

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.

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 *Knowledge Assessment for Healthcare Providers*
3. Complete and submit this one-time *Clozapine REMS Pharmacy Enrollment Form* along with the completed *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 further copies of Clozapine REMS Program documents, please visit the program website at www.clozapinerems.com, or call the Clozapine REMS Program 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* 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 ANC monitoring
3. There is a different ANC monitoring algorithm for patients with 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:

5. 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:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
 - 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
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

FOR INPATIENT PHARMACIES ONLY

12. Inpatient pharmacies are not required to obtain a Predispose Authorization (PDA) prior to dispensing clozapine.

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

- Verify the prescriber is certified in the Clozapine REMS Program
- Verify the patient is enrolled in the Clozapine REMS Program

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

1. Sign in into the Clozapine REMS Program website at www.clozapinerems.com, or
2. Call the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies must verify the ANC or prescriber's authorization for a patient to continue clozapine treatment in one of three ways:

1. By signing into the Clozapine REMS Program website at www.clozapinerems.com
2. By calling the Clozapine REMS Program contact center at 844-267-8678
3. By reviewing the patient's medical record in their hospital's medical record system

Prescribers or their designee(s) must submit ANC to the Clozapine REMS Program within 7 days of blood draw.

FOR OUTPATIENT PHARMACIES ONLY

12. Outpatient pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions.

Can your outpatient pharmacy management system adjudicate claims online?

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 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.

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 #5) before dispensing each clozapine prescription. A complete Predispose Authorization request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

Pharmacy Information (All Fields Required)

Pharmacy Name:

Pharmacy Type (select one): Inpatient Pharmacy Outpatient Pharmacy

Address:

City: _____ State: _____ Zip Code: _____

Inpatient Identifiers (At least one required)

NCPDP: _____ NPI: _____ DEA: _____

Outpatient Identifiers (NCPDP and NPI Required)

NCPDP: _____ NPI: _____ DEA: _____

Authorized Representative Information (All Fields Required)

First Name: _____ Last Name: _____

Credentials: R.Ph PharmD BCPS Other

Phone: _____ Fax: _____ Email: _____

Contact Preference (please select one): Email Fax

Authorized Representative Signature:

Date (MM/DD/YYYY):