New York State Psychiatric Association

THE E-BULLETIN
NEW YORK STATE PSYCHIATRIC ASSOCIATION
Bringing New York State Psychiatrists Together

August 30, 2021

Clozapine Risk Evaluation and Mitigation Strategy (REMS) requirements will change on November 15, 2021

The following information regarding changes to the Clozapine Risk Evaluation and Mitigation Strategy requirements has been posted on the FDA website. To access this information directly from the FDA site, click https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021.

[Updated 7/29/21] CPMG and FDA continue to work to ensure that patients relying on clozapine have continued access to this medication and appropriate management of associated risks.

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** at www.clozapinerems.com 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 recevied within 37 calendar days after the date of the first dispensing or the last Patient Status Form.
    - A Patient Staus 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/μL for a general population patient or < 500/μL for a BEN patient
        - Designate the patient as a hospice patient

New York State Psychiatric Association Veterans Mental Health - Primary Care Training Initiative

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CLASSIFIEDS

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To learn more about this important program, please click here.

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VMH-PCTI: The Clinical Importance of Understanding Military Culture
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VMH-PCTI: Recognition, Management and Prevention of Veteran Suicide
To register, please click here

December 7, 2021
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