

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 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 *Knowledge Assessment for Healthcare Providers*
4. Complete and submit this one-time Clozapine REMS Chain Headquarters Pharmacy Enrollment Form along with the completed *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 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*, 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 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 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
 - 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 and acceptable or the prescriber has authorized continuing treatment if the ANC is abnormal
 - This information will be verified 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
6. 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
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 documentation available to the clozapine manufacturers and/or a designated third party or the FDA to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. 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
10. 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)
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into 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: R.Ph PharmD BCPS Other

Phone:

Fax:

Email:

Contact Preference (please select one): Email Fax

Authorized Representative Signature:

Date (MM/DD/YYYY):

Next Steps

1. Once this form is processed, you will receive instructions on submitting test transaction(s) to the Clozapine REMS Program to ensure that your pharmacy management system has been 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 their training
3. Once each dispensing location is trained, it is your responsibility to report documentation of training to the Clozapine REMS Program online through www.clozapinerems.com, or by contacting 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, this dispensing location will be certified and permitted to purchase, receive, and dispense clozapine