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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

SINGLE SHARED SYSTEM FOR CLOZAPINE

I. GOALS

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 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. REMS ELEMENTS

A. Elements To Assure Safe Use

1. Certain Healthcare Providers who prescribe clozapine are certified

- 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 successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*; and,

- iii. Enroll in the Clozapine REMS Program by completing the *Clozapine REMS Prescriber Enrollment Form*.
- d. As a condition of certification, prescribers must:
 - i. Enroll each patient in the Clozapine REMS Program by:
 - 1.) Informing the patient about the risks associated with clozapine including severe neutropenia and the Clozapine REMS Program requirements by using *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* and providing it to the patient or caregiver unless clinical judgment indicates 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 and Neutropenia*
 - 2.) Completing the *Clozapine REMS Patient Enrollment Form* for each patient. Submit the completed form to the Clozapine REMS Program
 - ii. Perform the following requirements on an ongoing basis for each patient and submit to the Clozapine REMS Program via the online system, by fax, or by calling the Clozapine REMS Program Contact Center:
 - 1.) Order ANC according to the monitoring schedule described in the Prescribing Information
 - 2.) Submit ANC according to the patient's monitoring frequency on file with the Clozapine REMS Program as described in the Monitoring Schedule of the Prescribing Information:
 - a) For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw date
 - b) For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw date
 - c) For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of the lab draw date
 - 3.) Provide authorization of treatment for patients (i.e., Treatment Rationale) with an ANC that falls below the acceptable range described in the Prescribing Information, when the prescriber determines the benefits outweigh the risks of developing severe neutropenia
 - 4.) Verify the patient monitoring frequency on file with the Clozapine REMS Program is aligned with the patient's monitoring frequency as described in the Prescribing Information

e. Clozapine Sponsors must:

- i. Ensure that Healthcare Providers who prescribe clozapine as described in II.A.1.a-b are certified in accordance with the requirements described above
- ii. Ensure that Healthcare Providers can complete the certification process, patient enrollment and management online or by fax to the Clozapine REMS Program
- iii. Ensure that Healthcare Providers who prescribe clozapine as described in II.A.1.a-b are notified when they have been certified in the Clozapine REMS Program
- iv. Maintain a validated, secure database of Healthcare Providers who are certified to prescribe clozapine in the Clozapine REMS Program. Clozapine Sponsors must ensure that the prescriber's REMS requirements are met and may de-certify noncompliant prescribers if the requirements do not continue to be met
- v. Maintain a validated, secure database of patients enrolled in the Clozapine REMS Program
- vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients
- vii. Provide *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* to Healthcare Providers who:
 - 1.) Attempt to prescribe clozapine as described in II.A.1.a-b and are not yet certified, or
 - 2.) Inquire about how to become certified
- viii. Ensure that within 30 calendar days of REMS approval, the REMS materials listed below are available on the Clozapine REMS Program Website, www.clozapinerems.com, and by calling the Clozapine REMS Program Contact Center at 844-267-8678

The following materials are part of 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 Program Website

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:
 - 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:
 - 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 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
 - 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*
 - 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

- 3.) Recertify in the Clozapine REMS Program every two years
- 4.) Comply with audits by the Clozapine Sponsors or a 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

b. As a condition of certification:

i. Pharmacies that support electronic communication verification with the Clozapine REMS Program system must:

- 1.) Ensure the pharmacy enables its pharmacy management system to support communication with the Clozapine REMS Program system using established telecommunication standards and runs validation test transaction(s) to validate the system enhancements
- 2.) Dispense clozapine to patients only after obtaining a Predispense Authorization each time by processing all clozapine prescriptions, including cash claims, through their pharmacy management system to electronically:
 - a.) Verify the prescriber is certified in the Clozapine REMS Program
 - b.) Verify the patient is enrolled in the Clozapine REMS Program
 - c.) Verify the ANC is current (within 7 days of the Predispense Authorization transaction date for weekly monitoring, 15 days for every two weeks monitoring and 31 days for monthly monitoring)
 - d.) Verify the ANC is within the acceptable range described in the Prescribing Information, or that a certified prescriber has authorized clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia
 - e.) Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program

ii. Pharmacies that do not support electronic telecommunication verification with the Clozapine REMS Program system must dispense clozapine to patients only after obtaining a Predispense Authorization each time by accessing the Clozapine REMS Program Website or calling the Clozapine REMS Program Contact Center to:

- 1.) Verify the prescriber is certified in the Clozapine REMS Program
- 2.) Verify the patient is enrolled in the Clozapine REMS Program

- 3.) Verify the ANC is current (within 7 days of the Predispose Authorization transaction date for 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 certified prescriber has authorized clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia
- 5.) Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program

Inpatient Pharmacies

- c. To become 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* 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. Put processes and procedures in place to ensure the following requirements are completed 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

with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

- iv. 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
 - v. Comply with audits by the Clozapine Sponsors or a 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
- d. As a condition of certification, inpatient pharmacies must:
- i. Dispense clozapine only after:
 - 1.) Performing an Eligibility Check by accessing the Clozapine REMS Program Website or calling the Clozapine REMS Program Contact Center to verify the patient is enrolled in the Clozapine REMS Program;
 - 2.) Verifying that the patient's ANC obtained from the Clozapine REMS Program Website, the Clozapine REMS Program Contact Center, or the patient's inpatient medical record is current; and,
 - 3.) Verifying that 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 the benefits outweigh the risks of developing severe neutropenia
 - ii. Dispense no more than a 7-day temporary supply of clozapine to an enrolled patient upon discharge from the healthcare facility
- e. Clozapine Sponsors must:
- i. Ensure that pharmacies that dispense clozapine are certified, in accordance with the requirements described above
 - ii. Ensure that authorized representatives can complete the pharmacy certification process and training online or by fax to the Clozapine REMS Program
 - iii. Ensure that pharmacies are notified when they have been certified in the Clozapine REMS Program
 - iv. Ensure that pharmacies renew certification in the Clozapine REMS Program every two years
 - v. Verify every two years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for

the certified pharmacy; and if different, require the pharmacy to recertify with a new authorized representative

The following materials are part of 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 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 in the Clozapine REMS Program, each prescriber must complete a *Clozapine REMS Patient Enrollment Form* indicating that the patient or their caregiver has:
 - i. Been provided *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* unless clinical judgment indicates 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 and Neutropenia*
 - ii. Been informed 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:
 - i. Ensure that the certified prescriber can submit the completed *Clozapine REMS Patient Enrollment Form* online or by fax to the Clozapine REMS Program
 - ii. Ensure that the certified pharmacy can verify that the prescriber is certified and each patient treated with clozapine is enrolled in the Clozapine REMS Program prior to dispensing (see 'Section II.A.2 Pharmacies that dispense clozapine are certified')

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

- *Clozapine REMS Patient Enrollment Form*

4. Each patient using clozapine is subject to certain monitoring

- a. Clozapine Sponsors must ensure that before dispensing clozapine the certified pharmacy can verify the ANC is current and,
 - i. Within the acceptable range described in the Prescribing Information; or,

- ii. The prescriber has authorized clozapine treatment (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

5. Each patient using clozapine is enrolled in a registry

- a. Clozapine Sponsors must ensure that certified prescribers enroll all patients in the Clozapine REMS Program using the *Clozapine REMS Patient Enrollment Form*
- b. Clozapine Sponsors must maintain the Clozapine REMS Program registry. The primary objective of the Clozapine REMS Program registry is to ensure patient safety and safe-use of clozapine through periodic monitoring for severe neutropenia
- 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 the wholesalers/distributors who distribute clozapine comply with the program requirements for wholesalers/ distributors. For a wholesaler/distributor to distribute clozapine, the wholesalers/distributors must:
 - i. Put processes and procedures in place to verify, prior to distributing clozapine, that the pharmacies are certified
 - ii. Train all relevant staff on the Clozapine REMS Program requirements
 - iii. Agree to be audited by the Clozapine Sponsors or a 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
 - iv. Maintain appropriate 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 the 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 pharmacies that are certified to dispense clozapine in the Clozapine REMS Program

3. Clozapine Sponsors must maintain adequate records of clozapine distribution, dispensing, certified prescribers, pharmacies, distributors/wholesalers, and patients to meet the Clozapine REMS Program requirements
4. Clozapine Sponsors must ensure that pharmacies' REMS requirements are met and may decertify noncompliant pharmacies if the requirements do not continue to be met
5. Clozapine Sponsors must maintain a validated, secure database of patients who are enrolled in the Clozapine REMS Program
6. Clozapine Sponsors must maintain a Clozapine REMS Program Contact Center to support prescribers and pharmacies interfacing with the Clozapine REMS Program
7. Clozapine Sponsors must ensure that within 70 calendar days of approval of the <MMDDYYYY> REMS modification, the Clozapine REMS Program Website is fully operational and all materials listed in or appended to the Clozapine REMS Program document are available through the Clozapine REMS Program Website (www.clozapinerems.com) or by calling the Clozapine REMS Program Contact Center at 844-267-8678
8. The Clozapine REMS Program Website (www.clozapinerems.com) must continue for the duration of the REMS. Additionally,
 - a. The Clozapine REMS Program Website must include the following online capabilities for certified Healthcare Providers, their designees, or pharmacy staff, as applicable:
 - i. completion of prescriber and pharmacy certification,
 - ii. enrollment and management of patients,
 - iii. provision of Predispense Authorizations; and,
 - iv. provision of Eligibility Check results
 - b. The Clozapine REMS Program Website must include the option to print versions of the Clozapine REMS Program materials
 - c. The individual, product-specific clozapine websites for Healthcare Providers must include a prominent REMS-specific link to the Clozapine REMS Program Website
9. Clozapine Sponsors must continuously monitor the certified pharmacies to ensure the requirements of the Clozapine REMS Program are being met. Clozapine Sponsors must institute corrective action if noncompliance is identified
10. Clozapine Sponsors must audit certified pharmacies that have ordered clozapine to ensure that all processes and procedures are in place and functioning to support the requirements of the Clozapine REMS Program on the following schedule:

- a. Initial 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.

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 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 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
- Versacloz® (clozapine, USP) oral suspension
- Clozapine, USP, orally disintegrating tablets
- 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 a certified prescriber to receive clozapine
- Must comply with the ANC testing requirements

Important Terms Used in the Clozapine REMS Program:

- **Predispose 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/ μ L for the general population) or severe neutropenia (ANC < 500/ μ L 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:

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

*neutrophils include “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 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 documented 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 with documented 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 with documented 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
Normal Range for a New Patient GENERAL POPULATION • ANC \geq 1500/ μ L BEN POPULATION • ANC \geq 1000/ μ L • 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 Prescribing Information
Mild Neutropenia (1000 - 1499/ μ L)*	GENERAL POPULATION <ul style="list-style-type: none"> • Continue treatment BEN POPULATION <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 	GENERAL POPULATION <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** BEN POPULATION <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 Prescribing Information
Moderate Neutropenia (500 - 999/ μ L)*	GENERAL POPULATION <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 BEN POPULATION <ul style="list-style-type: none"> • Recommend hematology consultation • Continue treatment 	GENERAL POPULATION <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** BEN POPULATION <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**
Severe Neutropenia (< 500/ μ L)*	GENERAL POPULATION <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 BEN POPULATION <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 	GENERAL POPULATION <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 BEN POPULATION <ul style="list-style-type: none"> • Daily until ANC \geq 500/μL • Three times weekly until ANC \geq patients established baseline • If patient rechallenged, resume treatment as a new patient under "Normal 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 for 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 in to 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 patients 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/ μ L) or severe clozapine-related neutropenia (ANC less than 500/ μ L), 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 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 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 requirements

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 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, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance or to 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 submit 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 submit 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	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 after 12 months	ANC must be submitted 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?](#)"

Clozapine and the Risk of Neutropenia:

A Guide for Healthcare Providers

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 Predispose 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: Accessing 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: Providing 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 into the Clozapine REMS Program Website at www.clozapinerems.com .
Step 2: Access the dashboard.
Step 3: Select ' <i>Predispense Authorization</i> ' from the drop-down menu and click the Go button.
Step 4: Enter the patient information on the ' <i>Predispense Authorization</i> ' screen and click Submit . The ' <i>Predispense Authorization Result</i> ' screen will appear with a reject message.
Step 5: Click the ' Provide a <i>Dispense Rationale</i> for this patient ' check box at the bottom of the ' <i>Predispense Authorization Result</i> ' screen and click the Submit button.
Step 6: If the <i>Dispense Rationale</i> 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 ' <i>Dispense Rationale</i> ' from the drop-down menu and click the Go button.
Step 4: Enter the patient information on the <i>Dispense Rationale</i> screen and click submit .
Step 5: The " <i>Dispense Rationale Result</i> " screen will appear with a reject message similar to the switch reject message.
Step 6: Click on the ' Provide a <i>Dispense Rationale</i> for this patient ' check box at the bottom of the ' <i>Dispense Rationale Result</i> ' screen and click Submit .
Step 7: If the <i>Dispense Rationale</i> 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/ μ L; three times weekly until ANC \geq 1500/ μ 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/ μ L; three times weekly until ANC \geq 1500/ μ 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 µL):
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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/µL for the general population) or severe neutropenia (ANC<500/µL for the 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):

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):

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 "Predispose 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.

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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 Risk Evaluation and Mitigation Strategy (REMS) Program?

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.

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):
-------------------------------	---------------

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): _____
------------------------------------	---------------------------------

*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.

Website Screen Captures

Clozapine REMS Program

November 2020

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1. Static Pages

1.1 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 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



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.



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.

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1.4 Site Guide – Patient Tab



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.

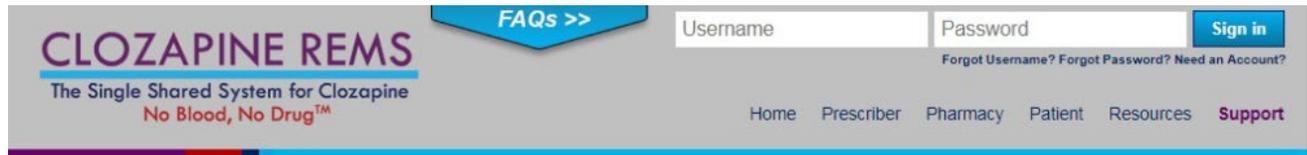
Additional information is available to patients by using the **Learn More** button below, which will navigate the patient to the patient information page or by visiting the **Patient** link at the top of the page.

[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



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.



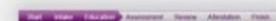
Prescriber designees can learn more about the certification process by using the **Learn More** button below, which will navigate the prescriber designee to the to the certification landing page or by visiting the **Prescriber** link at the top of the page.

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.

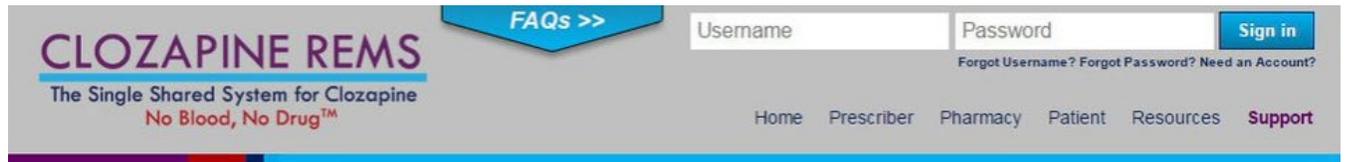
During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)



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

1.6 Site Guide – Pharmacy Staff Tab



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.



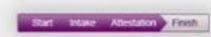
Pharmacy staff can learn more about the enrollment process by using the **Learn More** button below, which will navigate the pharmacy staff to the enrollment landing page or by visiting the **Pharmacy** link at the top of the page.

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

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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!](#)

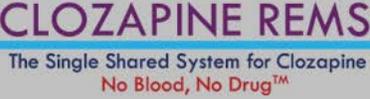
Program Materials

- [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



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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

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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

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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

The screenshot displays 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 links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation bar, the 'Program Materials' section is active, showing a list of forms under the 'Forms' tab. The forms listed are: 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, and Clozapine REMS Prescriber Enrollment Form. A note at the bottom of the page states: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.'

Note: Resources included under the other tabs are listed below:

- 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 Clozapine REMS Program by sending an email to info@clozapinedistributor.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 Representative Certification and Pharmacy Certification
 - Pharmacy Staff Enrollment
 - How to View Prescriber Alerts and Notifications
 - How to Use the Prescriber Dashboard
 - How to Enter a *Treatment Rationale*
 - How Prescribers Enter ANCs and Manage Patients
 - How Prescribers Can Enter Labs
 - How Outpatient Pharmacies Obtain a Web *Predispense Authorization* (PDA)
 - How Outpatient Pharmacies Enter ANCs
 - How Inpatient Pharmacies Check Eligibility and Enter ANCs
 - How to Obtain a *Dispense Rationale*

1.13 Prescribing Information



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Prescribing Information

Products covered under the Clozapine REMS Program

Brand Name Products			
Trade Name	Generic Name	Company	Link
Clozari®	Clozapine	HLS Therapeutics (USA), Inc.	Full Prescribing Information
Versacloz®	Clozapine, USP	Tasman Pharma 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 Tablets, USP	Aurobindo Pharma USA Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Aurobindo Pharma USA 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
Clozapine	Clozapine, USP ODT	Teva Pharmaceuticals USA Inc.	Full Prescribing Information

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

1.14 Certification Lookup

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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

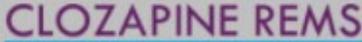
and

or or

[Search](#)

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

1.15 Certification Lookup Results



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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

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

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

CLOZAPINE REMS

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1.16 Site Map

FAQs >>

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Site Map

<p><u>Prescriber</u></p> <p>Prescriber Certification Prescriber FAQs Prescriber Resources Prescriber Support</p>	<p><u>Designee</u></p> <p>Prescriber Designee Certification Designee Support</p> <p><u>Pharmacy Staff</u></p> <p>Pharmacy Staff Enrollment Pharmacy Staff Support</p> <p><u>General</u></p> <p>Contact Us General FAQs Prescribing Information Privacy Professional Societies Resources Technical Support FAQs Terms of Use Wholesaler/Distributor FAQs Wholesaler/Distributor Resources</p>	<p><u>Account</u></p> <p>Forgot Password Forgot Username Need an Account</p>
<p><u>Pharmacy</u></p> <p>Pharmacy Certification Pharmacy FAQs Pharmacy Resources Pharmacy Support</p>		
<p><u>Patient</u></p> <p>Patient FAQs Patient Information Patient Resources Patient Support</p>		

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

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1.17 FAQs

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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?								

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

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Note:

Resources included under the other tabs are listed below:

- Prescriber
 - How can a prescriber become certified in the single shared Clozapine REMS Program?

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- When do I need to complete certification?
- What are the changes for prescribers in an inpatient setting with the <MM/YYYY> Clozapine REMS Program Modification?
- If a prescriber is going to be out of the office for an extended period of time, can another prescriber cover during the absence?
- 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?
- Can a nurse practitioner, physician assistant, resident, or intern certify as a prescriber in the Clozapine REMS Program?
- Can a member of the prescriber's office staff help manage patients in the Clozapine REMS Program?
- How can a prescriber find a list of pharmacies that are certified in the Clozapine REMS Program?
- Where can I find the Patient ID for the Clozapine REMS ANC Lab Reporting Form?

- Prescriber Designee
 - What actions can a prescriber designee perform in the Clozapine REMS Program?

- Patient Management
 - Do patients need to be enrolled in the Clozapine REMS Program in order to receive clozapine?
 - How are patients enrolled into the Clozapine REMS Program?
 - Can a healthcare provider not certified in the Clozapine REMS Program submit an ANC?
 - Will the program send notices if the patient experiences a low ANC or substantial drop?
 - What is a Treatment Status?
 - What is a "Treatment Rationale"?
 - How can I provide a *Treatment Rationale*?
 - What happened to patients previously on the National Non-Rechallenge Master File (NNRMF)?
 - How are patient ANCs submitted to the Clozapine REMS Program?
 - Does the Clozapine REMS Program need to be advised when a patient is admitted to or discharged from an acute or long-term healthcare setting?
 - When discontinuing treatment, does the patient's ANC need to be monitored for 4 weeks?
 - If a patient is eligible to reduce their monitoring frequency does the Clozapine REMS Program 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 does a patient in an inpatient setting become enrolled if prescribers in this setting are not required to be certified in the Clozapine REMS Program?

- Pharmacy Management
 - What are the different pharmacy certification types in the Clozapine REMS Program?
 - What is a *Predispense Authorization (PDA)*?
 - What is an *Eligibility Check*?

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- How is an *Eligibility Check* different from a *Predispense Authorization* (PDA)?
- What is a “Dispense Rationale?”
- How can I provide a *Dispense Rationale*?
- How does a pharmacy certify in the Clozapine REMS Program?
- How often must pharmacies *recertify*?
- How does a pharmacy recertify in the Clozapine REMS 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?

- Wholesaler/Distributor
 - Does a distributor have to enroll in the Clozapine REMS Program?
 - How can a distributor enroll in the Clozapine REMS Program?
 - How can enrolled distributors access a list of pharmacies that participate in the Clozapine REMS Program?
 - A pharmacy has requested clozapine, but they are not yet certified in the Clozapine REMS 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 need help using the Clozapine REMS Program website?
 - What browser types and versions does the Clozapine REMS Program Website support?
 - How does the Clozapine REMS Program Website use cookies?
 - What do I do if I can't view a document on the Clozapine REMS Program Website?
 - How do I report a problem with the Clozapine REMS Program Website?
 - Why does the Clozapine REMS Program Website use Captcha?
 - How do I obtain a username and password for the Clozapine REMS 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 the username previously?
 - How does a healthcare provider change the email address on their REMS profile if they previously created an account with an 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 REMS Program? If I'm not enrolled, how do I become enrolled in the Clozapine REMS Program?
 - Where do I find a list of local pharmacies that participate in the Clozapine REMS Program?

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1.18 FAQ – Pharmacy Authorized Representative

The screenshot shows the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline on the left, and a login section with 'Username' and 'Password' fields and a 'Sign In' button on the right. Below the login section are links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Frequently Asked Questions (FAQs)' and features a horizontal menu with categories: 'General', 'Prescriber', 'Prescriber Designee', 'Patient Mgmt', 'Pharmacy Mgmt', 'Pharmacy Auth Rep' (highlighted in red), 'Wholesaler/Distributor', 'Technical Support', and 'Patient'. Under the 'Pharmacy Auth Rep' category, there is a list of 15 questions, each preceded by a plus sign icon. 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', 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

CLOZAPINE REMS
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[FAQs >>](#)

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[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
Mayne Pharma Inc.	844-825-8500
Mylan Pharmaceuticals Inc.	800-796-9526
Sun Pharmaceuticals Industries Inc.	800-818-4555
Tasman Pharma Inc.	257-317-4104
Teva Pharmaceuticals USA Inc.	800-292-4283

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

2. User Identification and Record Search

2.1 User Identification

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FAQs >>

Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Support

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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Note:

Upon starting an enrollment or certification process the users are asked to identify what type of user they are and what their role is.

1 – 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 now removed).

- New User – Users who are new to clozapine and have not previously submitted an enrollment form to the contact center 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 Designee, and Pharmacy Staff.

2.2 Phone/Fax User Prescriber Search

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 blue 'Sign in' button. Below the password field are links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. A horizontal navigation menu contains links for '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.

2.3 Phone/Fax User Prescriber Search with Results

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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

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'.

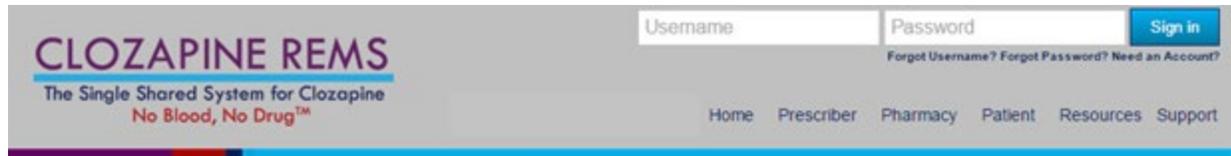
Phone/Fax User

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 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 Results



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

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 a 'Zip Code' field followed by 'and' and three fields: 'DEA', 'NPI', and 'NCPDP'. The second section is titled 'Authorized Representative Information' and contains fields for 'First Name', 'Last Name', and 'Certification ID (opt)'. Below these are three optional fields: '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



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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.

Pharmacy Information (at least one identifier is required):

 and

Authorized Representative 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	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

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo: "CLOZAPINE REMS" in blue, "The Single Shared System for Clozapine" in black, and "No Blood, No Drug™" in red. On the right, there are input fields for "Username" and "Password", followed by a blue "Sign in" button. Below the password field are links: "Forgot Username? Forgot Password? Need an Account?". At the bottom of the header is a navigation menu with 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 form titled "Phone/Fax User" for checking certification status. It is divided into two sections: "Pharmacy Information" and "Authorized Representative Information".

Pharmacy Information: A single text input field labeled "REMS Chain ID".

Authorized Representative Information: A row of three text input fields: "First Name", "Last Name", and "Certification ID (opt)". Below this is another row of three text input fields: "Phone (opt)", "Fax (opt)", and "Email (opt)".

A blue "Search" button is located at the bottom right of the form area.

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

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2.9 Phone/Fax User with 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.

Pharmacy Information

Authorized Representative Information

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 85283	555-555-5555

Showing 1 of 1 entries 1 10

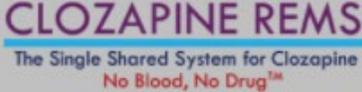
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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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 
hCAPTCHA Privacy - Terms

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

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3.2 Account Verification

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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

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Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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

Account Confirmation



✔ Your web account has been successfully activated. Please sign in to your account using the fields in the upper right corner of this page.

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

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4. Prescriber Certification

4.1 Prescriber Intake

Summer Hogan ▾ [My Dashboard](#)

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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 Program

The screenshot shows the user interface for the Clozapine REMS Prescriber Education Program. At the top, the logo and tagline are repeated. A navigation bar includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A progress bar shows steps: Start, Intake, Education (active), Assessment, Review, Attestation, and Finish. The main content area is titled 'Education Program' and contains a paragraph of instructions. Below this is a large white box with a dark border containing the title 'Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers' and a 'Next' button. At the bottom, there is a contact number and a footer with links for Privacy, Terms of Use, Site Map, FAQs, and 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

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™'. In the top right corner, the user 'Summer Hogan' is logged in, with 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 message 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'.

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the *Clozapine REMS Knowledge Assessment for Healthcare Providers* (KA). KA is shown only once below for all stakeholders except for prescriber designees.

4.4 Prescriber Intake Review

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

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4.5 Prescriber Attestation

Summer Hogan My Dashboard

CLOZAPINE REMS
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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 1-844-404-8676.

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*Reschedule the lab draw date to 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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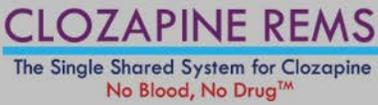
CLOZAPINE REMS

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4.6 Prescriber Confirmation

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™'. On the top right, the user 'Summer Hogan' is logged in, with 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', followed by a green checkmark and the message: 'You are now certified in the Clozapine REMS Program.' Below this, it 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. It also provides links for 'Enroll Patient' and 'Manage Your Patients'. At the bottom, it says: '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



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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

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

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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

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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

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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 Confirmation – Success

Summer Hogan ▾ [My Dashboard](#)

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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 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 Review

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[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

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Summer Hogan ▾ My Dashboard

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.

5.9 Prescriber Designee Confirmation

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 user profile for 'Summer Hogan' and a 'My Dashboard' button are visible. A progress bar below the navigation shows steps: Start, Intake, Education, Assessment, Review, Attestation, and Finish. The main content area is titled 'Certification Confirmation' and features a green checkmark icon and a message: 'Thank you! You are now certified in the Clozapine REMS program.' Below this, it states: 'Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.' The certification ID is 'HCP5627506077' with a printer icon. A link is provided: 'If you are ready to associate yourself as a designee for a prescriber, please go to the [Associate to Prescriber](#) page.' 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 | Contact Us'.

CLOZAPINE REMS
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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 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

Note: User will be presented with this screen upon selecting 'Phone/Fax User' type on the 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.

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6.4 Role Selection Confirmation – Inpatient Pharmacy

Note: 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 sign-in section with fields for Username and Password, and a 'Sign in' button. Below the navigation bar, there are links for Home, Prescriber, Pharmacy (highlighted), 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**.' There are three radio button options for role selection. 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).', and '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.' At the bottom of the dialog are 'Cancel' and 'Confirm' buttons. Below the dialog, there is a 'Continue' button. 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, and Contact Us.

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Username Password **Sign in**
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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**
certification and training requirements. This pharmacy cannot be used for inpatient care. This includes, but is not limited to, retail drug-stores, ambulatory care centers, and long-term care facilities and prison systems.
- Authorized Representative of Inpatient Pharmacy**
certification and training requirements. This pharmacy is responsible for ensuring that all claims are submitted to the appropriate payor. This includes, but is not limited to, inpatient hospitals, long-term care facilities, and prison systems. This pharmacy is responsible for ensuring that all patients are treated at a site of care and pharmacy that is certified to dispense clozapine. This pharmacy is responsible for ensuring that all patients receive medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition).
- Authorized Representative of Pharmacy Headquarters**
responsible for ensuring that all pharmacies in the network are certified to dispense clozapine. This pharmacy headquarters is responsible for ensuring that all pharmacies are contracted to participate with a pharmacy network.

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.

Cancel **Confirm**

Continue

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6.5 Role Selection Confirmation – Outpatient Pharmacy

Note: 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 search bar, and a 'Sign in' button. Below the navigation bar, there are links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. The main content area is titled 'Program Role Selection' and contains a list of radio button options for selecting a role. A pop-up window is overlaid on the 'Authorized Representative of Independent Outpatient Pharmacy' option. 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.

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 an independent outpatient pharmacy, you agree that your pharmacy is a retail, mail order or institutional outpatient pharmacy enrolling as a single pharmacy location with its own authorized representative (i.e., not a location covered by a central headquarters for enrollment or training).

If the pharmacy you are certifying does not meet this definition of an Outpatient Independent Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the pop-up are two buttons: 'Cancel' and 'Confirm'.

Below the pop-up, there is a 'Continue' button and a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' At the very bottom, there are links for Privacy, Terms of Use, Site Map, FAQs, and 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** - 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.
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual inpatient pharmacy. Inpatient pharmacy claims are submitted to the pharmacy network provider.

[Continue](#)

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

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6.7 Authorized Representative Intake

Summer Hogan ▾ [My Dashboard](#)

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[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

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 user 'Summer Hogan' is logged in, with a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A secondary navigation bar contains 'Intake', 'Education', 'Assessment', and 'Confirmation'. The 'Confirmation' section features a green box with the message: 'You have successfully completed the required authorized representative training.' Below this, a paragraph instructs the user to click 'Certify Pharmacy' to complete the process and use the 'My Dashboard' button to return to the dashboard. At the bottom, 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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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Intake Education Assessment Confirmation

Confirmation

You have successfully completed the required authorized representative training.

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.

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

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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 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.

2 – Adjudicate claims online question – This question will be displayed only if the Pharmacy Type selected on this page is 'Outpatient Pharmacy'.

6.10 Pharmacy Re-classification

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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

[Next](#)

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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 Program

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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.

6.12 Pharmacy Education Confirmation

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™'. In the top right corner, the user name 'Summer Hogan' is displayed next to a 'My Dashboard' button. A navigation menu below the header includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', and 'Support'. A secondary navigation bar contains 'Intake', 'Education' (highlighted), 'Assessment', and 'Confirmation'. The main heading is 'Education Program Confirmation'. Below this, a message states: 'You have now completed the Education Program'. A paragraph follows: '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 positioned below the text. At the bottom of the page, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a link menu for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the *Clozapine REMS Knowledge Assessment for Healthcare Providers*. KA is shown only once below for all stakeholders except for prescriber designees.

6.13 Pharmacy Attestation – Inpatient Pharmacy

Note: This page includes only the attestation text for the Inpatient Pharmacy from the *Clozapine REMS Inpatient Pharmacy Enrollment Form*.

Summer Hogan [My Dashboard](#)

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Home Prescriber **Pharmacy** Patient Resources Support

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](#)

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Clozapine REMS Program_Website_Screen_Captures

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Reference ID: 4748731

6.14 Pharmacy Attestation – Outpatient Pharmacy

Note: This page includes only the attestation text for the Outpatient Pharmacy from the *Clozapine REMS Outpatient Pharmacy Enrollment Form*.

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Home Prescriber **Pharmacy** Patient Resources Support

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.

6.15 Pharmacy Confirmation

Note: This page will be available for:

1. Inpatient Pharmacies
2. Outpatient Pharmacies who cannot adjudicate claims online

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo 'CLOZAPINE REMS' with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' and a 'My Dashboard' button. Below the logo, a navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted in red), 'Patient', 'Resources', and 'Support'.

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.

6.16 Pharmacy Test Transactions

Note: This page will be available for Outpatient Pharmacies who can adjudicate claims online

The screenshot shows the Clozapine REMS website interface. At the top left is the logo and tagline. The top right shows the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation bar includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', and 'Support'. Below this is a secondary navigation bar with 'Intake', 'Attestation', and 'Confirmation' buttons. The main heading is 'Pharmacy Test Transactions'. A green-bordered box contains a success message: '✓ Thank you! Your enrollment form was successfully submitted.' Below this, text explains the next step: 'To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system.' It further states that the user will receive communication with instructions on how to submit test transactions. A 'Download Instructions' button with a document icon is provided. 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 | Contact Us'.

7. Chain Pharmacy Certification

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 Identifiers

Please provide at least one:

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

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7.2 Chain Pharmacy Store Confirmation

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

Chain Store Confirmation

✓ The chain pharmacy store has been successfully added.

To add another store, please use the **Add Store** button below.

[Add Store](#)

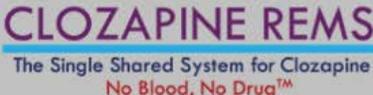
[My Dashboard](#)

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



The Single Shared System for Clozapine
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FAQs >>

Username: Password: [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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

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.

8.2 Pharmacy Search

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

[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):

<input type="text" value="Zip Code"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
---------------------------------------	-----	----------------------------------	----------------------------------	------------------------------------

[Search](#)

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

8.3 Pharmacy Search Results

Summer Hogan ▾ [My Dashboard](#)

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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):

<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

Summer Hogan ▾ [My Dashboard](#)

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

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

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](#)

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

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8.5 Pharmacy Staff Attestation

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Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

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

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

CLOZAPINE REMS

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8.6 Pharmacy Staff Confirmation

The screenshot shows the 'Enrollment Confirmation' page for a pharmacy staff member. At the top, the 'CLOZAPINE REMS' logo is on the left, and the user's name 'Summer Hogan' and a 'My Dashboard' button are on the right. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', and 'Support'. Below the navigation is a progress bar with four steps: 'Start', 'Intake', 'Attestation', and 'Finish'. The main heading is 'Enrollment Confirmation' with a decorative graphic of colored squares. A green checkmark icon is followed by the text 'You have now enrolled in the Clozapine REMS Program.' Below this, a message states: 'Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.' The 'Enrollment ID' is displayed as 'HCP123456789'. A final instruction reads: '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.' At the bottom, a call to action says: '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'.

CLOZAPINE REMS
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Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

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.

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

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9. Knowledge Assessment for Healthcare Providers

Note: The *Clozapine REMS Knowledge Assessment for Healthcare Providers* pages below are for prescribers, prescriber designees, and authorized representatives.

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 tagline, a user profile for Summer Hogan, and a navigation menu. A progress bar indicates the current step is 'Assessment'. The main content area includes a title, instructions, and a 'Start Assessment' button. A footer contains contact information and a call to action.

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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](#)

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

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CLOZAPINE REMS

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9.2 Knowledge Assessment Question 1

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left, the logo 'CLOZAPINE REMS' is displayed in purple, with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™' below it. On the right, the user name 'Summer Hogan' is shown next to a dropdown arrow, and a 'My Dashboard' button is visible. Below the logo, a navigation menu includes links for 'Home', 'Prescriber', 'Pharmacy' (highlighted in purple), 'Patient', 'Resources', and 'Support'.

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

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

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9.3 Knowledge Assessment Question 2

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Home Prescriber **Pharmacy** Patient Resources Support

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

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

9.4 Knowledge Assessment Question 3

Summer Hogan ▾ [My Dashboard](#)

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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](#)

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

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9.5 Knowledge Assessment Question 4

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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

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

9.6 Knowledge Assessment Question 5

Summer Hogan ▾ [My Dashboard](#)

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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

[Next](#)

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

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9.7 Knowledge Assessment Question 6

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are repeated. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A user profile for 'Summer Hogan' and a 'My Dashboard' link are visible. A progress bar shows the current step is 'Assessment', with other steps being 'Start', 'Intake', 'Education', 'Review', 'Attestation', and 'Finish'. The main content area is titled 'Knowledge Assessment' and features a 'QUESTION 6' header. The question text is: 'In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.' Below the question are two radio button options: 'A. True' and 'B. False'. A 'Next' button is positioned at the bottom of the question area. At the bottom of the page, a footer contains 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'.

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Home Prescriber Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation Finish

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

Next

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

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9.8 Knowledge Assessment Question 7

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Home **Prescriber** Pharmacy Patient Resources Support

Intake Education **Assessment** Confirmation

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

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

9.9 Knowledge Assessment Question 8

Summer Hogan ▾ [My Dashboard](#)

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[Start](#) [Intake](#) [Education](#) **[Assessment](#)** [Review](#) [Attestation](#) [Finish](#)

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

[Next](#)

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

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9.10 Knowledge Assessment Question 9

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Home **Prescriber** Pharmacy Patient Resources Support

Intake Education Assessment **Confirmation**

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

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

9.11 Knowledge Assessment Question 10

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

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

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

9.12 Knowledge Assessment Question 11

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

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](#)

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

9.13 Knowledge Assessment Question 12

CLOZAPINE REMS
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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

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

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

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9.14 Knowledge Assessment Question 13

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

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

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

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9.15 Knowledge Assessment Confirmation – Success

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Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment Results

✓ **Congratulations! You have now completed the assessment.**

You answered all the questions correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Code: [KA-1636-D098-1E12](#) 📄

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:

Next

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

9.16 Knowledge Assessment Confirmation – Not Successful

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are present. A navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. A secondary navigation bar shows 'Intake', 'Education', 'Assessment', and 'Confirmation', with 'Assessment' being the active tab. 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. A. True - correct), Question 2 (Clozapine is associated with severe neutropenia, which can lead to serious infection and death. B. False - incorrect), 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 contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us, along with the contact number 844-267-8678.

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Home Prescriber **Pharmacy** Patient Resources Support

Intake Education Assessment Confirmation

Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Below is a summary of your responses. We recommend you review the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* again before you attempt to retake the Knowledge Assessment. Once you feel your review is complete, please use the **Retake Assessment** button below to begin your assessment again.

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.
✗ B. False

QUESTION 3
Severe neutropenia is defined as:

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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10. Patient Enrollment

10.1 Patient Intake

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

[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

-- 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

Treatment Status
 1

Monitoring Frequency

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L) ?	None	None	None

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*



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.

600

Blood Draw Date
12/06/2017

Modify Lab

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L)	None	None	None

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

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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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11. Stakeholder Profiles

Note: Stakeholder profiles are accessed via the drop-down next to the signed-in user's name at the top of every page.

11.1 Prescriber Profile

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

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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Summer Hogan ▾ [My Dashboard](#)

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

My Profile

My Information Edit

First Name

Last Name

Phone / Ext

Fax

Contact Preference

My Certification

Certification ID: **HCP123456789**

Education Program

[Cancel](#) [Save](#)

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11.3 Authorized Representative Profile

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Summer Hogan ▾ [My Dashboard](#)

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

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 Representative Profile

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Summer Hogan ▾ [My Dashboard](#)

[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 representative will have two options via the drop-down next to the signed-in user's name at the top of every page; one for My Profile (authorized representative profile above) and Chain Headquarters Pharmacy Profile (below).

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

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

Summer Hogan ▾ [My Dashboard](#)

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

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

Note: My Account pages are accessed via the drop-down next to the signed-in user's name at the top of every page.

12.1 Forgot Username

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 blue "Sign in" button. Below the password field are links for "Forgot Username?", "Forgot Password?", and "Need an Account?". A horizontal menu contains links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "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.

The form is a light gray box containing three input fields: "First Name", "Last Name", and "Email Address". Below the fields is a green "Submit" button.

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

12.2 Change Username

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.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

12.3 Change Username Confirmation

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'. The main heading is 'Change Username'. A green-bordered box contains a confirmation message: '✓ Your username has been successfully saved.' Below this, a paragraph explains that the new username must be unique. A form area includes a 'Username' input field, a checkbox for 'Use Email Address as Username', and a 'Suggest Username' button. There are also links for 'Change Password' and 'Change Email Address'. At the bottom of the form are 'Cancel' and 'Save' buttons. A footer note provides a phone number for more information, and a bottom-most footer contains links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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Summer Hogan ▾ My Dashboard

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.

Username

Use Email Address as Username [Suggest Username](#)

[Change Password](#)
[Change Email Address](#)

Cancel Save

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

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12.4 Change Password

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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](#)

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

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12.5 Change Password Notification

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Summer Hogan ▾ [My Dashboard](#)

[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

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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

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

[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

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](#)

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

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13. Patient Groups

13.1 Manage Groups

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ⁶ 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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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

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

Summer Hogan ▾ [My Dashboard](#)

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

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

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Summer Hogan ▾ [My Dashboard](#)

[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](#)

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

13.5 Remove Group Warning

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 a red warning icon and the 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 bar with links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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13.6 Reassign Patients

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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 navigation, 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 entry:

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 common across all stakeholders.

The screenshot shows the Clozapine REMS dashboard interface. At the top, the logo and tagline are repeated. The user is identified as Summer Hogan, and there is a 'My Dashboard' button. A navigation menu includes Home, Prescriber, Pharmacy, Patient, Resources, and Support. Below this is a tabbed interface with 'Alerts' and 'Notifications' (both with a red notification badge), along with '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 present. A table lists the notification details:

<input type="checkbox"/>	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 a pagination control showing '1' of '10' items. 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](#).

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

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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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3 – Options available for *Dispense Rationale* status include:

- a. Active
- b. Expired
- c. Limit Reached
- d. Not on File

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

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14.2.3 Definitions of Terms Pop-up

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are visible. The navigation bar includes links for 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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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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 µL)
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

Treatment Status
 1

Monitoring Frequency

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per µL) ?	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**.

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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

14.2.5 View Patient History Lab History Tab

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Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Display WBC

Name: **Varsha Bhatia**

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

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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 ▲	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 View Patient History Monitoring Frequency Tab

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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	Monitoring Frequency
05/08/2017	Weekly

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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14.2.8 View Patient History *Dispense Rationale* Tab

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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
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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14.2.9 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 ⁸ 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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Alerts ¹ Notifications ¹⁰ 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 Results

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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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14.2.12 Remove Designee

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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 Designee

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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 screenshot displays the Clozapine REMS Prescriber Designee Dashboard. At the top, the logo and tagline 'The Single Shared System for Clozapine No Blood, No Drug™' are visible. The user is logged in as 'Summer Hogan' and is on the 'My Dashboard' page. The navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation, there are tabs for 'Alerts', 'Notifications', 'Patients', 'Prescribers', and 'Manage Groups'. The 'Patients' tab is selected. The main content area contains a search bar and a table of patients. The table has columns for 'First Name', 'Last Name', 'DOB', 'Enrollment', 'Group', 'Relationship', and 'Actions'. Two patients are listed: Mike Brown and John Smith, both enrolled and active. The 'Actions' column for each patient has a dropdown menu with '-- Please Select --' and a 'Go' button. Below the table, it says 'Showing 1 to 10 of 16 entries' and '1' of 10 items are displayed. A legend indicates that a red flag icon represents an NNRMF (National Non-Rechallenge Master File) patient. A link for definitions of terms is provided.

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 -- Go
John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- Go

Showing 1 to 10 of 16 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

The screenshot shows a web browser window with a 'Definition of Terms' pop-up. The background website header includes 'CLOZAPINE REMS', 'The Single Shared System for Clozapine', and 'No Blood, No Drug™'. The user is logged in as 'Summer Hogan' and is on the 'My Dashboard' page. The pop-up window has a purple header and lists the following definitions:

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 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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At the bottom of the pop-up, there are links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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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

Treatment Status
Active ▾ **1**

Monitoring Frequency
Weekly ▾

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.

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L) <input type="button" value="Calculator"/>	None	None	None

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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

14.3.5 View Patient History: Lab History Tab

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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

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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

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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

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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

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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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14.3.10 Prescriber Designee Dashboard Prescribers Tab

Don Herve ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Support

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

Go 10

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Home Prescriber Pharmacy Patient Resources Support

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

Go 10

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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

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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)"/>					
<input type="button" value="Search"/>					

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14.3.12 Remove Designee Relationship

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Home Prescriber Pharmacy Patient Resources Support

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 7 pharmacies, including 'aks shay ku', 'Test Pharma', 'Ilea 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', 'Eligibility Check', and 'Recertify Pharmacy'. A 'Go' button is next to each dropdown. A 'Showing 1 to 7 of 7 entries' message and a pagination control are at the bottom of the table. A footer contains contact information and a call to action: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.'

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
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 pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove 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
- 2 – *Eligibility Check* – will take the user to the *Eligibility Check* page.
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

14.4.2 Add Lab

Note: This Add Lab page is displayed for both Inpatient, Outpatient pharmacies on- and off-switch.

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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

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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

 [?](#)

Add Patient Lab

Dispensation Information (optional)

 [?](#)
 ▾
 ▾

At least one identifier is required

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

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14.4.4 Add Lab – Unsuccessful

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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

 [?](#)

Add Patient Lab

Dispensation Information (optional)

 [?](#)

At least one identifier is required

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

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14.4.5 Eligibility Check

Note: This *Eligibility Check* page displayed is for Inpatient Pharmacies.

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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 (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](#)

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

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](#)

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

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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](#)

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

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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](#)

2

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

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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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3

14.5 Pharmacy Dashboard – Outpatient Pharmacies

The screenshot shows the 'Pharmacies' tab in the Clozapine REMS system. 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 'Ikea Inc' row has a dropdown menu open, showing options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Dispense Rationale', and 'Recertify Pharmacy'. A 'Go' button is next to each dropdown. 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 -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	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	FAC5414119640	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	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 pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove 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
- 2 – *Dispense Rationale* – will take the user to *Dispense Rationale* page
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

14.5.1 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.

Note: This *Dispense Rationale* page is displayed for outpatient pharmacies on- & off-switch.

14.5.2 Dispense 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 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](#)

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

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14.5.3 Dispense Rationale Result Screen – Success (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 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](#)

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

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14.5.4 Dispense 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**

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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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 contains 7 entries. The 'Actions' column for the 'JC Penny' entry is expanded, showing options: Remove Pharmacy, View/Update Pharmacy Profile, Add Lab, Predispose Authorization, Dispense Rationale, and Recertify Pharmacy. Three callout boxes are present: '1' points to the 'Add Pharmacy' button, '2' points to the expanded actions menu, and '3' points to the 'Go' button in the actions column.

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 Remove Pharmacy View/Update Pharmacy Profile Add Lab Predispose Authorization Dispense Rationale Recertify Pharmacy
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

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

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 an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove 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
- 2 – *Predispense Authorization* – will take the user to the *Predispense Authorization* page
- 2 – *Dispense Rationale* – will take the user to *Dispense Rationale* page
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

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14.6.1 Predispose Authorization

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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 Predispose Authorization Result – Successful

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Predispose 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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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.

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](#)

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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.

14.6.4 *Predispense Authorization* Result – Success (After DR 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	<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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View Pharmacy Profile

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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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14.6.5 Remove Pharmacy

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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 on- and off-switch Pharmacies.

14.6.6.1 Pharmacy Recertification Wizard

Note: Users will be presented with a set of questions to recertify a pharmacy

The screenshot shows the top portion of the Clozapine REMS website. On the left, the logo 'CLOZAPINE REMS' is displayed in purple, with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™' below it. To the right of the logo is a login section with two input fields labeled 'Username' and 'Password', and a blue 'Sign in' button. Below the password field are links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. At the bottom of the header is a navigation menu with links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'.

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

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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.

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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 --

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

Note: 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 presented 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 is the logo 'CLOZAPINE REMS' with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' with a dropdown arrow and a 'My Dashboard' button. Below the navigation bar is a horizontal menu with links: Home, Prescriber, Pharmacy, Patient, Resources, and Support. The main content area contains a message: 'Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.' Below this message is a blue button labeled 'Reactivate'.

Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.

[Reactivate](#)

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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 presented 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 links for "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">-- Please Select --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 Remove Pharmacy Staff

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: [Salty 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

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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
	Hogan RX	2 Park Avenue, New York NY 10201	FAC2234583304	Certified	
<input checked="" type="checkbox"/>	Apollo Pharmacy	311 Bell Road, Anaheim CA 92805	FAC0057124807	Incomplete	-- Please Select -- Go
	Life Pharmacy	423 Main Street, Tampa FL 33614	FAC0057124807	Certified	-- Please Select -- Go
	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.

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

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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.

14.7.3 Remove Pharmacy

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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 Remove Pharmacy Staff

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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 the 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

Showing 1 to 5 of 5 entries

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

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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

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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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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

?

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

Add Patient Lab (optional)

Dispensation Information

?

At least one identifier is required

[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 for the *Eligibility Check* when the result is unsuccessful.

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

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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 *Predispense Authorization* Result – Unsuccessful

Note: This result is displayed for the *Predispense Authorization* when the result is 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**

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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15. Dispense Rationale – Static Pages

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.

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16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)

16.1 Pharmacy – Authorized Representative Dashboard

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.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
Hogan Rx	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- <input type="button" value="Go"/>
Test Pharma	2101 E. Dunlap Selma, Alabama 35848 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- <input type="button" value="Go"/>
Mercury Drug Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- <input type="button" value="Go"/>
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 7 of 7 entries

Navigation: < 1 > 10

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16.2 Pharmacy – Authorized Representative *Predispense Authorization*

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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.

16.3 Pharmacy – Authorized Representative *Predispose Authorization Result- Successful*

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Predispose 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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16.4 Pharmacy – Authorized Representative *Predispose Authorization Result- Unsuccessful*

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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**

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.

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 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 Authorization* Result – Unsuccessful

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo 'CLOZAPINE REMS' with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right is a user profile 'test testat' and a 'My Dashboard' button. Below the logo is a horizontal menu with links: Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support.

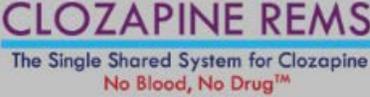
Predispense Authorization Result

 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.

17. Dispense Rationale – Pharmacy Staff (Non-Switch)

Pharmacy Staff Dashboard



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

Trish Kay ▾
My Dashboard

Home
Prescriber
Pharmacy
Patient
Resources
Support

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

Q

⚠ 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	<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;">Go</div> </div>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	<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;">Go</div> </div> <ul style="list-style-type: none"> Add Lab Predispense Authorization Dispense Rationale Remove Pharmacy Relationship
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	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;">Go</div> </div>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	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;">Go</div> </div>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	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;">Go</div> </div>

Showing 1 to 5 of 5 entries 10 ▾

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

17.1 Pharmacy Staff *Predispense Authorization*

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

Summer Hogan ▾ My Dashboard

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.

17.2 Pharmacy Staff *Predispense Authorization Result*- Successful

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

Summer Hogan ▾ [My Dashboard](#)

[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 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*- Unsuccessful

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

[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**

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.

17.4 Pharmacy Staff *Predispense Authorization* Result – Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
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Summer Hogan ▾ [My Dashboard](#)

[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.

17.5 Pharmacy Staff *Predispense Authorization Result-Successful* (After the *Dispense Rationale* is issued)

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

Summer Hogan ▾ My Dashboard

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 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.

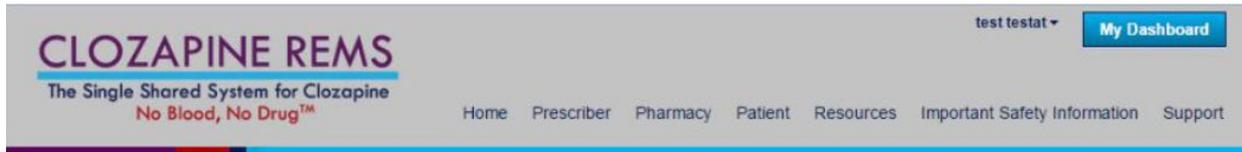
A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

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 – Unsuccessful



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 is a user profile dropdown labeled 'test testat' and a 'My Dashboard' button. Below the logo is a horizontal navigation menu with links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support.

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.

18. Dispense Rationale – Pharmacy Authorized Representative (Switch)

18.1 Pharmacy – Authorized Representative Dashboard



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

Summer Hogan ▾
My Dashboard

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

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 -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy </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	FAC5414118715	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

⏪
1
⏩
10 ▾

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

18.2 Pharmacy – Authorized Representative *Dispense Rationale*

CLOZAPINE REMS
The Single Shared System for Clozapine
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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

 ?

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

Add Patient Lab (optional)

Dispensation Information

 ?

At least one identifier is required

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

Note: This *Dispense Rationale* page is displayed for outpatient pharmacies on- & off-switch.

18.3 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success

CLOZAPINE REMS
The Single Shared System for Clozapine
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Summer Hogan ▾ [My Dashboard](#)

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

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.

18.4 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success (After DR is issued)

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

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 Rationale* Result Screen- Unsuccessful

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

[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	<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 Check Result- Successful*

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

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

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 Check Result- Unsuccessful*

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

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

19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy) 19.1 Pharmacy Staff Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
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Trish Kay ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

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.

CLOZAPINE REMS

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

19.2 Pharmacy Staff *Eligibility Check*

Summer Hogan ▾ [My Dashboard](#)

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

[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

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

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Summer Hogan ▾ [My Dashboard](#)

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

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](#)

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

19.4 Pharmacy Staff *Eligibility Check Result*

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

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources 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.

Note: If an authorized representative or pharmacy staff using the pharmacy network (switch) receives a rejection message due to "prescriber not certified", the following message will appear on their screen:

REMS Clozapine REMS – Prescriber must be certified or you can request a *Dispense Rationale* through www.clozapinerems.com or by calling 844-267-8678.

Once this message is received, the authorized representative or Pharmacy Staff can either call the Clozapine REMS Program contact center to obtain a *Dispense Rationale* or they can access the website and follow the above screens to obtain the *Dispense Rationale*. Once they receive confirmation of the *Dispense Rationale*, the authorized representative or Pharmacy Staff will need to re-run the claim to allow the authorization of the dispense.

CLOZAPINE REMS

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20. Dispense Rationale – Pharmacy Staff (Switch) 20.1 Pharmacy Staff Dashboard

Trish Kay ▾ [My Dashboard](#)

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

[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"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

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

20.2 Pharmacy Staff *Dispense Rationale*

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

Summer Hogan ▾ My Dashboard

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

Cancel

Submit

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

20.3 Pharmacy Staff *Dispense Rationale* Result- Success

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

Summer Hogan ▾ [My Dashboard](#)

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

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.

20.4 Pharmacy Staff *Dispense Rationale* Result- Success (After DR is issued)

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

Summer Hogan ▾ [My Dashboard](#)

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

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.

20.5 Pharmacy Staff *Dispense Rationale* Result- 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 - 1 Go
tammy	baker	10/18/2000	Incomplete		Active	- Please Select - Go
Jeff	Bradley	02/16/1910	Enrolled		Active	- Please Select - Go

2 Gender: Male
NNRMF: No
BEN: Yes

View ANC Monitoring Table	Current	Highest	Lowest
Blood Draw date	05/24/2016	03/14/2016	05/15/2016
ANC Level (per µL)	340	9000	200

Enrollment Id: PAT71
Dispense Rationale: Active

chola	chelan	10/10/1965	Enrolled		Active	- Please Select - Go
chola	chelan	04/10/2016	Enrolled		Active	- Please Select - Go
Patient	contactsingh	01/01/1934	Enrolled		Active	- Please Select - Go
Patient	Contactsingh	07/21/2016	Enrolled		Active	- Please Select - Go
Chris	Cruise	02/16/1990	Enrolled		Active	- Please Select - Go
John	Davidson	02/25/2016	Enrolled		Active	- Please Select - Go
John	Davidson	02/25/2016	Enrolled		Active	- Please Select - Go

Showing 1 to 10 of 49 entries < 1 2 3 4 5 > 10 ▾

■ = 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.

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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 Designee dashboard. This section provides information about the status of the *Dispense Rationale*.
3. Options available for *Dispense Rationale* status include:
 - a. Active
 - b. Expired
 - c. Limit Reached
 - d. Not on File

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21.2 Prescriber and Prescriber Designee *Dispense 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 ▾

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