

*****Important Program Update (as of 07/28/2021)*****

Update: New Clozapine REMS Coming November 15, 2021

Re-Certification and Re-Enrollment Required at www.newclozapinerems.com

- ALL Prescribers and Pharmacies **must re-certify** to continue to prescribe or dispense clozapine.
- ALL Patients continuing on clozapine **must be re-enrolled** by a certified prescriber or prescriber designee.
- **Start re-certification and re-enrollment on August 16, 2021 to avoid interruption in patient treatment**

Go to www.newclozapinerems.com

- Click on Log-in | Register tab. You need to create new login credentials before re-certifying by clicking on Register.

For more information, see [FDA Alert on 7/29/21](#) (summarized below)

On July 29, 2021, FDA approved a modification to the Clozapine REMS. The modification to Clozapine REMS will go into effect on November 15, 2021. Important changes include:

- **All prescribers and pharmacies must be re-certified** by November 15, 2021, **or they will no longer be able to prescribe/dispense clozapine.**
- **Prescribers must re-enroll their patients** who will continue clozapine by November 15, 2021. **Patients who are not re-enrolled by that day will no longer be able to receive clozapine.**
- Re-certification and re-enrollment can begin on **August 16, 2021.**
- Pharmacies will no longer be able to use the telecommunication verification (also known as the switch system) to verify safe use conditions. The authorization to dispense will be obtained either through the contact center or online via the REMS website.
- A new **Patient Status Form** will document absolute neutrophil count (ANC) monitoring for all outpatients. This form must be submitted monthly. Patient monitoring must continue per the Prescribing Information.

To re-certify and re-enroll in the Clozapine REMS please see the [Important Program Update](#)[External Link Disclaimer](#) at www.clozapinerems.com[External Link Disclaimer](#) More information on these changes and other Clozapine REMS requirements are included below.

Effective November 15, 2021, the Clozapine REMS requires:

For prescribers who prescribe for outpatient use or prescribers who are initiating treatment inpatient:

- Certify in the Clozapine REMS program
- Counsel the patient on the risk of severe neutropenia and enroll patients in the Clozapine REMS program
- Obtain and assess the patient's ANC in accordance to the patient's monitoring frequency in the clozapine Prescribing Information
- Document the ANC on the **Patient Status Form** and submit this form **monthly**.
 - Patient monitoring must still continue per the Prescribing Information.
 - If an ANC is missing, the prescriber is required to provide authorization to continue therapy.
 - A Patient Status Form must be received within 37 calendar days after the date of the first dispensing or the last Patient Status Form.
 - A Patient Status Form will be used to
 - Interrupt, Discontinue, or Resume Treatment
 - Designate the patient as a Benign Ethnic Neutropenia (BEN) patient
 - Create a Treatment Rationale when the patient's ANC level is < 1000/ μ L for a general population patient or < 500/ μ L for a BEN patient
 - Designate the patient as a hospice patient

For pharmacies that dispense clozapine for outpatient use:

- Certify in the Clozapine REMS
- Obtain a REMS Dispense Authorization (RDA) prior to each dispense utilizing either the REMS website or calling the REMS Contact Center.
 - For the first dispensing, the RDA will verify that the pharmacy is certified, patient is enrolled, and patient's treatment is not interrupted or discontinued
 - For subsequent dispensing, the RDA will verify that the pharmacy is certified, patient is enrolled, a Patient Status Form has been completed in the last 37 days, and patient's treatment is not interrupted or discontinued

For pharmacies that dispense clozapine for inpatient use:

- Certify in the Clozapine REMS
- Obtain a REMS Dispense Authorization (RDA) prior to the initial dispense utilizing either the REMS website or calling the REMS Contact Center. The RDA will verify that the pharmacy is certified, patient is enrolled, and patient's treatment is not interrupted or discontinued

For additional information about the Clozapine REMS, please call the Clozapine REMS Contact Center at 844-267-8678 or visit www.clozapinerems.com[External Link Disclaimer](#).

Beginning August 16, 2021, a Transition Contact Center will be available to support re-certification, re-enrollment activities and to answer questions at 888-586-0758.

