

State of Vermont

Department of Vermont Health Access (DVHA)

NOB 1 South, 280 State Drive

Waterbury, VT 05671-1010

November 10, 2021

****Attention Providers ****
Clozapine REMS Requirements Change

The Drug Utilization Review (DUR) Board is composed of practicing Vermont pharmacists and physicians who are responsible for reviewing and advising the Department of Vermont Health Access (DVHA) about drug utilization for Vermont Medicaid enrollees. During a recent meeting, the DUR Board discussed upcoming changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) requirements and recommended that providers be notified by DVHA about this important change to avoid potential access issues. The 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.**
- 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.

A review of pharmacy dispensing data from 2021 identified the following patient(s) who may be impacted by these upcoming changes:

Patient ID/Name/DOB

Please ensure the above steps have been completed to prevent delays in prescription access. More information can be found on the following sites. Thank you for your continued support of Vermont's pharmacy benefits programs.

https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021?utm_medium=email&utm_source=govdelivery

<https://www.clozapinerems.com/CpmgClozapineUI/home.u>