee Search with 3 Results



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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.6 Phone/Fax User Pharmacy Search 3

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there are input fields for 'Username' and 'Password', a 'Sign in' button, and links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. Below these are navigation links: 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'.

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

The screenshot shows a search form with two main sections. The first section is titled 'Pharmacy Information (at least one identifier is required):' and contains input fields for 'Zip Code', 'DEA', 'NPI', and 'NCPDP', with an 'and' label between 'Zip Code' and 'DEA'. The second section is titled 'Authorized Representative Information' and contains input fields for 'First Name', 'Last Name', 'Certification ID (opt)', 'Phone (opt)', 'Fax (opt)', and 'Email (opt)'. A blue 'Search' button is located at the bottom right of the form.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.7 Phone/Fax User Pharmacy Search with Results 3



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="AB1234567890"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
------------------------------------	-----	---	----------------------------------	------------------------------------

Authorized Representative Information

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone
Summer	Hogan	Joey's Apothecary	1 Main Street, New York, NY 10001	555-555-5555

Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.8 Phone/Fax User 3

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Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

[Search](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.9 Phone/Fax User with Results 4

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Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or press the **New User** button to begin your enrollment process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Phone
Summer	Hogan	Joey's Apothecary	1234 W Nowhere Lane Tempe, AZ 85263	555-555-5555

Showing 1 of 1 entries 1 10

[New User](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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3. Web Account 3.1 Create Account



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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)


Create Account

Please complete the form below and press **Submit**. The information you provide for your Username must be unique within the Clozapine REMS Program Website. Once you have submitted this form you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. All fields below are required.

My Information

Sign in

Use Email Address as Username Suggest Username

I'm not a robot 

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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3.2 Account Verification 4

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Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Account Verification



A verification email has been sent to remsprogram@gmail.com.
Please use the link within the email to activate your web account for
the Clozapine REMS Program.

Account Summary

Name: [Summer Hogan](#)
Email Address: remsprogram@gmail.com
Phone Number: [480-555-5555](tel:480-555-5555)
Username: [summerhogan](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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3.3 Account Confirmation 4

The screenshot shows the Clozapine REMS website interface. At the top left is the logo and tagline. On the top right, there are input fields for 'Username' and 'Password', and a 'Sign in' button. Below these are links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Account Confirmation' and features a green checkmark icon and a message box stating: 'Your web account has been successfully activated. Please sign in to your account using the fields in the upper right corner of this page.' At the bottom, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a list of links: 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

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4. Prescriber Certification 4

4.1 Prescriber Intake

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Summer Hogan ▾ [My Dashboard](#)

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake **Education** Assessment Review Attestation Finish

Prescriber Intake

To certify as a prescriber in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Prescriber Information

First Name MI (opt)

Last Name

-- Credentials -- ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

-- State -- ▾ Zip Code

Phone Ext (opt)

Fax

-- Contact Preference -- ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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4.2 Prescriber Education Program⁴

The screenshot shows the user interface for the Clozapine REMS Prescriber Education Program. At the top, the logo and tagline 'CLOZAPINE REMS The Single Shared System for Clozapine No Blood, No Drug™' are displayed. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A progress bar at the top indicates the current step: 'Start', 'Intake', 'Education' (highlighted), 'Assessment', 'Review', 'Attestation', and 'Finish'. Below the progress bar, the section is titled 'Education Program'. A paragraph of text explains that the education program is for clozapine and that it is estimated to take 15-20 minutes to complete. A large central box contains the title 'CLOZAPINE REMS' and the tagline, followed by a disclaimer in a smaller box. Below this is the main title of the education guide: 'Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers'. A 'Next' button is located at the bottom right of the central box. At the bottom of the page, there is a footer with the text 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a link to 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Start Intake **Education** Assessment Review Attestation Finish

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15-20 minutes to complete the Education Program and Clozapine REMS Knowledge Assessment for Healthcare Providers.

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This guide is intended to educate Healthcare Providers about clozapine and the Clozapine REMS Program. During the launch of the Clozapine REMS Program, there were challenges that required an extension of the phased implementation period. This guide is reflective of the full implementation of the Clozapine REMS Program, which is expected in 02/2019. For the current state of the Clozapine REMS Program, expected full implementation dates and important updates on the transition period, please see the *Clozapine REMS Frequently Asked Questions (FAQs)* on the Clozapine REMS Program Website at www.clozapinerems.com.

Clozapine and the Risk of Neutropenia:

A Guide for Healthcare Providers

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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4.3 Prescriber Education Confirmation 4

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The top right corner features the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber' (highlighted), 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation is a progress bar with steps: 'Start', 'Intake', 'Education' (highlighted), 'Assessment', 'Review', 'Attestation', and 'Finish'. The main heading is 'Education Program Confirmation'. The text reads: 'You have now completed the Education Program'. Below this, it says: 'Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site.' A blue 'Next' button is visible. At the bottom, a note states: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

Not : Upo pr ssi g th Next butto o th ducatio Co irmatio pag th us r will b avigat d through th *Clozapine REMS Knowledge Assessment for Healthcare Providers 4* (KA . KA is show no l o c b low or all stak hold rs xc pt or pr scrib r d sig s.

4.4 Prescriber Intake Review4

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
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[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) **Review** [Attestation](#) [Finish](#)

Prescriber Intake Review

Please review the information for completeness and accuracy. You may make any changes as necessary. When your review is complete, please use the **Next** button to save your information below and proceed to the final step in your certification process.

Prescriber Information

First Name / MI (opt)

Last Name

Credentials ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

State / Zip Code ▾

Phone / Ext (opt)

Fax

Contact Preference ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

4.5 Prescriber Attestation 4

Summer Hogan* [My Dashboard](#)

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation **Finish**

Prescriber Attestation

To complete the prescriber certification for **Summer Hogan** into the Clozapine REMS program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8678.

As a prescriber, I attest to the following Clozapine REMS Program requirements:

By signing this form, I attest that:

1. I understand that clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements to prescribe clozapine.
2. I have reviewed Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, reviewed the clozapine Prescribing Information, and successfully completed the Clozapine REMS Knowledge Assessment for Healthcare Providers.
3. I understand the risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
4. Prior to initiating treatment, I agree to provide A Guide for Patients and Caregivers: What You Need to Know about Clozapine to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing A Guide for Patients and Caregivers: What You Need to Know about Clozapine.
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program.
6. I understand the absolute neutrophil count (ANC) testing and monitoring requirements as described in the clozapine Prescribing Information.
7. I understand there is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN).
8. I will order ANC testing for each patient according to the clozapine Prescribing Information.
9. I will submit and verify the ANC according to each patient's monitoring frequency on file with the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date*Assumes the lab draw date is day 0
10. I will verify the patient's monitoring frequency on file with the Clozapine REMS Program is aligned with the patient's monitoring frequency as described in the Prescribing Information.
11. I understand that, as described in Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed.
12. I agree that personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
13. I understand that clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
14. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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ClozapMS

Program_Website_Screenshot_Captures

November 2018

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Reference ID: 4376730


CLOZAPINE REMS

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4.6 Prescriber Confirmation 4

The screenshot shows the 'Clozapine REMS' website interface. At the top left is the logo 'CLOZAPINE REMS' with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The top right shows the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation is a progress bar with steps: 'Start', 'Intake', 'Education', 'Assessment', 'Review', 'Attestation', and 'Finish'. The main heading is 'Certification Confirmation' with a decorative graphic of colored squares. A green checkmark icon is followed by the text 'You are now certified in the Clozapine REMS Program.' Below this, a message states: 'Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.' The 'Certification ID' is 'HCP123456789' with a copy icon. A note says: 'If you would like to enroll patients now, you can use [Enroll Patient](#). If you need to manage your patients, you can use [Manage Your Patients](#).' At the bottom, a call to action reads: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

5. Prescriber Designee Certification 5



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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber Designee Certification

Steps for Prescriber Designee Certification

The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a certified prescriber. Designees must be certified and approved in the Clozapine REMS Program before they can perform any duties or functions for their prescriber.

If you want to associate yourself to a pharmacy and have selected the Prescriber Designee Certification by accident, please go to [Pharmacy Staff Enrollment](#).

Prescriber Designee Certification in the Clozapine REMS Program includes the following three steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Educate: Review the REMS requirements

3. Confirm: Understanding of the requirements of the REMS

If the browser closes during certification, you can come back to the same point in the process

Please use the **Begin Now** button to start your certification today.

Begin Now!

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Designee Education Program](#)
-  [Clozapine REMS Prescriber Designee Enrollment Form](#)
-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
-  [Clozapine REMS Eligibility Check Fact Sheet](#)
-  [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5.1 Prescriber Designee Intake 5

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Designee Intake

To certify as a designee in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Designee Information

First Name

Last Name

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference -- ▾

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.2 Prescriber Designee Education Program Page 1 5

Summer Hogan ▾ [My Dashboard](#)

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[Start](#) [Intake](#) **[Education](#)** [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

General Information

Certified prescribers may identify and associate designees to their Clozapine REMS Program certification record. This allows prescribers to approve responsible individual(s) to act on behalf of the certified prescriber for patients being treated with clozapine. Prescriber designees can submit absolute neutrophil count (ANC) test results, enroll, and manage patients with the following exceptions:

- Designees cannot categorize a patient as having benign ethnic neutropenia (BEN).
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate to severe neutropenia (general population) or severe neutropenia (patients with documented BEN).
- Designees cannot categorize a patient as a hospice patient.

[1](#) [2](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.3 Prescriber Designee Education Program Page 2 5

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Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake **Education** Assessment Review Attestation Finish

Prescriber Designee Responsibilities

By signing this form, I acknowledge that I will act on behalf of the certified prescriber identified below to comply with the Clozapine REMS Program requirements.

I understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
- There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **Outpatient Settings¹:** An ANC must be submitted to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed and per the Monitoring Schedule described in the Prescribing Information:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

- A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient.
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
- Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
- I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine only via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

1 2

Back

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5.4 Prescriber Designee Knowledge Assessment 5

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) **Assessment** [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment

Please select the **best** answer for the following question. This question must be answered correctly to become certified:

I have reviewed the requirements of the Clozapine REMS Program.

A. Yes

B. No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.5 Prescriber Designee Knowledge Assessment 5 Confirmation – Success

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[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment Results

✔ **Congratulations! You have now completed the assessment.**

You answered the question correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Code: [KA-1652-A6F8-0BE7](#) 🖨

QUESTION 1

I have reviewed the requirements of the Clozapine REMS Program.

✔ A. Yes

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.6 Prescriber Designee Knowledge Assessment 5 Confirmation – Not Successful

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Home Prescriber Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Below is your response. Please use the **Retake Assessment** button below to begin your assessment again.

QUESTION 1

I have reviewed the requirements of the Clozapine REMS Program.

✘ B. No

ATTEMPT 1 2 3 4 5 6

Retake Assessment

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.7 Prescriber Designee Intake Review5

Summer Hogan ▾ [My Dashboard](#)

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education Assessment **Review** Attestation Finish

Designee Intake Review

Please review the information for completeness and accuracy. You may make any changes as necessary. When your review is complete, please use the **Next** button to save your information and proceed to the final step in your certification process.

Designee Information

First Name

Last Name

Email Address

Phone / Ext

Fax

Contact Preference

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.8 Prescriber Designee Attestation 5

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education Assessment Review **Attestation** Finish

Designee Attestation

To complete the designee certification for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online certification form and fax it to Clozapine REMS Program at 844-404-8876. 

By signing this form, I acknowledge that I will act on behalf of the certified prescriber identified below to comply with the Clozapine REMS Program requirements.

I understand:

1. Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
2. There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
3. **Outpatient¹ Settings:** An absolute neutrophil count (ANC) must be submitted to the Clozapine REMS Program for each patient according to the following monitoring frequency, and I understand these results must be provided before clozapine can be dispensed:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

4. A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient.
5. Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
6. Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine only via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

By checking this box, I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

Back

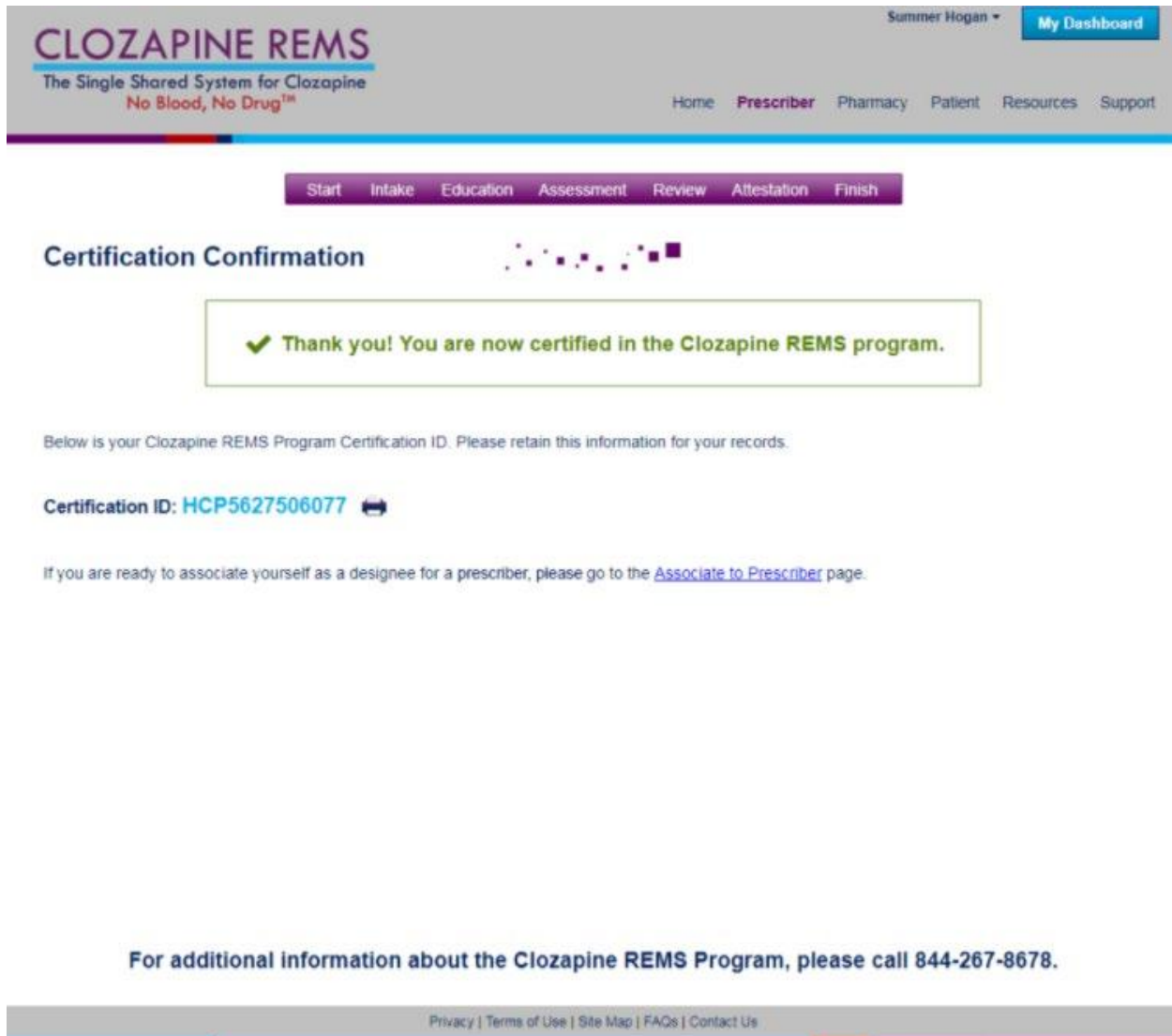
Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.9 Prescriber Designee Confirmation 5



The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are visible. A navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. A user profile for Summer Hogan and a My Dashboard button are also present. A progress bar indicates the current step is 'Finish'. The main content area features a 'Certification Confirmation' heading and a green message box stating: 'Thank you! You are now certified in the Clozapine REMS program.' Below this, a text block provides the Certification ID: HCP5627506077. A final instruction directs the user to the 'Associate to Prescriber' page. A footer contains contact information: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a list of links: Privacy | Terms of Use | Site Map | FAQs | Contact Us.

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation Finish

Certification Confirmation

✓ Thank you! You are now certified in the Clozapine REMS program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: **HCP5627506077** 🖨️

If you are ready to associate yourself as a designee for a prescriber, please go to the [Associate to Prescriber](#) page.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6. Pharmacy Certification

6.1 Pharmacy Certification – Home Page

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FAQs >>

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **Pharmacy** [Patient](#) [Resources](#) [Support](#)

Pharmacy Certification

Steps for Pharmacy Certification

All inpatient and outpatient pharmacies must be certified in the Clozapine REMS Program in order to purchase and dispense clozapine. Certification requires the identification of an authorized representative for the pharmacy to complete the certification process. The authorized representative must ensure all pharmacists with privileges to dispense understand that clozapine is only available to certified pharmacies through the Clozapine REMS Program.

Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a *Predispense Authorization (PDA)* from the Clozapine REMS Program Website, to enter absolute neutrophil count (ANC), verify the prescriber is certified, or verify the patient is enrolled. If the pharmacy is a non-switch pharmacy to comply with the REMS, the pharmacy staff will either need to obtain a PDA by calling the program or by signing in to the website. For more information on the Pharmacy Staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Certification in the Clozapine REMS Program includes the following four steps:

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)

2. Educate: Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*

3. Assess: Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Chain Headquarters Pharmacy Enrollment Form](#)
- [Clozapine REMS Inpatient Pharmacy Enrollment Form](#)
- [Clozapine REMS Outpatient Pharmacy Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

6.2 Role Selection – New User

Note: User will be presented with this screen upon selecting 'New User' type on the User 6 Identification screen.

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Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.
 - Outpatient pharmacy: A pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient's treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
 - Inpatient pharmacy: A pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition)
- Authorized Representative of Chain Headquarters Pharmacy** - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.
 - The Chain Headquarters Pharmacy certification process requires a **single** authorized representative to review the [Education Program](#), complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and the [Chain Headquarters Pharmacy Enrollment](#) form
 - Once completed, please contact your switch provider Account Manager for further instructions on submission of the *Clozapine REMS Knowledge Assessment for Healthcare Providers & Enrollment Form* for certification processing
 - A contract with your switch provider is required for a Chain Headquarters Pharmacy certification to be complete
 - Please review this [important communication to Chain Pharmacies](#)

[Continue](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.3 Role Selection – Phone/Fax User

Not : User will be presented with this screen upon selecting 'Phone/Fax User' type on the 6 User Identification screen.

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Username Password Sign in
Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Support

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.
 - Outpatient pharmacy: A pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient's treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
 - Inpatient pharmacy: A pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition)
- Authorized Representative of Chain Headquarters Pharmacy** - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.

Continue

For additional information about the Clozapine REMS Program, please call 844-267-8678.

6.4 Role Selection Confirmation – Inpatient Pharmacy 6

Not : This pop-up message is common to both New Users and Phone/Fax users.

The screenshot shows the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a login section with 'Username' and 'Password' fields and a 'Sign in' button, and a menu with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Program Role Selection' and contains a message: 'Please select the option below that **best** describes your role and press **Continue**.' Below this are three radio button options. The second option, 'Authorized Representative of Inpatient Pharmacy', is selected. A modal dialog box is open over this option, containing the following text: 'Authorized Representative of Inpatient Pharmacy. Based on the response selected, please confirm you are certifying as an Inpatient Pharmacy. An inpatient pharmacy dispenses clozapine only to patients treated receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition). If the pharmacy you are certifying does not meet this definition of an Inpatient Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.' The dialog has 'Cancel' and 'Confirm' buttons. Below the dialog, a 'Continue' button is visible. At the bottom of the page, there is a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

6.5 Role Selection Confirmation – Outpatient Pharmacy 6

Not : This pop-up message is common to both New Users and Profile/Fax users.

The screenshot shows the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a login section with 'Username' and 'Password' fields and a 'Sign in' button, and a menu with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Program Role Selection' and contains a prompt: 'Please select the option below that **best** describes your role and press **Continue**.' Below this are several radio button options. The 'Authorized Representative of Independent Outpatient Pharmacy' option is selected, and a white pop-up box with a purple border is overlaid on the page. The pop-up contains the following text: 'Authorized Representative of Independent Outpatient Pharmacy', 'Based on the response selected, please confirm you are certifying as an Independent Outpatient Pharmacy.', a detailed definition of an outpatient pharmacy, and instructions to press 'Cancel' or 'Confirm'. At the bottom of the pop-up are 'Cancel' and 'Confirm' buttons. Below the pop-up, a 'Continue' button is visible. At the bottom of the page, there is a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

6.6 Role Selection Confirmation – Chain Headquarters Pharmacy

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

Authorized Representative of Outpatient Pharmacy - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be

- Outpatient pharmacy limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems

Authorized Representative of Chain Headquarters Pharmacy

Based on the response selected, please confirm you are certifying as a Chain Headquarters Pharmacy of an Outpatient Pharmacy.

An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. As a Chain Headquarters Pharmacy, you agree that you are acting on behalf of a group of outpatient pharmacies as a corporate headquarters enrolling in the Clozapine REMS Program for multiple pharmacy locations (i.e., chain stores or a group of pharmacies owned/operated as a single entity); and, whose enrollment and certification activities will be handled centrally by one authorized representative acting on behalf of all the locations in the "chain".

If the pharmacies you are certifying do not meet this definition of requiring enrollment by a Chain Headquarters Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

[Cancel](#) [Confirm](#)

[Continue](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.7 Authorized Representative Intake 6

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Representative Information

First Name

Last Name

Credentials

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference --

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.8 Authorized Representative Confirmation 6

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The top right corner features the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation, a purple bar contains the steps: 'Intake', 'Education', 'Assessment', and 'Confirmation', with 'Confirmation' being the active step. The main content area is titled 'Confirmation' and features a green-bordered box with the message: 'You have successfully completed the required authorized representative training.' Below this, a paragraph of text provides instructions: 'If you are ready to certify your pharmacy now, please use [Certify Pharmacy](#). To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session today, simply close your browser.' At the bottom of the main content area, there is a call to action: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

6.9 Pharmacy Intake

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[Home](#) [Prescriber](#) **Pharmacy** [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Attestation](#) [Confirmation](#)


Pharmacy Intake

Note: Your pharmacy type has been updated. Click [here](#) to change.

To certify your Pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your Authorized Representative Intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Name

-- Select Type --  **1**

Address

Address 2 (opt)

City

--State-- Zip

Phone Ext (opt)

Fax (opt)

Pharmacy Identifiers

Please provide at least one identifier.

NCPDP (opt)

DEA (opt)

NPI (opt) **2**

[Cancel](#) [Next](#)

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Note:

1 – The options for type of Pharmacies are Inpatient and Outpatient. The tool-tip next to this field will include definition of inpatient and outpatient pharmacies, which are as below:

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- Inpatient pharmacy: A pharmacy with a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).
- Outpatient pharmacy: A pharmacy dispensing clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

2 – Adjudicated claims only question – This question will be displayed only if the Pharmacy Type selected on this page is 'Outpatient Pharmacy'. 6

6.10 Pharmacy Re-classification 7

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1

Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

Yes
 No

[Next](#)

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1A

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
- No

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1B

Is your pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- Yes
 No

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 2

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

[Next](#)

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Clozapine REMS Pharmacy Classification

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Clozapine REMS Pharmacy Classification

Please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.11 Pharmacy Education Program7

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Home Prescriber **Pharmacy** Patient Resources Support

Intake Education Assessment Confirmation

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15-20 minutes to complete the Education Program and *Clozapine REMS Knowledge Assessment for Healthcare Providers*.

Clozapine_REMS_HCP_Guide_v2_2015_08_11.ai 1 / 21

CLOZAPINE REMS
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Clozapine and the Risk of Neutropenia:
A Guide for Healthcare Providers

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.12 Pharmacy Education Confirmation 7



Intake Education Assessment Confirmation

Education Program Confirmation

You have now completed the Education Program

Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Not : Upo pr ssi g th Next butto o th ducatio Co firmatio pag , th us r will b 7
avigat d through th Clozapine REMS Knowledge Assessment for Healthcare Providers.
KA is sho o ly o c b lo for all sta hold rs xc pt for pr scrib r d sig s.

6.13 Pharmacy Attestation – Inpatient Pharmacy

Not : This page includes only the attestation text for the Inpatient Pharmacy from the 7 Clozapine REMS Inpatient Pharmacy Enrollment Form.

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Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for **ABC Pharmacy** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8876.

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. Establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the patient is enrolled in the Clozapine REMS Program by:
 - Signing in to the Clozapine REMS Program Website at www.clozapinerems.com to complete an "Eligibility Check", or
 - Calling the Clozapine REMS Program Contact Center at 844-267-8678
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the *Eligibility Check* date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Inpatient pharmacies must complete an *Eligibility Check* and verify ANC/prescriber authorization before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
7. Provide dispensing location information to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
9. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

Note: Inpatient pharmacies are not required to obtain a "Predispense Authorization™" (PDA) prior to dispensing clozapine.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

[Back](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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ClozapMS

Program_Website_Screenshot

November 2018

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Reference ID: 4376730

6.14 Pharmacy Attestation – Outpatient Pharmacy

Note: This page includes only the attestation text for the Outpatient Pharmacy from the 7 Clozapine REMS Outpatient Pharmacy Enrollment Form.

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Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for **ABC Pharmacy** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8876. 🖨

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers and the Prescribing Information* and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the "Predispense Authorization" (PDA) transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for continuing clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Provide dispensing location information to the Clozapine REMS Program
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
8. Outpatient pharmacies must obtain a PDA each time before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
9. Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program.
10. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.15 Pharmacy Confirmation

Not : This page will be available for:

1. Inpatient Pharmacists
2. Outpatient Pharmacists who cannot adjudicate claims on their own

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[Intake](#) [Attestation](#) [Confirmation](#)

Certification Confirmation



✓ Your pharmacy is now certified in the Clozapine REMS Program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: [FAC7771640309](#)

To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

Please download the Education Program, Knowledge Assessment for Healthcare Providers, and Knowledge Assessment Answer Guide from your Profile page. These tools should be used to train all pharmacists and relevant staff involved in dispensing clozapine. A record of the training must be maintained for future review by the Clozapine REMS Program.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

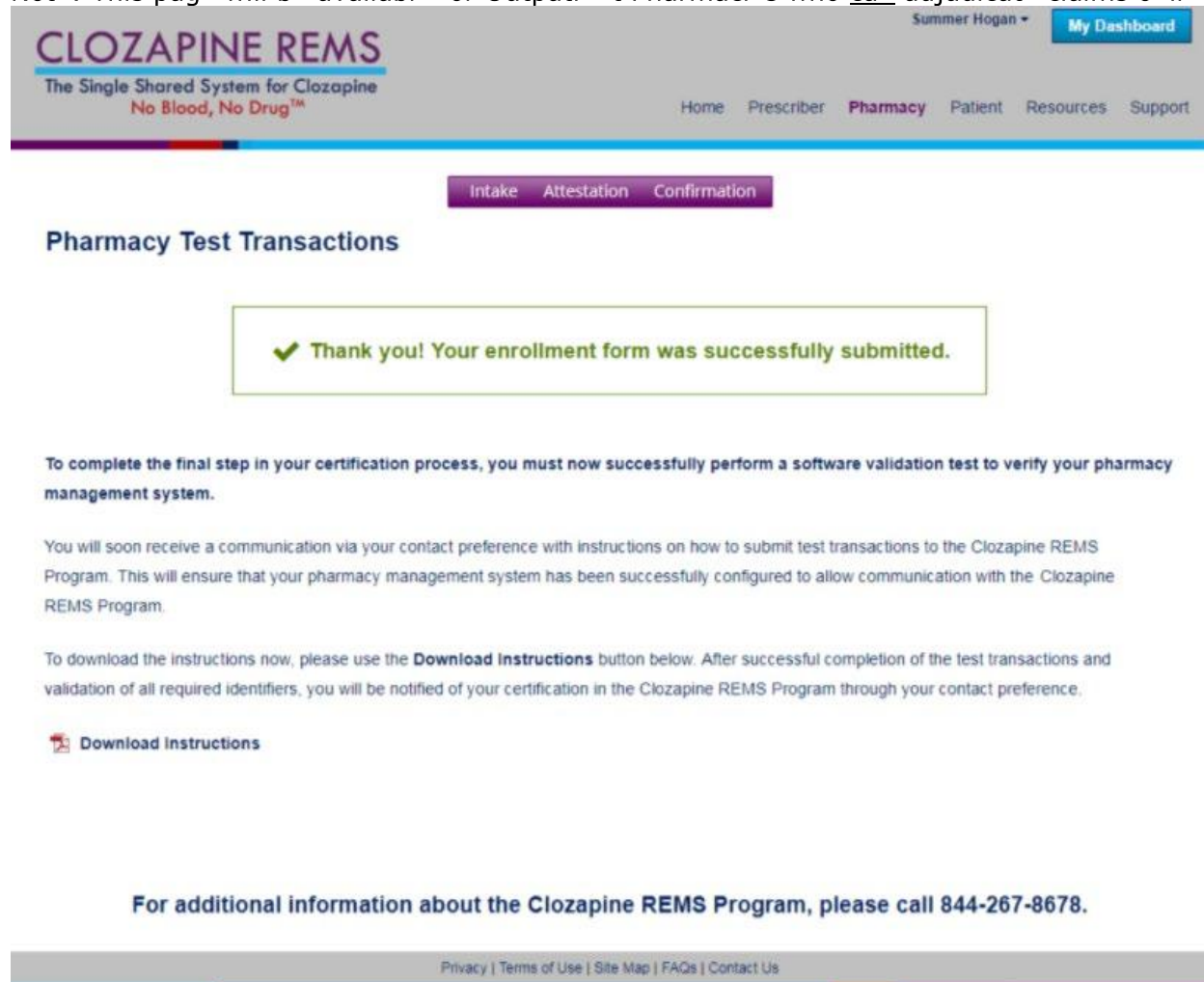
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6.16 Pharmacy Test Transactions

Not : This page will be available for Outpatient Pharmacists who can adjudicate claims on behalf of



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Home Prescriber **Pharmacy** Patient Resources Support

Intake Attestation Confirmation


Pharmacy Test Transactions

✓ **Thank you! Your enrollment form was successfully submitted.**

To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system.

You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Program. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program.

To download the instructions now, please use the **Download Instructions** button below. After successful completion of the test transactions and validation of all required identifiers, you will be notified of your certification in the Clozapine REMS Program through your contact preference.

 [Download Instructions](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7. Chain Pharmacy Certification f

7.1 Chain Pharmacy Store Intake

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Pharmacy Intake

To certify your chain pharmacy store, please complete the form below and press **Next**. Once the store is certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Name

Address

Address 2 (opt)

City

-- State -- ▾

Phone

Fax

--Training Status-- ▾

Pharmacy Identifiers

NCPDP

Please provide at least one:

DEA

NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

7.2 Chain Pharmacy Store Confirmation 3

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Chain Store Confirmation

✓ The chain pharmacy store has been successfully added.

To add another store, please use the **Add Store** button below.

[Add Store](#) [My Dashboard](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8. Pharmacy Staff Enrollment

8.1 Enrollment Home Page

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FAQs >>

Username Password [Sign in](#)

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Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense clozapine, pharmacy staff can enroll in the Clozapine REMS Program to have access to the Clozapine REMS Program Website. Pharmacy staff can link to multiple REMS-certified pharmacy locations.

Pharmacy staff enroll by creating an online account. Education is not required for enrollment but will be available after your enrollment is complete through your authorized representative.

For Outpatient Pharmacies: Pharmacy staff must enroll in the Clozapine REMS Program to obtain a *Predispose Authorization* (PDA) before dispensing each clozapine prescription. Pharmacy staff who are enrolled can obtain a PDA by calling the Clozapine REMS Program Contact Center or through electronic claim adjudication if your pharmacy has set up that process. Talk to your authorized representative if you are not sure how your pharmacy must obtain a PDA. Pharmacy staff must enroll to obtain a PDA through the Clozapine REMS Program Website.

For Inpatient Pharmacies: Pharmacy Staff must enroll to perform *Eligibility Checks* through the Clozapine REMS Program Website or the Clozapine REMS Program Contact Center.

Pharmacy staff enrollment in the Clozapine REMS Program includes the following two steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Attest: Complete and sign the Pharmacy Staff Attestation

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8.2 Pharmacy Search 5

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

and

[Search](#)

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8.3 Pharmacy Search Results 6

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Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

[Submit](#)

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8.4 Pharmacy Staff Intake 7

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Pharmacy Staff Intake

To enroll as a pharmacy staff in the Clozapine REMS Program, please complete the form below and press **Next**. Once enrolled, you will receive an enrollment confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Pharmacy Staff Information

First Name

Last Name

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference -- ▾

[Cancel](#) [Next](#)

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8.5 Pharmacy Staff Attestation f

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Start Intake Attestation Finish

Pharmacy Staff Attestation

To complete the pharmacy staff enrollment for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

As a pharmacy staff, I attest to the following Clozapine REMS Program requirements:

Pharmacy Staff can access the Clozapine REMS Program online at www.clozapinerems.com to complete the following:

- Enter an absolute neutrophil count (ANC) result for a patient
- Verify a patient is enrolled in the Clozapine REMS Program
- In an outpatient pharmacy:
 - Obtain a "Predispense Authorization" (PDA)^{1,2} or
 - Provide a "Dispense Rationale"
- In an inpatient pharmacy:
 - Complete an "Eligibility Check"

For online access to perform the above tasks, you must enroll by creating an account.

¹Inpatient pharmacies do not need to obtain a PDA.

²Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunications standards do not obtain a PDA via the Clozapine REMS Program Website.

By enrolling, you agree not to share your credentials for the Clozapine REMS Program Website or allow others to sign in to the website using your credentials.

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense clozapine. It is your responsibility to update this information as necessary.

By checking this box, I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

Back

Submit

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8.6 Pharmacy Staff Confirmation 9

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Start Intake Attestation Finish

Enrollment Confirmation

✓ You have now enrolled in the Clozapine REMS Program.

Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.

Enrollment ID: [HCP123456789](#)

To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session for today, simply close your browser.

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9. Knowledge Assessment for Healthcare Providers

Not : Th Clozapine REMS Knowledge Assessment for Healthcare Providers pag s b low 9 ar for pr scrib rs, pr scrib r d sig s, a d authoriz d r pr s tativ s.

9.1 Knowledge Assessment for Healthcare Providers Landing Page

The screenshot shows the landing page for the Clozapine REMS Knowledge Assessment for Healthcare Providers. The page features a header with the Clozapine REMS logo and navigation links. A progress bar indicates the current step is 'Assessment'. The main content area includes instructions for the assessment and a 'Start Assessment' button. The footer contains contact information and a phone number.

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Start Intake Education **Assessment** Review Attestation Finish

Clozapine REMS Knowledge Assessment for Healthcare Providers

You are now going to review questions that will test your knowledge of appropriate use and administration of clozapine. To be certified in the Clozapine REMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question.

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education program is required to be reviewed again before retaking the knowledge assessment. After six unsuccessful attempts, your access to retake the knowledge assessment will be suspended and you will need to contact the Clozapine REMS Program to reinstate your ability to complete the knowledge assessment.

[Start Assessment](#)

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9.2 Knowledge Assessment Question 1 9

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Intake Education **Assessment** Confirmation

Knowledge Assessment

QUESTION 1

All clozapine products are only available under the single shared Clozapine REMS Program.

- A. True
- B. False

Next

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9.3 Knowledge Assessment Question 2 9

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Intake Education Assessment Confirmation

Knowledge Assessment

QUESTION 2

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- A. True
- B. False

Next

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9.4 Knowledge Assessment Question 3 9

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Intake Education **Assessment** Confirmation

Knowledge Assessment

QUESTION 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L
- C. An absolute neutrophil count (ANC) less than 500/ μ L
- D. None of the above

Next

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9.5 Knowledge Assessment Question 4 9

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ μ L for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ μ L for a patient who is part of the general population (i.e., the patient does not have documented BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

Next

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9.6 Knowledge Assessment Question 5 9

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[Intake](#) [Education](#) **[Assessment](#)** [Confirmation](#)

Knowledge Assessment

QUESTION 5

Before clozapine is dispensed to a patient, a certified prescriber must:

- A. Determine if the patient has documented BEN
- B. Enroll the patient in Clozapine REMS Program
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and submit it to the Clozapine REMS Program
- F. All of the above

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9.7 Knowledge Assessment Question 6 9

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Knowledge Assessment

QUESTION 6

In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.

A. True
 B. False

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9.8 Knowledge Assessment Question 7 9

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Knowledge Assessment

QUESTION 7

Before clozapine can be dispensed, a pharmacist in an outpatient pharmacy must:

- A. Verify the patient is enrolled in the single shared Clozapine REMS Program
- B. Verify the prescriber is certified in the single shared Clozapine REMS Program
- C. Verify the ANC is acceptable or verify the prescriber has authorized continuing treatment if the ANC is abnormal
- D. Obtain a "Predispose Authorization" each time from the Clozapine REMS Program
- E. All of the above

Next

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9.9 Knowledge Assessment Question 8 9

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Knowledge Assessment

QUESTION 8

How much clozapine can be dispensed?

- A. A 30-day supply
- B. A 90-day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

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9.10 Knowledge Assessment Question 9 9

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Knowledge Assessment

QUESTION 9

Regarding patients with documented BEN, which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

Next

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9.11 Knowledge Assessment Question 10 f

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Knowledge Assessment

QUESTION 10

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

Next

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9.12 Knowledge Assessment Question 11 f

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Knowledge Assessment

QUESTION 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC $\geq 1500/\mu\text{L}$ if the patient is part of the general population (i.e., if the patient does not have documented BEN)
- B. Mild neutropenia is within the normal range for a patient with documented BEN
- C. If the patient has documented BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

Next

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9.13 Knowledge Assessment Question 12 f

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Knowledge Assessment

QUESTION 12

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
- D. None of the above

Next

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9.14 Knowledge Assessment Question 13 3

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Knowledge Assessment

QUESTION 13

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the general population (i.e. if the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

Next

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9.15 Knowledge Assessment Confirmation – Success 4

The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are repeated. A navigation bar includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A progress bar indicates the user is in the 'Assessment' stage. A green box with a checkmark and the text 'Congratulations! You have now completed the assessment.' is centered. Below this, a message states: 'You answered all the questions correctly and have passed the assessment. Please press the **Next** button to complete your certification.' The 'Knowledge Assessment Code: KA-1636-D098-1E12' is displayed with a copy icon. A scrollable area contains three questions, all marked as correct. Question 1: 'All clozapine products are only available under the single shared Clozapine REMS Program. A. True'. Question 2: 'Clozapine is associated with severe neutropenia, which can lead to serious infection and death. A. True'. Question 3: 'Severe neutropenia is defined as:'. A blue 'Next' button is located at the bottom right of the scrollable area. At the bottom of the page, a message reads: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' A footer bar contains links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

9.16 Knowledge Assessment Confirmation – Not 5 Successful

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are present, along with a user profile for Summer Hogan and a 'My Dashboard' button. A navigation menu includes Home, Prescriber, Pharmacy, Patient, Resources, and Support. A progress bar below the navigation shows 'Intake', 'Education', 'Assessment', and 'Confirmation', with 'Assessment' being the active step. The main heading is 'Knowledge Assessment Results'. A red-bordered box contains the message: 'We're sorry, you did not pass the Knowledge Assessment.' Below this, a paragraph explains that the user should review the 'Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers' before retaking the assessment. A scrollable window shows three questions: Question 1 (All clozapine products are only available under the single shared Clozapine REMS Program. Answer: A. True), Question 2 (Clozapine is associated with severe neutropenia, which can lead to serious infection and death. Answer: B. False), and Question 3 (Severe neutropenia is defined as:). Below the questions is an 'ATTEMPT' counter showing 1 out of 6 attempts, and a 'Retake Assessment' button. At the bottom, a footer provides contact information: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a link to 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

10. Patient Enrollment 6

10.1 Patient Intake

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

Patient Intake

To enroll your patient in the Clozapine REMS Program, please complete the form below and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via your contact preference. All fields listed below are required.

Patient Information

First Name

Last Name

Date of Birth (MM/DD/YYYY)

Zip Code

-- Gender -- ▾

-- Race -- ▾

-- Patient Group -- ▾ ? Groups can be used to categorize your patients.

Does the patient have Benign Ethnic Neutropenia (BEN)?

-- Please Select -- ▾

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

10.2 Patient Lab Intake



Start Intake Lab Info Finish

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Jackie Collins

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

Blood DrawDate

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L)	None	None	None

Treatment Status
 1

Monitoring Frequency

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

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10.3 Patient Lab Intake with *Treatment Rationale*

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Home Prescriber Pharmacy **Patient** Resources Support

Start Intake Lab Info Finish

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Jackie Collins

Lab Entry

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L) ?	None	None	None

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

600

Blood Draw Date
12/06/2017

Modify Lab

Treatment Status
Active ▾

Treatment Rationale 1 --Please Select-- ▾

Treatment Rationale Duration 2 --Please Select-- ▾

Monitoring Frequency
Weekly ▾

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

Cancel Next

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Note:

The Add Lab page allows the user to enter Patient Lab Information.

1 – Options available for *Treatment Status* include:

- a. Benign Ethnic Neutropenia (BEN) Patient
- b. Benefit Outweighs Risk

2 – Treatment Rationale Duration

- a. Until next ANC Lab
- b. Until (MM/DD/YYYY)

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10.4 ANC Calculator 9

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ANC Calculator

WBC count (x10 ⁹ /mm ³)	Segs (%)	Bands (%)	ANC value (per μL)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

WBC count (x10 ⁹ /mm ³)	Neutrophils (%)	ANC value (per μL)
<input type="text"/>	<input type="text"/>	<input type="text"/>

NOTE:
For WBC count, data should be entered in decimal format (a value of 4,300 should be entered as 4.3).
For Segs, Bands, or Neutrophils, data should be entered without percent sign (20% should be entered as 20).
If the ANC value is populated with a value, the same value is populated in the ANC value field on the form.

Source: Mosby's Diagnostic and Laboratory Test Reference, 6th ed. 2003. White blood cell count and differential, page 942.

Cancel Next

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Lab Information

The Treatment Status and Monitoring Frequency are required to be entered in the fields provided below.

Frank Adam

Lab Entry

ANC value (per μL)

660

Blood Draw Date

10/21/2014

Treatment Status

Active ▾

Treatment Rationale

-- Please Select -- ▾

Treatment Rationale Duration

-- Please Select -- ▾

Monitoring Frequency

Weekly ▾

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

11. Stakeholder Profiles

Not : Stakeholder profiles are accessed via the drop-down next to the signature user's name at the top of every page.

11.1 Prescriber Profile

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My Profile

My Information

[Edit](#)

First Name / MI:

Last Name:

Credentials: ▾

Clinic / Practice Name:

Address:

Address 2:

City:

State / Zip Code:

Phone / Ext:

Fax:

Contact Preference: ▾

DEA:

NPI:

My Certification

Certification ID: [HCP123456789](#) ↗

Education Program

[Cancel](#) [Save](#)

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11.2 Prescriber Designee Profile

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My Profile

My Information [Edit](#)

First Name:

Last Name:

Phone / Ext:

Fax:

Contact Preference:

My Certification

Certification ID: **HCP123456789**

Education Program

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11.3 Authorized Representative Profile

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My Profile

My Information Edit

First Name

Last Name

Position/Title

Phone / Ext

Fax

Contact Preference

Education Program

Clozapine REMS Knowledge Assessment for Healthcare Providers

Knowledge Assessment Answer Guide

[Cancel](#) [Save](#)

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11.4 Chain Headquarters Pharmacy Authorized 3 Representative Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information [Edit](#)

First Name

Last Name

Position / Title

Phone / Ext

Fax

Contact Preference

Education Program

[Cancel](#) [Save](#)

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11.5 Chain Headquarters Pharmacy Profile

Note: The chain headquarters pharmacy authorized prescriber will have two options via the drop-down next to the signature's name at the top of every page; one for Profile (authorized prescriber profile above) and Chain Headquarters Pharmacy Profile (below).

Summer Hogan ▾ [My Dashboard](#)

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Chain Headquarters Pharmacy Profile

Chain Headquarters Pharmacy Information [Edit](#)

Chain Name:

Address:

Address 2:

City:

State / Zip:

Phone / Ext:

Fax:

Chain ID: **CS5123**

Chain Headquarters Pharmacy Certification

Certification ID: **FAC5471595906** [↗](#)

[Cancel](#) [Save](#)

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11.6 Pharmacy Staff Profile 5

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My Profile

My Information [Edit](#)

First Name

Last Name

Phone / Ext

Fax ▾

Contact Preference

My Enrollment

Enrollment ID: [HCP123456789](#) ↗

[Cancel](#) [Save](#)

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12. My Account

Not : Account pages are accessed via the drop-down next to the sign-in user's name at the top of every page.

12.1 Forgot Username

CLOZAPINE REMS
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Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Forgot Username

Please enter your credentials in the spaces provided below. Your username will be sent to the email you registered on file with the Clozapine REMS Program.

First Name

Last Name

Email Address

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.2 Change Username 7

Summer Hogan [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program Website.

Use Email Address as Username Suggest Username
[Change Password](#)
[Change Email Address](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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12.3 Change Username Confirmation f

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Username

✓ Your username has been successfully saved.

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program Website.

Use Email Address as Username [Suggest Username](#)

[Change Password](#)
[Change Email Address](#)

[Cancel](#) [Save](#)

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12.4 Change Password 9

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Password

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

[Cancel](#) [Save](#)

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12.5 Change Password Notification f

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Change Password

⚠ Your Password needs to be changed.

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

Cancel

Save

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.6 Change Password Confirmation f

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Password

✔ Your password has been successfully saved.

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.7 Change Email Address f

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Email Address

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)
[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.8 Change Email Address Confirmation 3

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Email Address

✓ Your email address has been successfully updated. A verification email has been sent to <email address>. Please use the link within the email to confirm this change.

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)

[Cancel](#) [Save](#)

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13. Patient Groups

13.1 Manage Groups

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ¹ Patients Designees **Manage Groups**

The table below contains all of your patient groups. If you need to add a new patient group, please use the **Add Group** button.

Add Group Search

Group Name	Actions
Group A	-- Please Select -- <input type="button" value="Go"/>
Group B	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

My Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The Manage Groups page will include a list of all groups the prescriber or designee has created for themselves. The actions the prescriber and designee can take are:

- 1 – Add Group – will take the user to the Add Group page
- 2 – Change Group Name – will take the user to the Edit Group page
- 2 – Remove Group – will take the user to the Remove Group page

13.2 Add Group

Summer Hogan ▾ [My Dashboard](#)

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Add Group

To add a new group, please specify the group name below and press **Submit**. You can add a patient to the group by accessing the patient's profile.

[Cancel](#) [Submit](#)

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13.3 Change Group Name 6

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Change Group Name

To change the group, simply edit the group name in the field below and press **Submit**.

Group Name

[Cancel](#) [Submit](#)

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13.4 Remove Group 7

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Group

To remove the group below simply press **Remove**; otherwise, press **Cancel** to return to Manage Groups.

Group Name: **Group A**

[Cancel](#) [Remove](#)

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13.5 Remove Group Warning f

The screenshot displays the Clozapine REMS website interface. At the top, the logo 'CLOZAPINE REMS' is visible, along with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The user 'Summer Hogan' is logged in, and a 'My Dashboard' button is present. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Remove Group' and shows a form with 'Group Name: Group A'. A warning dialog box is overlaid on the page, containing the following text: 'Warning', 'Patients are currently assigned to the group you are removing.', and 'Would you like to reassign all the patients to a new group?'. The dialog box has 'No' and 'Yes' buttons. Below the dialog box, there are 'Cancel' and 'Remove' buttons. At the bottom of the page, there is a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation menu with 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

13.6 Reassign Patients 9

Summer Hogan ▾ [My Dashboard](#)

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Reassign Patients

Please select the new group below and press **Submit**.

Search

Group Name:

[Cancel](#) [Submit](#)

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14. Dashboard

14.1 Dashboard Alerts and Notifications

14.1.1 Dashboard Alerts

Note: Alerts will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

The screenshot shows the 'Alerts' tab selected in the dashboard. The header includes the Clozapine REMS logo and navigation links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. The user is identified as Summer Hogan. Below the header, there are tabs for Alerts (1), Notifications (5), Patients, Designees, and Manage Groups. The main content area displays a message: 'All program alerts are listed below. Please use the link within the alert to take the necessary action to satisfy the alert.' A search bar is present. A table lists one alert:

Alert Date	Alert Category	Alert Reference Name	Alert Subject
09/10/2018	Designee/Pharmacy Staff	Hogan, Summer	Designee Determination

Showing 1 to 1 of 1 entries

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14.1.2 Dashboard Notifications

Note: Notifications will be displayed for all stakeholders. The Alerts and Notifications tabs are 3 common across all stakeholders.

The screenshot shows the Clozapine REMS dashboard interface. At the top, the logo and tagline are present, along with the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below this, there are tabs for 'Alerts', 'Notifications', 'Patients', 'Designees', and 'Manage Groups'. The 'Notifications' tab is active, displaying a message: 'All program notifications are listed below. Please select a notification and use the Acknowledge button to clear the notification.' A search bar is located to the right of this message. Below the message is a table with the following data:

	Notification Date	Notification Category	Notification Reference Name	Notification Subject
<input type="checkbox"/>	09/10/2018	Certification/Enrollment	Hogan, Summer	Certification Confirmation

Below the table, it says 'Showing 1 to 6 of 6 entries' and there are navigation arrows and a page number '10'. An 'Acknowledge' button is located at the bottom right of the notification area.

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14.2 Prescriber Dashboard

14.2.1 Prescriber Dashboard Patient Tab Collapsed

Summer Hogan ▾ My Dashboard



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Home Prescriber Pharmacy Patient Resources Support


Alerts Notifications ¹ Patients Designees Manage Groups

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

Enroll Patient Search

	First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
	Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
	John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 18 entries « 1 » 10 ▾

 = NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

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14.2.2 Prescriber Dashboard Patient Tab Expanded

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select --
John	Smith	05/01/2000	Enrolled		Active	-- Please Select --

Showing 1 to 10 of 18 entries

■ = NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The dashboard for the prescriber will include a list of all patients the prescriber is managing. The actions the prescriber can take are:

For patients with an enrollment status of "Incomplete", the prescriber can "Resume Patient Enrollment"

1 – Enroll Patient – will take users to the Patient Intake page and through the patient enrollment process

For patients with an enrollment status of "Enrolled", the prescriber can take the following actions:

2 – Add Lab – will take the user to the Lab Information page

2 – Change Treatment Status – will take the user to the Lab Information page

2 – Change *Treatment Rationale* – will take the user to the Lab Information page

2 – View Patient History – will take the user to the Patient History page

2 – View Patient Profile – will take the user to the Patient Profile page

2 – Remove from Program – will remove the patient from the program

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- Options available for *Dispense Rationale* status include :
 - a. Active
 - b. Expired
 - c. Limited
 - d. Not on File

4 - For definitions of terms used on this page - will pop-up the definitions on the page (see next 3 mockup)

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14.2.3 Definitions of Terms Pop-up 3

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are visible. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation, there are tabs for 'Alerts', 'Notifications', 'Patients', 'Designees', and 'Manage Groups'. The main content area features a table of patients with an 'Enroll Patient' button and a search bar. A 'Definition of Terms' pop-up window is overlaid on the table, providing detailed definitions for various terms used in the program.

Definition of Terms

Treatment Status

- Pretreatment** - new patient with no baseline ANC submitted who has not started clozapine
- Active** - receiving clozapine at regular intervals consistent with their monitoring frequency
- Interrupted** - clozapine usage has stopped temporarily pending next actions before resuming therapy or being permanently discontinued
- Discontinued** - clozapine usage has stopped

Enrollment Status

- Enrolled (patients and pharmacy staff)** - All enrollment requirements have been met
- Certified (for all other stakeholders)** - All certification requirements have been met
- Incomplete** - Requirements for enrollment or certification have not been met and must be continued

BEN Patient - Benign Ethnic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANCs are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine

NNRMF - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program

Showing 1 to 10 of 16 entries

☒ = NNRMF (National Non-Rechallenge Master File) patients.

For definitions of terms used on this page, click [here](#).

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14.2.4 Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers

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Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below.

Joe M

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.



Blood Draw Date

[Verify Lab](#)

Treatment Status
 1

Monitoring Frequency

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

I attest that all ANC results for this patient in the past year were within normal limits per label and this patient has been on clozapine therapy continuously for one year making them eligible for **monthly monitoring**.

[Cancel](#) [Next](#)

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Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

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14.2.5 View Patient History Lab History Tab 3

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History


Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: **Varsha Bhatia** Display WBC

DOB: **05/01/2000**

Gender: **Female**

Entry Date	Blood Draw Date	ANC
05/08/2017	05/08/2017	1500
05/09/2017	05/09/2017	500

Showing 1 to 2 of 2 entries  << 1 >> 10 ▾

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14.2.6 View Patient History Treatment Status Tab 3

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Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: [Varsha Bhatia](#)
DOB: [05/01/2000](#)
Gender: [Female](#)

Entry Date	Treatment Status	Rationale	Duration
05/08/2017	Active		
05/09/2017	Active	Benefit Outweighs Risk	

Showing 1 to 2 of 2 entries

« 1 » 10 ▾

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14.2.7 Viewing Patient History Monitoring Frequency Tab 3

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History **Monitoring Frequency History** Dispense Rationale

Name: **Varsha Bhatia**
DOB: **05/01/2000**
Gender: **Female**

Entry Date	Monitoring Frequency
05/08/2017	Weekly

Showing 1 to 1 of 1 entries

« 1 » 10 ▾

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14.2.8 View Patient History Dispense Rationale Tab 4

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History **Dispense Rationale**

Name: [Jeff Bradley](#)
DOB: [02/16/1910](#)
Gender: [Male](#)

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

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1.2.9 View Patient Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient Profile

Patient Information [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender

Race

Group

BEN Patient No

NNRMF Patient No

Patient Enrollment Information

Enrollment ID: [PAT132456789](#)

[Cancel](#) [Save](#)

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14.2.10 Prescriber Dashboard Designees Tab

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Ether Thomas ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts Notifications ¹ Patients **Designees** Manage Groups

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

Add Designee Search

First Name	Last Name	Certification ID	Approval Status	Actions
Don	Herve	HCP5414002422	Approved	-- Please Select -- -- Please Select -- Remove Designee

Showing 1 to 1 of 1 entries

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Home Prescriber Pharmacy Patient Resources Support

Alerts ¹ Notifications ¹ Patients **Designees** Manage Groups

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

Add Designee Search

First Name	Last Name	Certification ID	Approval Status	Actions
John	Smith	HCP5415021792	Approved	-- Please Select -- Go
Mark	Brown	HCP5414002422	Approved	-- Please Select -- Go
Scott	Abbot	HCP5627729840	Pending	-- Please Select -- -- Please Select -- Approve Designee

Showing 1 to 3 of 3 entries

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Note: The dashboard for the prescriber will include a list of all designees the prescriber is associated to. The actions the prescriber can take are:

- 1 – Add Designee – will take the user to the Add Designee page
- 2 – Remove Designee – will take the user to the Remove Designee page
- 3 – Approve Designee – will take the user to the Approve Designee page

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14.2.11 Add Designee with Screenshot 4

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Add Designee

To add a designee, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Designee Information

<input type="text" value="Terry"/>	<input type="text" value="White"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned the designee you want to associate to, please select the row and press **Submit**. If you do not see the designee you are looking for, please try your search again or contact the designee to ensure they are certified in the program.

First Name	Last Name	Phone
Terry	White	555-555-5555

Showing 1 of 1 entries

[Cancel](#) [Submit](#)

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Remove Designee

Removing this designee will revoke their ability to perform actions on your behalf. To continue, please check the box below and press **Submit**.

Designee Name: [Anantharaman Manickavasagam](#)

Certification ID: [HCP123456](#)

I hereby remove this designee's ability to perform actions on my behalf in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

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14.2.13 Approve Designation

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Designee Determination

This designee will act on my behalf in fulfilling the requirements for the Clozapine REMS Program.

Designee Name: [Jane Brown](#)

Certification ID: [HCP055254](#)

[Decline](#) [Approve](#)

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14.3 Prescriber Designee Dashboard

14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, select a prescriber from the Prescribers tab and use the **Add Patient Action** to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

	First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
	Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
	John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 18 entries < 1 > 10 ▾

= NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

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14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, select a prescriber from the Prescribers tab and use the **Add Patient Action** to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
Gender: Female NNRMF: No BEN: No		View ANC Monitoring Table			Enrollment ID: PAT5414000800	
		Blood Draw date	10/04/2017	05/08/2017	10/04/2017	
		ANC Level (per µL)	400	1500	400	
John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 18 entries

- NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

1

2

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Note:

The dashboard for the prescriber designee will include a list of all patients the designee's prescriber is managing. The actions the prescriber designee can take are:

For patients with an enrollment status of "Incomplete", the prescriber designee can "Resume Patient Enrollment".

For patients with an enrollment status of "Enrolled", the prescriber can take the following actions:

- 1 - Add Lab - will take the user to the Lab Information page
- 1 - Change Treatment Status - will take the user to the Lab Information page
- 1 - Change *Treatment Rationale* - will take the user to the Lab Information page
- 1 - View Patient History - will take the user to the Patient History page
- 1 - View Patient Profile - will take the user to the Patient Profile page
- 1 - Remove from Program - will remove the patient from the program
- 2 - For definitions of terms used on this page - the definitions will pop-up when "here" is clicked (see next mockup)

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14.3.3 Definitions of Terms Pop-up 4

The screenshot shows a web browser displaying the Clozapine REMS website. A pop-up window titled "Definition of Terms" is open, listing definitions for Treatment Status and Enrollment Status. The background website shows the user's name "Summer Hogan" and a "My Dashboard" link. The pop-up window has a purple header and a white body with a close button (X) in the top right corner.

Definition of Terms

Treatment Status

- Pre-treatment - new patient with no baseline ANC submitted who has not started clozapine
- Active - receiving clozapine at regular intervals consistent with their monitoring frequency
- Interrupted - clozapine usage has stopped temporarily pending next actions before resuming therapy or being permanently discontinued
- Discontinued - clozapine usage has stopped

Enrollment Status

- Enrolled (patients and pharmacy staff) - All enrollment requirements have been met
- Certified (for all other stakeholders) - All certification requirements have been met
- Incomplete - Requirements for enrollment or certification have not been met and must be continued

BEN Patient - Benign Ethnic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANCs are lower than "standard" laboratory ranges from neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

NNRMF - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program.

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14.3.4 Add Lab and Change Treatment Status for Prescriber Designees

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Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below.

Joe M

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

Blood Draw Date

[Verify Lab](#)

Treatment Status
Active 1

Monitoring Frequency
Weekly

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L)	None	None	None

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

I attest that all ANC results for this patient in the past year were within normal limits per label and this patient has been on clozapine therapy continuously for one year making them eligible for monthly monitoring.

[Cancel](#) [Next](#)

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Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

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14.3.5 View Patient History: Lab History Tab 5

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Patient History


Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: **Varsha Bhatia** Display WBC

DOB: **05/01/2000**

Gender: **Female**

Entry Date	Blood Draw Date	ANC
05/08/2017	05/08/2017	1500
05/09/2017	05/09/2017	500

Showing 1 to 2 of 2 entries  << 1 >> 10 ▾

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14.3.6 View Patient History: Treatment Status Tab 5

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Patient History

[Lab History](#) **[Treatment Status History](#)** [Monitoring Frequency History](#) [Dispense Rationale](#)

Name: [Varsha Bhatia](#)
DOB: [05/01/2000](#)
Gender: [Female](#)

Entry Date	Treatment Status	Rationale	Duration
05/08/2017	Active		
05/09/2017	Active	Benefit Outweighs Risk	

Showing 1 to 2 of 2 entries

« 1 » 10 ▾

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14.3.7 View Patient History: Monitoring Frequency Tab 5

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Patient History

[Lab History](#) [Treatment Status History](#) **[Monitoring Frequency History](#)** [Dispense Rationale](#)

Name: [Varsha Bhatia](#)
DOB: [05/01/2000](#)
Gender: [Female](#)

Entry Date	Monitoring Frequency
05/08/2017	Weekly

Showing 1 to 1 of 1 entries

« 1 » 10 ▾

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14.3.8 View Patient History: Dispense Rationale Tab 5

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Patient History

Lab History Treatment Status History Monitoring Frequency History **Dispense Rationale**

Name: Jeff Bradley
DOB: 02/16/1910
Gender: Male

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

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14.3.9 View Patient Profile 5

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Patient Profile

Patient Information [Edit](#)

First Name:

Last Name:

DOB:

Zip Code:

Gender: ▾

Race: ▾

Group: ▾

BEN Patient:

NNRMF Patient:

Patient Enrollment Information

Enrollment ID: [PAT132456789](#) ↗

[Cancel](#) [Save](#)

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14.3.10 Prescriber Designee Dashboard Prescribers Tab

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Alerts Notifications ¹ Patients **Prescribers** Manage Groups

The table below contains all the prescribers that you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Associate to Prescriber Search

First Name	Last Name	Certification ID	Approval Status	Actions
Ether	Thomas	HCP5414006589	Approved	<ul style="list-style-type: none">-- Please Select ---- Please Select --Remove Designee RelationshipAdd Patient

Showing 1 to 1 of 1 entries

1

2

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Alerts Notifications ¹ Patients **Prescribers** Manage Groups

The table below contains all the prescribers that you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Associate to Prescriber Search

First Name	Last Name	Certification ID	Approval Status	Actions
Hetal	Diwan	HCP5405480914	Pending	<ul style="list-style-type: none">-- Please Select ---- Please Select --Cancel Designee Request

Showing 1 to 1 of 1 entries

3

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Note: The dashboard for the prescriber designee will include a list of all prescribers the designee is acting on behalf of. The actions the prescriber designee can take are:

- 1 – Associate to Prescriber – will take the user to the Associate to Prescriber page
- 2 – Remove Designee Relationship – will take the user to the Remove Designee Relationship page
- 2 – Add Patient – user can add a patient using this option
- 3 – Cancel Designee Request – will take the user to the Cancel Designee Request page

14.3.11 Associate to Prescriber 5

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Associate to Prescriber

To associate a prescriber, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>					

[Search](#)

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Remove Designee Relationship

To remove your relationship with this prescriber, please check the box below and press **Submit**.

Prescriber Name: **Summer Hogan**

Relationship Status: **Approved**

I hereby remove my relationship with this prescriber and understand that I will no longer have the ability to perform actions on their behalf in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

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14.3.13 Cancel Designee Request

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Cancel Designee Request

To cancel the approval request to act on behalf of this prescriber, please check the box below and press **Submit**.

Prescriber Name: [Summer Hogan](#)

Relationship Status: [Pending](#)

I hereby cancel my request to act on behalf of this prescriber in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

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14.4 Pharmacy Dashboard – Inpatient Pharmacies

14.4.1 Inpatient Pharmacy Dashboard Pharmacies Tab

The screenshot shows the 'Pharmacies' tab in the Clozapine REMS dashboard. At the top, there are navigation tabs for Alerts, Notifications, Pharmacies (selected), and Pharmacy Staff. A search bar and an 'Add Pharmacy' button are also present. Below the navigation is a table with 7 columns: Pharmacy Name, Address, Pharmacy Type, Certification ID, Certification Status, and Actions. The table lists several pharmacies, including 'aks shay ku', 'Test Pharma', 'Ilea Inc', 'JC Penny', 'Tata Pharma', 'Sharma Pharma', and 'Inpatient'. Each row has a dropdown menu in the 'Actions' column. A callout box labeled '2' points to the dropdown menu for 'Test Pharma', which is open and shows options: 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Eligibility Check', and 'Recertify Pharmacy'. Another callout box labeled '3' points to the 'Go' button in the 'Actions' column for 'Tata Pharma'. A callout box labeled '1' points to the 'Add Pharmacy' button. At the bottom of the table, it says 'Showing 1 to 7 of 7 entries' and has a pagination control showing '1' of 10 items. Below the table, there is a text box: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- Go Remove Pharmacy View/Update Pharmacy Profile Add Lab Eligibility Check Recertify Pharmacy
Ilea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- Go

Note: The dashboard for the authorized representative of inpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

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For pharmacists with a enrollment status of "Certified," the authorized representative can take the following actions:

- 2 - Move Pharmacy - will take the user to the Move Pharmacy page
- 2 - View/Update Pharmacy Profile - will take the user to the Pharmacy Profile page
- 2 - Add Lab - will take the user to the Add Lab page
- 2 - *Eligibility Check* - will take the user to the *Eligibility Check* page.
- 2 - Certify Pharmacy - will take the user to the Pharmacy Certification page
- 3 - For pharmacists with a enrollment status of "Incomplete," the authorized representative can
"Resume Pharmacy Certification"

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14.4.2 Add Lab

Note: This Add Lab page is displayed for both Inpatient, Outpatient pharmacist and off-switch. 6

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Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab

ANC value per microlitre

Blood Draw Date

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

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14.4.3 Add Lab – Successful 6

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Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

Add Patient Lab

ANC value per microlitre

Blood Draw Date

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

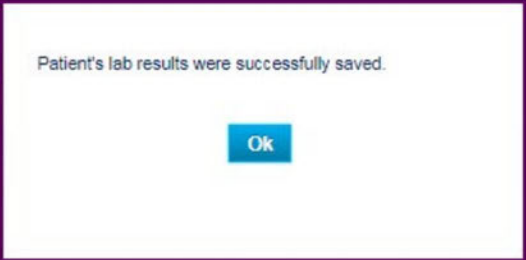
Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

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A white dialog box with a purple border is centered on the screen. It contains the text "Patient's lab results were successfully saved." and a blue "Ok" button below it.

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14.4.4 Add Lab – Unsuccessful 6

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Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

Add Patient Lab

ANC value per microlitre

Blood Draw Date

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

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14.4.5 Eligibility Check

Not : This *Eligibility Check* page displayed is for Inpatient Pharmacist.

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Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

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14.4.6 Eligibility Check Result – Successful

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Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None


Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

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Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	Lab Status Lab was Saved
DOB	For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

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14.4.7 Eligibility Check Result – Successful with warning message

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Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status **Lab was Saved**

A *Treatment Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.4.8 Eligibility Check Result – Unsuccessful

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Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

1

Name [Summer H](#)

DOB

✘ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

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Note:

- 1 – The tool-tip next to this field will display this Monitoring Frequency text:
 - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
 - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
 - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

- 2 – Patient's Lab History – This button will take the user to the Patient's Lab History page

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14.5 Pharmacy Dashboard – Outpatient Pharmacies

The screenshot shows the 'Pharmacy Dashboard' for 'Outpatient Pharmacies'. At the top, there is a navigation bar with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below this is a search bar and an 'Add Pharmacy' button. The main content is a table with the following columns: Pharmacy Name, Address, Pharmacy Type, Certification ID, Certification Status, and Actions. The table lists seven pharmacies, including 'aks shay ku', 'Test Pharma', 'Ikea Inc', 'JC Penny', 'Tata Pharma', 'Sharma Pharma', and 'Inpatient'. The 'Actions' column for each pharmacy contains a dropdown menu with options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Dispense Rationale', and 'Recertify Pharmacy'. A 'Go' button is next to each dropdown. A '1' is placed over the 'Add Pharmacy' button, a '2' is placed over the dropdown menu for 'Ikea Inc', and a '3' is placed over the 'Go' button for 'Tata Pharma'.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- Go
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- Go Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414110715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119640	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414702350	Incomplete	-- Please Select -- Go

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The dashboard for the authorized representative of outpatient pharmacy types will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

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For pharmacists with a enrollment status of "Certified," the authorized representative can take the following actions:

- 2 - Move Pharmacy - will take the user to the Move Pharmacy page
- 2 - View/Update Pharmacy Profile - will take the user to the Pharmacy Profile page
- 2 - Add Lab - will take the user to the Add Lab page
- 2 - *Dispense Rationale* - will take the user to *Dispense Rationale* page
- 2 - Certify Pharmacy - will take the user to the Pharmacy Certification page
- 3 - For pharmacists with a enrollment status of "Incomplete," the authorized representative can "Resume Pharmacy Certification"

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14.5.1 Dispense Rationale 7

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Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

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Not : This Dispense Rationale page is displayed for outpatient pharmacists only - & off-switch 7 7

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14.5.2 Dispense Rationale sult Scr – Succ ss 7

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	Lab Status Lab was Saved
DOB	For further assistance with this patient's eligibility, please contact the patient's prescriber.
Authorization Number	

[Patient's Lab History](#)

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14.5.3 Dispense Rationale Result Scr – Success (After DR is issued) 7

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>▲ Current ANC is not on file.</p> <p>A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p> 
DOB	
Authorization Number	

[Patient's Lab History](#)

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14.5.4 Dispense Rationale sult Scr – U succ ssful 7

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Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p> 
DOB	
Authorization Number	

Patient's Lab History

Provide *Dispense Rationale* for this patient.

Cancel

Submit

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14.6 Pharmacy Dashboard – Outpatient Pharmacies on switch

The screenshot shows the 'Pharmacies' tab in the Clozapine REMS dashboard. At the top, there is a navigation bar with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below this is a search bar and an 'Add Pharmacy' button. The main content is a table with the following columns: Pharmacy Name, Address, Pharmacy Type, Certification ID, Certification Status, and Actions. The table lists seven pharmacies, including 'aks shay ku', 'Test Pharma', 'Ikea Inc', 'JC Penny', 'Tata Pharma', 'Sharma Pharma', and 'Inpatient'. The 'Actions' column for each pharmacy contains a dropdown menu with options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Predispose Authorization', 'Dispense Rationale', and 'Recertify Pharmacy'. A 'Go' button is next to each dropdown. A '1' is placed in a box above the 'Add Pharmacy' button. A '2' is placed in a box next to the dropdown menu for 'JC Penny'. A '3' is placed in a box next to the 'Go' button for 'Sharma Pharma'. At the bottom of the table, it says 'Showing 1 to 7 of 7 entries' and has a pagination control showing '1' of '10' items.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- Go
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- Go

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Note: The dashboard for the authorized representative of the on-switch outpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

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For pharmacies with a rollme t status of "C rtifi d," th authoriz d r pr s tativ ca tak th 7 followi g actio s:

- 2 - mov Pharmacy - will tak th us r to th mov Pharmacy pag
- 2 - Vi w/Updat Pharmacy Profil - will tak th us r to th Pharmacy Profil pag
- 2 - Add Lab - will tak th us r to th Add Lab
- 2 - *Predispense Authorization* - will tak th us r to th *Predispense Authorization* pag
- 2 - *Dispense Rationale* - will tak th us r to *Dispense Rationale* pag
- 2 - c rtify Pharmacy - will tak th us r to th Pharmacy c rtificatio pag
- 3 - For pharmacies with a rollme t status of "I compl t ," th authoriz d r pr s tativ ca 7 "sume Pharmacy C rtificatio "

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14.6.1 Predispose Authorization 7

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Predispose Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the Predispose Authorization information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the Predispose Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispose Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

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14.6.2 Predispense Authorization Result – Successful 7

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Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

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14.6.3 Predispose Authorization Result – Unsuccessful

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Predispose Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

1

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H
DOB
Authorization Number

✖ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.
⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

2 Patient's Lab History

3 Provide Dispense Rationale for this patient.
Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

- 1 – The tool-tip next to this field will display this text:
 - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
 - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
 - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

- 2 – Patient's Lab History – This button will take the user to the Patient's Lab History page.
- 3 – Provide "Dispense Rationale" for this patient – This check box will take the user to the *Dispense Rationale* screen.

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14.6.4 Predispense Authorization Result – Successful (Authorization Issued) for

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Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

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View Pharmacy Profile f

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Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name:

Pharmacy Type: **Outpatient**

Address:

Address 2:

City:

State / Zip Code:

Phone / Ext:

Fax:

NCPDP:

DEA:

NPI:

Pharmacy Certification Information

Certification ID: **HCP123456789** ⇄

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Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: [Joey's Apothecary](#)

Certification ID: [PRS123456789](#)

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

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14.6.6 Recertify Pharmacy

Note: This Recertify Pharmacy page is displayed for Inpatient, Outpatient, and Off-switch 3 Pharmacies.

14.6.6.1 Pharmacy Recertification Wizard

Note: Users will be presented with a set of questions to recertify a pharmacy.

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Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1

Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

- Yes
- No

Next

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1A

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
- No

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1B

Is your pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- Yes
 No

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Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 2

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

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Clozapine REMS Pharmacy Classification

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Clozapine REMS Pharmacy Classification

Please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

[Next](#)

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14.6.6.2 Pharmacy Recertification – Intake

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[Intake](#) [Attestation](#) [Confirmation](#)

Pharmacy Intake

2

⚠ Note: Your pharmacy type has been updated. Click [here](#) to change.

To certify your Pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your Authorized Representative Intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Name

-- Select Type -- **1**

Address

Address 2 (opt)

City

--State-- Zip

Phone Ext (opt)

Fax (opt)

Pharmacy Identifiers

Please provide at least one identifier.

NCPDP (opt)

DEA (opt)

NPI (opt)

[Cancel](#) [Next](#)

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Note:

- 1 – After the user attempts all the questions during pharmacy recertification, the user will be presented with the Pharmacy Intake page where the Pharmacy Type field will be disabled.
- 2 – If the user wishes to change the pharmacy type, then the user can click on the link and he will have to re-take the recertification wizard.

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14.6.6.3 Pharmacy Reactivation: Non-Chain Pharmacy

Not : If a pharmacy does not recertify within the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be prompted with the screen below upon logging in to their dashboard. This screen applies to Non-Chain Pharmacy only.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left, the logo 'CLOZAPINE REMS' is displayed with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is shown next to a dropdown arrow, and a 'My Dashboard' button is visible. Below the navigation bar, a message states: 'Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.' A blue 'Reactivate' button is positioned below the message.

Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.

[Reactivate](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.6.6.4 Pharmacy Reactivation: Chain Pharmacy

Note: If a pharmacy does not recertify with the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be provided with the screen below upon logging in to their Dashboard. This screen applies to Chain Pharmacy only.

The screenshot displays the Clozapine REMS Program website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". On the top right, the user name "Summer Hogan" is shown next to a "My Dashboard" button. A navigation menu includes "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support". The main content area features a message: "Pharmacies are required to renew their certification in the Clozapine REMS Program every two years. Our records indicate your pharmacy has not recertified and therefore your certification in the Clozapine REMS Program is no longer active. To recertify your pharmacy, please call the Clozapine REMS Program Contact Center at 844-267-8678." Below this message, a call to action states: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy | Terms of Use | Site Map | FAQs | Contact Us".

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14.6.7 Pharmacy Dashboard Pharmacy Staff Tab

The table below contains all the pharmacy staff that are currently assigned to you.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	<ul style="list-style-type: none">Remove Pharmacy Staff

Showing 1 of 1 entries

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Note: The dashboard for the authorized representative of inpatient and outpatient pharmacy types will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

- 1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

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14.6.8 mov Pharmacy Staff 9

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.7 Chain Pharmacy Dashboard

14.7.1 Chain Pharmacy Dashboard Pharmacies Tab

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ³ Notifications ¹ Pharmacies Pharmacy Staff

To certify a store that has been trained on all program requirements, select the store(s) and use the **Certify Store** button.
To add a store not in your list, use the **Add Chain Store** button. For all other activities, use the Actions list for the store.

Add Chain Store Search

<input type="checkbox"/>	Store Name	Address	Certification ID	Certification Status	Actions
<input type="checkbox"/>	Joey's Apothecary	1 East Main Street, New York NY 10001	FAC1002345831	Certified	-- Please Select -- Go View Pharmacy Profile Remove Pharmacy
<input type="checkbox"/>	Hogan RX	2 Park Avenue, New York NY 10201	FAC2234583304	Certified	-- Please Select -- Go
<input checked="" type="checkbox"/>	Apollo Pharmacy	311 Bell Road, Anaheim CA 92805	FAC0057124807	Incomplete	-- Please Select -- Go
<input type="checkbox"/>	Life Pharmacy	423 Main Street, Tampa FL 33614	FAC0057124807	Certified	-- Please Select -- Go
<input type="checkbox"/>	Mercury Drug	52 Milky Way Dr, Anchorage, AK 99508	FAC2585234583	Certified	-- Please Select -- Go

Showing 10 of 10 entries

Certify Store

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all chain store pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1 – Add Chain Store – will take the users to the Chain Pharmacy Store Intake page and through the chain store certification process

For pharmacies with an enrollment status of "Certified," the authorized representative can take the following actions:

2 – View Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page

3 – Certify Store button – for pharmacies with a certification status of "Incomplete," the authorized representative can check one, numerous, or all checkboxes (located on the left side of the data grid) and press the button to certify the store once the staff is trained.

14.7.2 View Pharmacy Profile 9

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext


Fax

NCPDP

DEA

NPI

Pharmacy Certification Information

Certification ID: **HCP123456789** 

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.7.3 mov Pharmacy 9

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: **Joey's Apothecary**

Certification ID: **PRS123456789**

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.7.4 Chain Pharmacy Dashboard Pharmacy Staff Tab

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Home Prescriber Pharmacy Patient Resources Support

Alerts ⁰ Notifications ¹ Pharmacies Pharmacy Staff

The table below contains all the pharmacy staff that are currently assigned to you.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	<input type="text" value="-- Please Select --"/> Go Remove Pharmacy Staff

Showing 10 of 10 entries

1

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Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

- 1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

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14.7.5 mov Pharmacy Staff 9

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.8 Pharmacy Staff Dashboard

14.8.1 Pharmacy Staff Dashboard Pharmacies Tab

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If a pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- Go
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- Go
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- Go
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- Go
Pharma co	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- Go Add Lab Eligibility Check Remove Pharmacy Relationship -- Please Select -- Go

Showing 1 to 5 of 5 entries

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Note: The dashboard for the pharmacy staff will include a list of all pharmacies the pharmacy staff is representing. The actions the pharmacy staff member can take are:

- 1 - Associate to Pharmacy - will take the user to the Associate to Pharmacy page.
- 2 - Add Lab- will take the user to the Add Lab page
- 3 - Eligibility Check - will take the user to the Eligibility Check page.
- 4 - Predispense Authorization - will take the user to the Predispense Authorization page.
- 5 - Dispense Rationale- will take the user to the Dispense Rationale page.
- 6 - Remove Pharmacy Relationship- will take the user to Remove Pharmacy page.

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14.8.2 Associate to Pharmacy f

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Associate to Pharmacy

To identify the pharmacy you represent, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

- Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.8.3 Eligibility Check

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.8.4 Eligibility Check result – Unsuccessful

Note: This result is displayed on the Eligibility Check when the result is unsuccessful.

The screenshot shows the top of the Clozapine REMS website. On the left is the logo and tagline. On the right, the user name 'Summer Hogan' and a 'My Dashboard' button are visible. Below the logo is a navigation menu with links for Home, Prescriber, Pharmacy, Patient, Resources, and Support.

Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None


Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.8.5 Predispose Authorization 3

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Home Prescriber Pharmacy Patient Resources Support

Predispose Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispose Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispose Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispose Authorization Request

Date of Service ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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14.8.6 Predispose Authorization Result – Unsuccessful

Note: This result is displayed for the Predispose Authorization when the result is unsuccessful.

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Predispose Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

Patient's Lab History

Provide Dispense Rationale for this patient.

[Cancel](#)

[Submit](#)

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15. Dispense Rationale – Static Pages 5

15.1 Home Page

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[FAQs >>](#)

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber

All prescribers of clozapine products must certify in the Clozapine REMS Program. Certification requires prescribers to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

The <MM/YYYY> Clozapine REMS Program Modification went live on <MM/DD/YYYY>. Prescribers are required to certify in the Clozapine REMS Program as soon as possible to continue patient therapy. If prescribers are not certified at the time of the <MM/YYYY> Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the [Important Program Update \(IPU\)](#) button for more information.

[Start Prescriber Certification](#)

Pharmacy

All pharmacies dispensing clozapine products must certify in the Clozapine REMS Program. Certification requires pharmacies to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- **Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

The <MM/YYYY> Clozapine REMS Program Modification went live on <MM/DD/YYYY>. Pharmacies are required to certify in the Clozapine REMS Program. If pharmacies are not certified at the time of the <MM/YYYY> Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the [Important Program Update \(IPU\)](#) button for more information.

[Start Pharmacy Certification](#)

***** Important Program Update (as of MM/DD/YYYY) *****
Please click to open the IPU

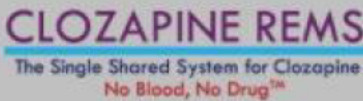
What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/uL), which can lead to serious and fatal infections. The requirements to prescribe, dispense and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)

16.1 Pharmacy – Authorized Representative Dashboard



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Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications Pharmacies Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Add Pharmacy

Q

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
Hogan Rx	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>
Test Pharma	2101 E. Dunlap Selma, Alabama 35848 85054	Inpatient	FAC5413316247	Certified	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>
Mercury Drug Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; width: 100px;"> -- Please Select -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Predispense Authorization Dispense Rationale Recertify Pharmacy </div> Go </div>
+ Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>
+ Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>
+ Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	<div style="display: flex; align-items: center;"> -- Please Select -- Go </div>

Showing 1 to 7 of 7 entries

↔ < 1 > 10

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.2 Pharmacy – Authorized Representative *Predispense* 7 *Authorization*

Summer Hogen • My Dashboard

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Home Prescriber Pharmacy Patient Resources Support

Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispense Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispense Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required.

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.3 Pharmacy – Authorized Representative *Predispense* f *Authorization Result- Successful*

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly


Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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16.4 Pharmacy – Authorized Representative *Predispense* 9 *Authorization Result- Unsuccessful*

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

Patient's Lab History

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.5 Pharmacy – Authorized Representative *Predispense Authorization* Result – Successful

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✔ The *Dispense Rationale* has been provided.
Please resubmit the request to receive the authorization to dispense clozapine to the patient.

[Resubmit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.6 Pharmacy – Authorized Representative *Predispense* f *Authorization Result- Successful (After the Dispense Rationale is issued)*

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Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.7 Pharmacy – Authorized Representative *Predispense* f *Authorization* Result – Unsuccessful

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Predispense Authorization Result

 The maximum number of allowable *Dispense Rationales* has been reached for this patient.
For further assistance with this patient's eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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17. Dispense Rationale – Pharmacy Staff (Non- Switch) Pharmacy Staff Dashboard

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[Alerts](#) [Notifications ¹](#) [Pharmacies](#)

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- Add Lab <input type="button" value="Go"/> Predispense Authorization <input type="button" value="Go"/> Dispense Rationale Remove Pharmacy Relationship
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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17.1 Pharmacy Staff *Predispense Authorization* 4

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Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispense Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispense Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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17.2 Pharmacy Staff *Predispense Authorization Result*- 5 Successful

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Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly


Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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17.3 Pharmacy Staff *Predispense Authorization Result*- 6 Unsuccessful

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Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

Patient's Lab History

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.4 Pharmacy Staff *Predispense Authorization* Result – Successful

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Predispense Authorization Result

✔ *The Dispense Rationale* has been provided.
Please resubmit the request to receive the authorization to dispense clozapine to the patient.

[Resubmit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.5 Pharmacy Staff *Predispense Authorization Result- f* Successful (After the *Dispense Rationale* is issued)

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Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.6 Pharmacy Staff *Predispense Authorization* Result – 9 Unsuccessful

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Predispense Authorization Result


 The maximum number of allowable *Dispense Rationales* has been reached for this patient.
For further assistance with this patient's eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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18. Dispense Rationale – Pharmacy Authorized Representative (Switch)

18.1 Pharmacy – Authorized Representative Dashboard



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My Dashboard

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Support

Alerts
Notifications
Pharmacies
Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Add Pharmacy

🔍

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ <div style="margin-left: 5px; border: 1px solid #ccc; padding: 2px;"> <div style="padding: 2px 5px;">-- Please Select --</div> <div style="padding: 2px 5px; background-color: #007bff; color: white;">Remove Pharmacy</div> <div style="padding: 2px 5px;">View/Update Pharmacy Profile</div> <div style="padding: 2px 5px;">Add Lab</div> <div style="padding: 2px 5px;">Dispense Rationale</div> <div style="padding: 2px 5px;">Recertify Pharmacy</div> </div> Go </div>
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>
+ Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414119715	Incomplete	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>
+ Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119640	Incomplete	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>
+ Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">-- Please Select --</div> ▾ Go </div>

Showing 1 to 7 of 7 entries

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18.2 Pharmacy – Authorized Representative *Dispense Rationale*

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Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Not : This *Dispense Rationale* page is displayed for outpatient pharmacists only - & only switch.

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18.3 Pharmacy – Authorized Representative *Dispense f* *Rationale* Result Screen- Success

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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18.4 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success (After DR is issued) 3

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.5 Pharmacy – Authorized Representative *Dispense* 4 *Rationale* Result Screen- Unsuccessful

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Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.6 Pharmacy – Authorized Representative *Eligibility 5* Check Result- Successful

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Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.7 Pharmacy – Authorized Representative *Eligibility* 6 Check Result- Unsuccessful

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Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None


Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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19. Dispense Rationale – Pharmacy Staff 7 (Inpatient Pharmacy) 19.1 Pharmacy Staff Dashboard

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Alerts Notifications ¹ Pharmacies

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy Search

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- <input type="button" value="Go"/>
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/> Add Lab <input type="button" value="Go"/> Eligibility Check Remove Pharmacy Relationship
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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19.2 Pharmacy Staff *Eligibility Check* f

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Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required.

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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19.3 Pharmacy Staff *Eligibility Check Result- Successful* 9

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Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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19.4 Pharmacy Staff *Eligibility Check Result* 3

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Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Not3: If a authoriz d r pr s tativ or pharmacy staff usi g th pharmacy twork (switch) r c iv s ar j ctio messag du to "pr scrib r ot c rtifi d", th followi g messag will app ar o th ir scr :

* S* ClozapiMS – Pr scrib r must b c rtifi d or you can r qu st a *Dispense Rationale 3* through www.clozapi_r.ms.com or by calli g 844-267-8678.

Onc this messag is r c iv d, th authoriz d r pr s tativ or Pharmacy Staff ca ith r call th Clozapi Prsgram co tact c t r to obtai a *Dispense Rationale* or th y ca acc ss th websit a d follow th abov scr s to obtai th *Dispense Rationale*. Onc th y r c iv co firmatio of th *Dispense Rationale*, th authoriz d r pr s tativ or Pharmacy Staff will d to r -ru th claim to allow th authorizatio of th disp s . 3

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20. Dispense Rationale – Pharmacy Staff (Switch) 3

20.1 Pharmacy Staff Dashboard

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Alerts Notifications ¹ Pharmacies

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- <input type="button" value="Go"/>
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- Add Lab Dispense Rationale Remove Pharmacy Relationship <input type="button" value="Go"/>

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For additional information about the Clozapine REMS Program, please call 844-267-8678.

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20.2 Pharmacy Staff *Dispense Rationale* 3

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Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.3 Pharmacy Staff *Dispense Rationale Result- Success* 3

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No Blood, No Drug™

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.4 Pharmacy Staff *Dispense Rationale* Result- Success 3 (After DR is issued)

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Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.
DOB	▲ Current ANC is not on file.
Authorization Number	A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.
	For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.5 Pharmacy Staff *Dispense Rationale* Result- 3 Unsuccessful

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Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

21. Dispense Rationale – Prescriber and Prescriber Designee

21.1 Prescriber and Prescriber Designee Dashboard

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates an NNRMF patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
John	Abraham	01/19/1982	Enrolled		Transferred	- Please Select
Sammy	Baker	10/18/2000	Incomplete		Active	- Please Select
Jeff	Bradley	02/16/1910	Enrolled		Active	- Please Select

Gender: Male
NNRMF: No
BEN: Yes

View ANC Monitoring Table	Current	Highest	Lowest
Blood Draw date	05/24/2016	03/14/2016	05/15/2014
ANC Level (per µL)	340	8000	290

Enrollment ID: PAT71
Dispense Rationale: Active

Chola	Chelon	10/10/1965	Enrolled		Active	- Please Select
Chola	Chelon	04/10/2016	Enrolled		Active	- Please Select
Patient	Contact Singh	01/01/1934	Enrolled		Active	- Please Select
Patient	Contact Singh	07/21/2016	Enrolled		Active	- Please Select
Chris	Cruise	02/16/1990	Enrolled		Active	- Please Select
John	Davidson	02/25/2016	Enrolled		Active	- Please Select
John	Davidson	02/25/2016	Enrolled		Active	- Please Select

Showing 1 to 10 of 45 entries

■ = NNRMF patient

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

1. Prescriber and Prescriber Designees can also view the *Dispense Rationale* history by clicking on the drop-down menu and selecting '*Dispense Rationale History*'.

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2. This expandable section is functionality that will be on both the Prescriber and Prescriber Design dashboard. This section provides information about the status of the *Dispense Rationale*.
 - . Options available for *Dispense Rationale* status include:
 - a. Active
 - b. Expired
 - c. Limited
 - d. Not on File

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21.2 Prescriber and Prescriber Designee *Dispense* 3 *Rationale* History

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Patient History

Lab History Treatment Status History Monitoring Frequency History **Dispense Rationale**

Name: [Jeff Bradley](#)
DOB: [02/16/1910](#)
Gender: [Male](#)

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottsdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

019758Orig1s090

SUMMARY REVIEW

Risk Evaluation and Mitigation Strategy (REMS) Memorandum
REMS Modification

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Office of Drug Evaluation I
DIVISION OF PSYCHIATRY PRODUCTS

NDA/BLA #s:	NDA 19758
Products:	Clozaril(clozapine HCl) 25 mg and 100 mg Tablets.
APPLICANT:	HERITAGE LIFE SCIENCES
FROM:	Marc Stone, M.D. Deputy Director for Safety
DATE:	December 18, 2018

A REMS for Clozapine was approved on March 27, 2008 and the most recent REMS modification was approved on September 15, 2015, to ensure the benefits of the drug outweighed the risks of neutropenia. The REMS consists of elements to assure safe use and an implementation system, and a timetable for submission of assessments of the REMS.

On July 24, 2018 and amended on December 13, 2018, the sponsor submitted a proposed major REMS modification that includes adding educational materials, modifying the inpatient prescriber certification requirements, and initiating the operational restrictions for prescriber and pharmacy certification.

In accordance with section 505-1 of the FDCA, we have determined that the following REMS modifications are necessary to ensure the benefits of the drug outweigh the risks: the addition of educational materials, changes to the inpatient prescriber certification requirements and patient monitoring, and initiating the operational restrictions for prescriber and pharmacy certification.

After consultations between the Office of New Drugs (OND) and the Office of Surveillance and Epidemiology (OSE), we have determined that the sponsor submitted an adequate rationale to support the proposed modification.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ERMIAS ZERISLASSIE
12/18/2018

MARC B STONE
12/18/2018

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

019758Orig1s090

**RISK ASSESSMENT AND RISK MITIGATION
REVIEW(S)**

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

REMS MODIFICATION REVIEW

Date: January 16, 2019

Reviewer(s) Leah Hart, Pharm.D., Division of Risk Management (DRISK)
Joan E. Blair, R.N., M.P.H., Health Communication Analyst, DRISK

Team Leader Selena Ready, Pharm.D., DRISK

Deputy Division Director: Jamie Wilkins, Pharm.D., DRISK

Drug Name(s): Clozapine

Therapeutic class: Atypical Antipsychotic

Dosage forms: Oral Tablet, Orally Disintegrating Tablet, Oral Suspension

OND Review Division Division of Psychiatric Products

PDUFA/Action Date January 16, 2019

OSE RCM #: 2018-2259

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1 INTRODUCTION

This review by the Division of Risk Management (DRISK) evaluates the proposed major modification of the single, shared system (SSS) risk evaluation and mitigation strategy (REMS) for clozapine, known as the Clozapine REMS Program, submitted by the application holders [hereinafter, referred to as the Applicants or Clozapine Products Manufacturers Group (CPMG)] on July 20, 2018. This modification adds additional educational materials and modifies the inpatient prescriber certification requirements. Additionally, with the approval of this modification, the currently approved, but not yet initiated operational restrictions for prescriber and pharmacy certification will initiate.

2 BACKGROUND

2.1 PRODUCT INFORMATION

Clozapine is an antipsychotic approved in the United States (US) in 1989. It is available in the US as an oral tablet (Clozaril and generics), orally disintegrating tablet (Fazaclo and generics), and an oral suspension (Versacloz).

Clozapine is indicated for treatment resistant schizophrenia and for reduction of risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder. According to the prescribing information, the mechanism of action is unknown. However, it has been proposed that the therapeutic efficacy of clozapine in schizophrenia is mediated through antagonism of the dopamine type 2 (D₂) and serotonin type 2A (5-HT_{2A}) receptors. Clozapine also acts as an antagonist at adrenergic, cholinergic, histaminergic and other dopaminergic and serotonergic receptors.¹

2.2 RISK MANAGEMENT BACKGROUND

Because of the risk of what was termed as agranulocytosis at the time of initial approval, Clozaril was approved under Subpart H² with a restricted distribution program. Prior to 2007, as clozapine Abbreviated New Drug Applications (ANDAs) and new formulations (i.e., Fazaclo) were approved, each manufacturer developed a separate but comparable restricted distribution program for their product(s). On March 27, 2008, the Food and Drug Administration Amendments Act (FDAAA) took effect providing FDA the authority to require REMS to ensure that the benefits of the drug outweighed the risks. Clozapine was included on the list of products deemed to have in effect an approved REMS under section 505-1 of the Federal Food, Drug, and Cosmetic Act with the passage of FDAAA.³ The sponsors of

¹ Clozaril [package insert]. East Hanover, NJ:Novartis Pharmaceuticals Corporation;2014.

² See Code of Federal Regulations title 21 “Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses” (57 FR 58958, Dec. 11, 1992, as amended at 64 FR 402, Jan. 5, 1999).

³ See Federal Register Notice “Identification of Drugs and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies (REMS) for Purposes of the Food and Drug Administration Amendments Act of 2007” (73 FR 16313, March 27, 2008).

such listed products were required to submit a REMS proposal on September 16, 2008. Of note, a new formulation of clozapine was approved after 2008 under the tradename Versacloz⁴; this product was approved with a REMS because the application was submitted after FDAAA took effect.

In addition, the Agency became aware of registry/program practices that deviated from the recommendations in the approved labeling, therefore the Division of Psychiatry Products (DPP) re-evaluated clozapine labeling with regard to how best to address the risk of neutropenia (referred to as agranulocytosis at the time of approval) and determined the neutropenia monitoring recommendations and treatment algorithms were outdated and required revision.⁵ In summary, the currently approved clozapine labeling includes:

- Neutropenia will be monitored by absolute neutrophil count (ANC) only
- The ANC thresholds for continuing clozapine treatment are lower
- Patients with benign ethnic neutropenia (BEN) have separate neutropenia monitoring recommendations
- Patients who experience moderate to severe neutropenia can continue clozapine treatment or be rechallenged with clozapine if the prescriber determines that the benefits of continuing/restarting clozapine treatment outweigh the risk of severe neutropenia. (This change eliminates the need to maintain the National Non-Rechallenge Master File (NNRMF).⁶

Subsequently, the Clozapine REMS Program was approved on September 15, 2015 and consists of elements to assure safe use (ETASU) including prescriber certification, pharmacy certification, documentation of safe use conditions, patient monitoring, patient enrollment in a registry, an implementation system, and a timetable for submission of assessments.

The Clozapine REMS Program was approved with the transition plan described in a DRISK review dated 9/14/15⁷ however during Phase 1 of the transition plan the Agency became aware of implementation challenges including data migration problems and website issues that were impacting the ability for stakeholders to certify into the REMS Program which ultimately resulted in delay of the full implementation of the program.

⁴ Versacloz was approved on February 6, 2013 with a REMS.

⁵ For information regarding the labeling revisions, refer to the review completed by Duncan, LE. Signed in DARRTS on August 15, 2014 by Duncan LE.

⁶ NNRMF is a national database to identify patients who meet clozapine's current "no rechallenge" criteria (WBC less than 2,000/ μ L or ANC less than 1000/ μ L). Only patients who meet these stated criteria are part of this registry. All sponsors are responsible for verifying patients are not listed in the NNRMF at time of enrollment and for reporting any non-rechallengeable patient promptly.

⁷ Robottom S., Blair J., Oswell, K. DRISK. REMS Review for Clozapine SSS, dated September 14, 2015.

During development of the Clozapine SSS REMS, the Sponsors utilized data from the previous legacy registries (i.e. the registries used by each individual manufacturer in their respective risk mitigation programs) to estimate the number of prescribers, patients and pharmacies that would need to certify into the REMS Program, thus providing a baseline to compare the number of stakeholders currently certified (or enrolled) in the Clozapine REMS Program. Given the significant data migration issues encountered, the CPMG's estimated number of stakeholders who would need to certify into the REMS Program was unable to be accurately obtained. To prevent patient access issues, the November 23, 2015 prescriber certification deadline and the December 14, 2015 pharmacy certification deadline were extended. This extension was communicated to stakeholders on November 19, 2015. In addition to the certification deadlines being extended, an initial "soft" launch of the restrictions was determined to be necessary to gather an accurate number of stakeholders who would need to certify into the Clozapine REMS Program.

In May 2016, the soft-launch of the restrictive elements began. This soft-launch includes evaluation of all of the safe-use conditions, however it only provides a do not dispense message if a patient is not enrolled in the Clozapine REMS Program, if the Clozapine REMS Program does not have any ANC on file, or if the Clozapine REMS Program has a low ANC on file with no treatment rationale entered by the prescriber. During the soft launch, if the prescriber or pharmacy is not certified the pharmacy receives a warning message and the Clozapine REMS Program receives information on the stakeholder not certified in the REMS Program this however does not stop a clozapine prescription being dispensed. With the information obtained, the REMS program reaches out to any stakeholder not certified in the REMS Program and encourages certification.

Further it was discovered that during data migration, patients with any ANCs missing from their file were reverted to weekly monitoring even if the patient was eligible for every two weeks or monthly. This resulted in access concerns and a fix was implemented immediately to allow prescribers correct the patient's monitoring frequency by attesting the patient is eligible for every two weeks or monthly monitoring. This is now reflected in the ANC Reporting Form as well as the *How to Start Clozapine and Monitor Patients Fact Sheet*.

The currently approved REMS requires that labs be reported within 7 days, no matter the patient's monitoring frequency. In August 2016, the CPMG reported that the average time for lab reporting in the legacy registries was 56 days. Due to concerns with access, the Agency proposed that the definition of "current" align with the monitoring frequency of the patient. For example, a weekly patient must have had a lab within 7 days when presenting at the pharmacy, bi-weekly 15 days and monthly 30 days. During these discussions, using data from the soft-launch period, the CPMG brought to the Agency's attention that if the safe use condition of the lab being current (within 7/15/31 days of the lab draw) was implemented, 52% of all clozapine patients would not be eligible to receive clozapine. Therefore, the Agency agreed with the CPMG that enforcing the lab reporting requirements has the potential to cause an unacceptable amount of treatment interruptions during the soft launch period. The decision was made to postpone the implementation of the restriction for an out of date lab until after the current modification, allowing additional time to reinforce to prescribers that an ANC must be submitted to the program as soon as possible.

To continue to implement the REMS program, a modification was attempted in 2016 with a full launch planned for December 2016 however, during the final negotiations the CPMG informed the Agency that they were unable to continue with the REMS Modification. The programming of the REMS program needed to be interrupted to add new National Drug Code (NDC) numbers to the program database. Given the interruption of that modification, it was decided that all changes, except for the implementation of the current lab, should instead be included with the next approved modification.

In the interim several meetings, including a two-day face to face meeting, were held to discuss the program structure and continued implementation. Subsequently, in October 2017 the current modification negotiations began. The Agency received materials from the CPMG and provided comments via email and participated in several live document reviews due to the volume of materials and changes required to the program for this modification. Once we were in alignment with the documents, a DMF submission was submitted and the Agency and CPMG agreed to not make any additional changes to allow the programming to proceed.

2.3 REGULATORY HISTORY

In addition to weekly implementation telephone conferences with the CPMG, the following is a summary of the regulatory history relevant to this modification review:

- 09/15/2015: Clozapine Single Shared System REMS Program approved
- 10/12/2015: The Clozapine REMS Program implemented (website, call center, fax number and eligibility check)
- 10/14/2015: T-con with CPMG to discuss implementation concerns being brought to the Agency's attention via list-serves, through the Division of Drug Information, and the FDA ombudsman
- 02/17-18/2016: Face to face meeting with the CPMG
- 08/05/2016: CPMG submitted a REMS Major Modification to DMF 030496
- 10/07/2016: Amendment received consistent with Agency proposed edits incorporated
- 10/14/2016: CPMG communicates that they are unable to continue with the planned December 2016 launch of the modification underway
- 02/14-02/16: Face to face meeting with the CPMG
- 07/20/2018: REMS Major Modification submitted to DMF 030496
- 12/12/2018: Amendment received to DMF 030496

Due to the large number of communications between the Agency and the CPMG, see appendix 7.3 for details on REMS correspondences.

3 AGENCY RATIONALE FOR REMS MODIFICATION

This major modification changes the inpatient prescriber certification and patient monitoring requirements and adds additional educational materials to the REMS. Of note, although not a modification, the restrictions for prescriber and pharmacy certification will initiate at the time of launch of this modification.

3.1 INPATIENT PRESCRIBER CERTIFICATION

The currently approved Clozapine REMS requires all prescribers to become certified in the program to prescribe clozapine. However, during the extended implementation period several concerns regarding the burden of inpatient prescriber certification were brought to the attention of the Agency. Having every prescriber who admits patients to an inpatient facility become certified to prescribe clozapine would potentially be a large burden on the healthcare delivery system. The AMA⁸ reports that, "...the share of physicians who work in a practice with at least some hospital ownership or who are direct hospital employees was 32.8 percent in 2016. In a 2016 census of actively licensed physicians in the United States, a total of 953,695 actively licensed physicians.⁹ Therefore an estimate for the number of prescribers who would potentially need to become certified in the Clozapine REMS Program for inpatient medical care is 312,812.

Subsequently, the CDER Network of Experts was engaged. Pharmacists from the College of Psychiatric and Neurologic Pharmacists were asked about current best practices for the safe management of patients admitted to an acute care patient setting who are currently on clozapine therapy. All participants expressed that patient access would improve if the requirement for inpatient prescribers was eliminated. Three-fourths of those surveyed believed that inpatient pharmacies should develop their own policies and procedures that would ensure the safe use of clozapine while minimizing the burden on the healthcare delivery system.

Therefore, to minimize the burden on the healthcare delivery system, specifically inpatient prescribers managing clozapine patients for a short period of time, as well as to ensure continuity of therapy, the requirement for an inpatient prescriber continuing therapy for a patient currently enrolled in the Clozapine REMS Program is being removed. Any prescriber (whether inpatient or outpatient) initiating therapy for a non-enrolled patient will continue to require certification in the program. This should improve access to clozapine for patients being admitted for an acute diagnosis, while maintaining the safety of all clozapine patients.

3.2 CERTIFIED INPATIENT PHARMACY REQUIREMENTS

The currently approved REMS requires lab reporting within 7 days of the blood draw for all patients regardless of inpatient or outpatient status. However, due to the aforementioned inpatient burden, as well as an assurance that the patient is likely being continuously monitored for adverse events and

⁸ Kane, Carol K.; Policy Research Perspectives- Updated Data on Physician Practice Arrangements: Physicians Ownership Drops Below 50 Percent; American Medical Association; 2017

⁹ Young, A., et.al. (2017). A Census of Actively Licensed Physicians in the United States, 2016. *Journal of Medical Regulation*, 103(2). Retrieved from <https://www.fsmb.org/globalassets/advocacy/publications/2016census.pdf>

white blood cell count changes in an inpatient setting, the monitoring requirements for those admitted to an inpatient facility will be modified. The new requirement will be to check eligibility to receive clozapine once upon admission before dispensing the first dose. This eligibility check will ensure that a patient is currently enrolled in the program and thus under the care of a certified prescriber, as well as verify that the patient has an ANC on file. If the patient does not have a recent (or any) ANC on file with the Clozapine REMS Program, the inpatient pharmacist has the option of obtaining that information from the patient's medical records and may choose to enter the value into the REMS program, although not required.

Further, a change in the definition of inpatient pharmacies is warranted as facilities other than acute care hospitals may have varying standard monitoring schedules for patients. In the currently approved clozapine REMS, an inpatient pharmacy is defined as any facility with a pharmacy within its 4 walls. Therefore, it is plausible that a long-term care or other type of non-acute care facility could have certified as an inpatient pharmacy. As these facilities may not complete laboratory monitoring as frequently as an acute care facility, patients taking clozapine admitted here may not be undergoing frequent monitoring by default and therefore may not be adhering to their required monitoring frequency if included in the new inpatient pharmacy requirements. In keeping with the definition of inpatient hospital services put forth by the Centers for Medicare & Medicaid Services (CMS), the newly agreed upon definition of an inpatient pharmacy is: a pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition). The newly agreed upon definition of outpatient pharmacy is: a pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. With the change in definition of inpatient and outpatient pharmacies, the Sponsor estimates that 3,088 certified inpatient pharmacies will need to recertify as outpatient pharmacies.

Pharmacies certified in the Clozapine REMS Program are required to recertify every two years from the date of their initial certification. When a pharmacy attempts to recertify a series of questions determines inpatient or outpatient status. If the original status is incorrect based on the responses to the question, the pharmacy will recertify as the correct pharmacy type.

3.3 CERTIFIED OUTPATIENT PHARMACY REQUIREMENTS

Although not yet implemented, the currently approved REMS requires that all prescriptions are written by certified prescribers. Given that there will be some prescribers who are not yet certified in the REMS Program, pharmacies will have the opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient's prescriber is not certified, provided all other safe use conditions have been met. The pharmacists' decision to dispense clozapine must be documented in the Clozapine REMS program by entering a dispense rationale via the website or calling the contact center. This dispense rationale is limited and can only be used three times per rolling 6-month period. This will

allow patients to maintain access while prescribers continue to become certified in the Clozapine REMS Program.

3.4 MONITORING REQUIREMENTS

Definition of Current Lab

The currently approved REMS instructs the prescriber to submit labs consistent with the patient's monitoring frequency per the labeling; however the pharmacy is given a 7-day window of approvability from the date of the blood draw to dispense a prescription. During the planned implementation phase, the CPMG used a business rule that a lab would be considered "current" if the lab was within 56 days of the dispense date. This value was chosen by the CPMG based on data showing that 56 days was the average time for a prescriber to report a lab to the legacy programs (which were largely a retroactive ANC monitoring program from a database standpoint; pharmacies were still instructed to have current labs on file prior to dispensing). The CPMG carried this definition forward after approval during the extended transition period given the technical difficulties immediately post-approval and delayed deadlines for certification.

During the extended transition period, the Agency expressed concern with the discrepancy between the prescriber's reporting requirement and the pharmacy's requirement for obtaining a successful PDA. The Agency decided that due to access concerns, the currently approved definition of current (within 7 calendar days of the blood draw) was too stringent for patients on twice monthly or monthly monitoring schedules. To allow flexibility for those patients, the Agency and the CPMG agreed to re-define a current lab as a lab within 7 days of the dispense date for weekly monitored patients, within 15 days of the dispense date for twice monthly monitored patients and within 31 days of the dispense date for monthly monitored patients.

As the laboratory data in legacy programs was largely retroactively reported, the timely reporting of ANCs to the Clozapine REMS Program will likely be a change in practice for clozapine prescribers. Given this need to change the reporting practices of prescribers this REMS modification will evaluate if the lab is "current" however this will not prevent a dispense. A warning message will be given to pharmacists that the lab is not current.

3.5 NEW PROGRAM MATERIALS

1. Pharmacy Enrollment Forms

- a. Given the varied requirements between inpatient and outpatient pharmacies, the Pharmacy Enrollment Form has been separated into the Inpatient Pharmacy Enrollment Form and the Outpatient Pharmacy Enrollment Form. These forms now reflect the changes in pharmacy responsibilities.

2. PDA Fact Sheet and Frequently Asked Questions

- a. The complexity of the Clozapine REMS Program, the implementation challenges and the planned multi-phased implementation, caused the Agency and CPMG concern that there would be significant stakeholder confusion during the extended transition period. To alleviate this confusion several new educational materials were developed and approved using enforcement discretion¹⁰ to allow for rapid distribution. The *Pre-Dispense Authorization (PDA) Fact Sheet* was developed to detail the process an outpatient pharmacy uses to obtain a PDA. It reflects the current state of the PDA and will be revised with the approval of this modification to reflect the requirements. *Frequently Asked Questions (FAQs)* were developed to address common questions the CPMG and the Agency received from stakeholders during the extended transition period, and in anticipation of questions that may occur as the operational restrictions are implemented.

3. Eligibility Check Fact Sheet

- a. The *Eligibility Check Fact Sheet* was developed to detail the process an inpatient pharmacy uses to safely dispense clozapine to patients in their institution.

4. Stakeholder Letters

- a. To communicate with clozapine stakeholders, transition letters were developed under enforcement discretion¹¹ to provide detailed information about the phased implementation approach. The letters are the *Dear Inpatient Pharmacy Letter*, *Dear Outpatient Pharmacy Using Web PDA Letter*, *Dear Outpatient Pharmacy Using Switch Letter*, *Dear Prescriber Letter*, *Dear Chain Pharmacy Letter*, as well as a cover letter to accompany communication provided to prescriber and pharmacy professional societies. These letters will be modified to reflect the implementation status following the approval of this modification. These additional materials and letters have been added to the Clozapine REMS Program Website and are appended to the REMS Supporting Document.

5. How to Start Clozapine and Monitor Patients Fact Sheet

- a. There are several other materials to aid with program understanding being added to the REMS with this modification. The *How to Start Clozapine and Monitor Patients Fact Sheet* was developed to provide concise information on how to start and monitor

¹⁰ The agency's exercise of enforcement discretion with regard to certain requirements will not extend to fraud or other illegal conduct, and that the agency could, at its discretion, initiate enforcement action for violations of any and all applicable statutory and regulatory provisions implicated by fraudulent or illegal activity.

¹¹ See REMS correspondence submission 04/11/16 and 4/18/2016 to DMF 030496

patients on clozapine. This is in addition to the information contained in the Healthcare Provider Education Program and focuses solely on how to clinically manage patients.

4 PROPOSED REMS MODIFICATIONS

4.1 RESULTS OF REVIEW OF THE APPLICANTS' PROPOSED REMS MODIFICATION

4.2 REMS GOALS

The Sponsor did not propose changes to the goals of the REMS.

4.2.1 Elements to Assure Safe Use

The following is a review of the changes proposed to the REMS Document and REMS appended materials.

REMS Document

Due to the changes in inpatient prescriber certification, certified inpatient pharmacy requirements, certified outpatient pharmacy requirements, monitoring requirements, and the addition of new program materials, the REMS document was revised to reflect these changes. See submission on July 20 and December 12, 2018 in Drug Master File (DMF) 030496.

Reviewer comment: These changes are acceptable.

REMS Appended Materials: Global Changes

1. During the review of materials there was inconsistent terminology used throughout the REMS appended materials. To ensure consistency, a terminology matrix was developed. All materials were updated according to the terminology matrix. For example, instead of "report an ANC" the correct terminology throughout all documents is "submit an ANC".
2. The risk message that clozapine has a risk of severe neutropenia associated with its use was revised by Office of Prescription Drug Promotion (OPDP) to include the possible consequence of the risk- serious infection and death. This was added to the risk message throughout all REMS materials to read, clozapine can cause severe neutropenia, which can lead to serious infections and death.
3. As described in section 3 of this review, a current lab was re-defined as a lab within 7 days of the dispense date for weekly monitored patients, within 15 days of the dispense date for twice monthly monitored patients and within 31 days of the dispense date for monthly monitored patients. This change was made throughout the REMS materials.

There were other editorial changes to all the appended materials, see submission on July 20 and December 12, 2018.

Reviewer comment: These changes are acceptable.

In addition to the aforementioned changes throughout all educational materials, the following materials were modified as follows:

Pharmacy Enrollment Forms

In the currently approved program, there is one pharmacy enrollment form. Consistent with the changes made to the requirements for inpatient dispensing, the pharmacy enrollment form was split into an inpatient pharmacy enrollment form and an outpatient enrollment form.

Reviewer comment: These changes are acceptable.

Educational Materials

New educational materials

As discussed in Section 3 several new educational materials were added to guide stakeholders.

Fact Sheets:

The *How to Start Clozapine and Monitor Patients Fact Sheet* is targeted to prescribers of clozapine. This fact sheet reiterates the prescribing requirements, specifically what activities need to be completed prior to prescribing, the monitoring requirements, and steps for discontinuing clozapine treatment.

The *Eligibility Check Fact Sheet* targets inpatient pharmacies who utilize the Eligibility Check (EC). This fact sheet includes instructions on how to perform an EC, the elements evaluated by the EC, the possible results of the EC based on the information provided to the program, and action needing to be taken by the pharmacy based on the results of the EC. The *PDA Fact Sheet* targets outpatient pharmacies who utilize the PDA to verify that an outpatient is eligible to receive clozapine. This fact sheet includes instructions on how to perform a PDA, the elements evaluated by the PDA, the possible results of the PDA based on the information provided to the program, and action needing to be taken by the pharmacy based on the results of the PDA.

A *Frequently Asked Questions* (FAQ) document was developed to further assist stakeholders in understanding the program and the requirements of the program. The FAQs are questions that are likely to need operationally based (and not safety based) responses. The FAQs are included on the Clozapine REMS Website.

Reviewer comment: These changes are acceptable.

REMS Letters

The currently approved Clozapine REMS Program includes letters to prescribers and pharmacies to make them aware of the changes to the program and the need to certify in the Clozapine REMS Program. These letters were initially to be distributed at specified intervals during the implementation of the REMS program, however given the delayed full implementation; these letters no longer contained accurate information. They were therefore removed from distribution and have been replaced with updated letters to each stakeholder. The updated letters are the *Dear Prescriber Letter*, *Dear Inpatient Pharmacy Letter*, *Dear Outpatient Pharmacy using Web PDA Letter*, and *Dear Outpatient Pharmacy using Switch Letter*.

The currently approved program also reaches out to both prescriber and pharmacy professional societies, these letters have been updated to reflect the changes described in Section 3.

Further, several additional communications were added to the REMS program- certification reminder letters and a deactivation letter. These letters are directed to stakeholders who are going to be deactivated and those who have already been deactivated based upon required re-certification timelines in the REMS.

Reviewer comment: These changes are acceptable.

REMS Website

The Website Screen Captures reflect the updated REMS document and all appended materials. The submission contains all required captures of functionality, including the newly added Dispense Rationale.

Reviewer comment: These changes are acceptable.

4.2.2 Timetable for Submission of Assessments

To align with the implementation of system functionality that was initially deferred at program launch, assessments are now due annually beginning with the implementation of this REMS modification.

Reviewer comment: These changes are acceptable.

4.2.3 REMS Assessment Plan

With the changes to the REMS with this modification, the assessment plan has changed to add metrics regarding the Dispense Rationale, add metrics regarding the requirement of a lab being current to dispense clozapine, and clarify language added regarding unique prescriptions submitted for authorization. In addition, obsolete transition metrics in the assessment plan have been removed.

The Assessment Plan

A. REMS Program Implementation and Operations

1. REMS Program Utilization:

a. Pharmacies, Prescribers, Prescriber Designees, and Distributors:

- i. Number of each stakeholder, status of certification or enrollment (as applicable), and method of certification or enrollment (as applicable)
- ii. Summary of reasons certification or enrollment is incomplete for each stakeholder (Examples may include “Pharmacy unable to configure pharmacy management system,” “Prescriber missing information on form,” etc.)

b. Patient Treatment Status by Patient Type (general population, BEN patients, NNRMF patients, hospice patients) for the reporting period and cumulatively:

- i. Active
- ii. Interrupted
- iii. Discontinued

c. A nationally estimated number of patients that received a dispensed prescription for clozapine (all dosage forms) from U.S. outpatient retail pharmacies for the reporting period. Provide rationale for discrepancies between this estimate and the number of unique patients enrolled in the clozapine REMS and receiving at least one PDA during the reporting period.

2. Contact Center Report:

a. Number of contacts

b. Summary of reason for contacts (examples may include “Enrollment question,” “Lab query,” etc.) by reporter (i.e., pharmacy, prescriber, patient)

c. Narrative of any corrective actions resulting from issues identified

3. Clozapine REMS Program Compliance (to be included in the REMS Assessment Report after full implementation):

a. Audits

- i. Summary of audit findings for audits conducted during the reporting period
- ii. Summary of corrective actions taken to address findings, the status of the corrective actions, and any resulting preventative actions that were taken

- b. Number of clozapine prescriptions dispensed that were written by non-certified prescribers (reported or detected through audit):
 - i. Actions taken (examples may include “Provision of clozapine program materials,” “Prescriber becomes certified,” etc.)
 - ii. Outcome of actions taken
- c. Number of prescriptions dispensed by noncertified outpatient pharmacies and actions taken to prevent future occurrences (reported or detected through audit)
- d. Number of shipments sent to noncertified pharmacies, source of report, and actions taken to prevent future occurrences
- e. Number of times a clozapine prescription dispensed because a pharmacy bypassed REMS edits; and, if any such events occurred, describe how these events were identified, the root cause of the failure, and any corrective actions taken (reported or detected through audit). Stratify by pharmacy type (switch or non-switch)
- f. Number of times a clozapine prescription was dispensed by a pharmacy for more than a 3-day supply during the 3-day/72-hour Dispense Rationale window
- g. Number of patients receiving a clozapine prescription under a Dispense Rationale stratified by the number of prescriptions authorized under a Dispense Rationale per patient in a 6-month time-frame
 - i. Summary of outreach to prescribers and number of resulting prescriber certifications.
- h. Number of prescriptions dispensed under a Dispense Rationale stratified by prescriber
- i. Number of pre-dispense authorizations without current lab value based on the patient’s monitoring frequency (7/15/31), provided as
 - i. Total number of individual patients receiving PDA without current lab (i.e., aggregate)
 - ii. Number of PDAs for each unique patient without current lab; provide range and average number of PDAs per patient
- j. Noncompliance with the Clozapine REMS Program requirements, source of report, and any corrective action or resolution
 - i. Number of PDAs without ANC (excluding hospice patients) and number of these resulting in clozapine dispensing

- ii. Number of PDAs without a Treatment Rationale provided when the ANC was unacceptable, and number of these resulting in clozapine dispensing
- 4. Barriers or Delays in Patient Access: Provide outcome wherever possible
 - a. False negatives: e.g., all entities are certified, but system generated a prescription rejection notice
 - b. Inadvertent enrollment deactivations or failures to notify enrollees of forthcoming enrollment expirations
 - c. Reported lack of certified prescribers and/or pharmacies in a patient's local area
 - d. Unintended system interruptions and resolutions
 - e. For PDAs via electronic verification: Number of times and reasons a manual back-up system was used to validate a prescription and source of problem (e.g., switch level, pharmacy level, REMS database, etc.)
- 5. Inappropriate Patient Access:
 - a. Inpatient pharmacy dispensing for outpatient use (reported or detected through audit)
 - b. False positives: e.g., one or all entities were not certified but system verified dispensing/generated a PDA
- 6. Evaluation of Safe-Use Behaviors:
 - a. Prescription Rejections:
 - i. Number of unique prescriptions submitted for authorization
 - ii. Number of unique prescriptions submitted for authorization that did not encounter any REMS-related rejections prior to being authorized stratified by authorization type (Clozapine REMS Program Website PDA or pharmacy claims PDA)
 - iii. Number of unique prescriptions submitted for authorization that encountered any REMS-related rejections, stratified by authorization type (Clozapine REMS Program Website PDA or pharmacy claims PDA)
 - iv. Mean, median, and range or the duration of time to authorize stratified by authorization type
 - v. Provide reasons for prescription rejections stratified by type of PDA (via pharmacy management system or Clozapine REMS Program Website) and duration of time to authorize prescription if initially rejected

- b. Treatment Rationales:
 - i. Number of Treatment Rationales submitted, stratified by type
 - ii. Mean number of Treatment Rationales submitted per prescriber
 - c. Number of notifications and alerts sent, stratified by type and stakeholder type (prescriber, pharmacy) and resulting actions by stakeholder (clozapine discontinued, pharmacy became enrolled, etc.)
 - (a) For overdue lab notifications and severe neutropenia notifications, provide the number of notifications per unique patient and any actions by stakeholder (clozapine discontinued, pharmacy became enrolled, etc.) resulting from the notification.
7. Evaluation of Knowledge/Surveys:
- a. An evaluation of knowledge of certified prescribers of the risk of severe neutropenia, appropriate monitoring of clozapine and REMS requirements
 - b. An evaluation of knowledge of authorized representatives and pharmacists of the risk of severe neutropenia, appropriate monitoring of clozapine and REMS requirements
 - c. An evaluation of knowledge of patients or caregivers of the risk of severe neutropenia, and the need for appropriate monitoring
8. Evaluation of Required Monitoring:
- a. Total instances of severe neutropenia for unique patients (reported as lowest ANC for each unique patient whose ANC drops below 500/ μ L within each month)
 - b. Total instances of neutropenia for unique patients (reported as lowest ANC for each unique patient whose ANC drops below 1500/ μ L, but remains at 500/ μ L or above within each month)
9. With respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified (Section 505-1(g)(3)).
10. Clozapine REMS Program Outreach and Communication after the REMS modification in <MM/YYYY> and after any subsequent modifications that are approved in each assessment period:
- a. Dates of distribution of the Dear HCP Letter, Dear Distributor Letter, Dear Professional Society Letter, Chain Pharmacy Letter, Inpatient Pharmacy Letter, Outpatient Pharmacy Letter (Non-switch), Outpatient Letter (Switch), and Prescriber Letter and the numbers

sent on each date. Provide a list of the documents included with each distribution including the revision date

- b. Number of undeliverable and returned communications for each distribution date, by method of distribution
- c. A summary of the Clozapine REMS Program Website utilization

11. Knowledge Assessments:

- a. Number of completed Clozapine REMS Knowledge Assessment for Healthcare Providers (KAs) for certified prescribers and pharmacy authorized representatives, and pharmacy staff that have elected to take the KA, including method of enrollment and number of attempts to complete, by stakeholder
- b. Summary of the most frequently missed KA questions, stratified by prescriber and pharmacy
- c. A summary of potential comprehension or perception issues identified with the KA
- d. Proposed remediation for Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers and/or the Clozapine REMS Knowledge Assessment for Healthcare Providers

12. The Important Program Update on the Clozapine REMS Program Website is used to communicate important program changes to stakeholders. This section on the website will provide frequent updates to stakeholders regarding the program. A summary of the number of updates communicated in this section of the website will be provided during the assessment reporting period.

13. Data Sources for Safety Surveillance:

- a. Adverse event reports will be processed according to each Sponsor's Standard Operation Procedures and criteria outlined in 21 CFR 314.80 The Sponsors will process hematologic adverse drug experiences on clozapine collected by the single shared system as follows:
 - i. All adverse events (hematologic and non-hematologic) will be considered "solicited" events and reported per 21 CFR 314.80(e). In other words, any adverse event collected by the single shared system that is determined to be serious, unexpected, and related will be reported as a 15-Day Alert Report
 - ii. Expedited 15-Day Alert Reports will be submitted for both serious and non-serious outcomes for all cases of neutropenia ($ANC < 1000/\mu l$) for all patients (general population and BEN) for the first 3 years after the initiation of the Clozapine REMS Program

- iii. Serious, expected events will be reported within the line listing and SOC tabulations in the product's periodic report
- iv. Non-serious neutropenic events (ANC 1000/ μ l to 1499/ μ l) not associated with any other adverse event will not be submitted as an Individual Case Safety Report (ICSRs). The Clozapine REMS Program will retain any lab records that fall between 1000/ μ L and 1499/ μ L. All ANCs between 1000/ μ L and 1499/ μ L will be reported in the REMS Assessment Reports. FDA may request the ICSRs of ANCs that fall within the specified range above, to be provided within a timeline agreed upon with FDA

b. All serious and non-serious adverse events reported for clozapine outside of the single shared system (e.g., an adverse event reported to the sponsor) will be reported in accordance with 21 CFR 314.80

Reviewer comment: These changes are acceptable.

5 Discussion

DRISK agrees with the Sponsor's proposed changes made to the REMS document, appended materials, Supporting Document and Assessment Plan.

6 Conclusion & Recommendations

The Sponsors' proposed REMS modification, as submitted on July 20-27, 2018 and amended on December 12, 2018, is acceptable to DRISK. Therefore, DRISK recommends approval of the supplement.

7 Appendices

7.1 REFERENCES

- Division of Psychiatric Products (DPP) Supplement Approval Letter for the Clozapine REMS Single-Shared System, dated September 15, 2015.

7.2 SUBMISSIONS

Drug	Application # / Supplement #	Applicant	Date Received	eCTD Sequence # / Supporting Doc #
Clozaril	NDA 19758/S-090	Heritage Life Sciences Barbados Inc.	07/20/2018	0117/528
			12/13/18	0122/533

Drug	Application # / Supplement #	Applicant	Date Received	eCTD Sequence # / Supporting Doc #
Fazaclo	NDA 21590/ S-031	Jazz Pharmaceuticals International III LTD	07/26/2018 12/18/18	0047/406 0048/407
Versacloz	NDA 203479/ S-011	Tasman Pharma Inc.	07/26/2018 12/14/18	0099/142 0103/146
Clozapine	ANDA 202873/ S-005	Accord Healthcare Inc.	07/25/2018 12/14/18	0036/47 0037/49
Clozapine	ANDA 206433/ S-004	Aurobindo Pharma LTD	07/24/2018 12/13/2018	0028/29 0030/31
Clozapine	ANDA 203807/ S-006	Mayne Pharma LLC	07/25/2018 12/13/18	0062/064 0065/67
Clozapine	ANDA 75417/ S-0041	Mylan Pharmaceuticals Inc.	07/25/2018 12/13/18	0064/161 0066/166
Clozapine	ANDA 201824/ S-009	Mylan Pharmaceuticals Inc.	07/25/2018 12/13/18	0075/88 0079/93
Clozapine	ANDA 75713/ S-045	Sun Pharmaceutical Industries, Inc.	07/25/2018 12/14/18	053/164 0055/166
Clozapine	ANDA 74949/ S-075	Ivax Pharmaceuticals Inc. an indirect wholly owned subsidiary of Teva Pharmaceuticals USA Inc.	07/27/2018 12/18/18	0047/403 0050/406
Clozapine	ANDA 76809/ S-038	Ivax Pharmaceuticals Inc. an indirect wholly owned subsidiary of Teva Pharmaceuticals USA Inc.	07/27/2018 12/18/18	0045/246 0049/250
Clozapine	ANDA 203039/ S-005	Teva Pharmaceuticals USA	07/27/2018 12/19/18	0048/50 0053/54
Clozapine	ANDA 90308/ S-003	Barr Laboratories Inc.	07/27/2018 12/19/18	0042/083 0047/87

7.3 IR RESPONSE SUBMISSIONS

Date of IR Response Submission	Date of IR	Details
6/28/2016	6/17/16	CPMG provided a list REMS program materials
7/6/2016	June 2016	Bundled responses to IRs received
8/5/2016	7/14/16	Approach to contents of REMS Document and REMS Supporting Document
12/16/16	8/8/2016 to 11/8/16	Bundled responses to IRs received
7/14/2017	1/4/2017 to 6/8/17	Bundled responses to IRs received
1/26/2018	10/23/2017 to 11/16/2017	Bundled responses to IRs received

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