

Clozapine REMS Program Updates

NAMI would like to share important updates with our members, their families, and others who take clozapine (Clozaril, FazaClo, or Versacloz) to manage a mental health condition. There have been updates to the Clozapine Risk Evaluation and Mitigation Strategies (REMS) Program, a system used by prescribers and pharmacies to ensure the safe, effective use of this medication.

Any changes to how clozapine is prescribed, what blood work is required, or how it's dispensed from pharmacies, could affect anyone who is taking clozapine as a part of their treatment plan. This information is being shared to prevent potential interruptions in treatment, and help you communicate with clinicians and pharmacists as they transition to this new system.

Background Information

The [Clozapine REMS Program](#) is a shared system developed to manage the rare risk of health complications that have been associated with using this medication. This system has successfully helped ensure that the benefits of clozapine outweigh any risk for each person that it's prescribed to.

On July 29, 2021, the Food and Drug Administration (FDA) [approved changes](#) to the Clozapine REMS Program. These changes went into effect on November 15, 2021.

The program has been updated for easier access and reporting by prescribers, pharmacies, and drug manufacturers who are required to use it. Because it's a new system, they will need to reenroll and ensure that their patients are reenrolled as well.

- All prescribers must recertify and reenroll in the new system.
- All patients must be reenrolled by their prescribers.
- All pharmacies must recertify and reenroll.

Updates also include a few changes to treatment recommendations. You are the team leader in your own care, so it's important to understand what these changes are and how they might affect your treatment plan. These changes are summarized below, including tips for your medical self-advocacy, as well as additional information and resources. First, let's briefly review the medication itself.

The Benefits of Clozapine

Clozapine is a medication approved by the FDA for schizophrenia that hasn't responded well to other treatment approaches. Tremendous positive outcomes are regularly experienced by people who use clozapine, including:¹⁻³

- Fewer symptoms of anxiety, delusions, and hallucinations
- Improved sleep

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- Lower rates of hospitalization, and shorter hospital stays
- Reduced side effects, such as tremors or shaking
- Lower incidence of suicide and suicidal feelings
- Improvement in quality of life and social functioning
- Reduced caregiver stress and worry

These are significant, and you've probably also noticed a remarkable difference in your day-to-day life while taking clozapine. This success in improving symptoms and better quality of life is an important reason to continue including it in your treatment plan.

Potential Risks

When clozapine was first suggested as a treatment for you, your prescriber discussed the possibility of a rare, but serious side effect known as neutropenia. Neutropenia happens when there is an unusually low amount of white blood cells in the body, and it can range from mild to severe. White blood cells help fight off infection, so when these levels in the bloodstream are too low, the risk of infection becomes much higher.

This happens very rarely. In fact, one research study found the rate of severe neutropenia to be less than 1% — and the longer someone is on clozapine, the less risk there is of developing this condition.⁴ The FDA has made it mandatory that clozapine drug manufacturers monitor its safe use. The Clozapine REMS Program was established to help manage the risk.

Changes to the Clozapine REMS Program That May Affect My Treatment

- The new Clozapine REMS system will require all prescribers and pharmacists to reenroll and also recertify that they understand how to manage the medication, blood test results, and any potential risks.
- Prescribers must complete this process, or they won't be able to continue prescribing clozapine. Pharmacists must also complete it, or they won't be able to continue dispensing clozapine.
- Additionally, all of their patients must be reenrolled with up-to-date lab results that have been completed within the past 30 days. This means that the provider who prescribes clozapine for you is responsible for putting information in the new system on your behalf. You aren't required to do anything, other than having your usual scheduled blood work done.
- Your blood work will continue to be tested to check levels of ANC (advanced neutrophil count, or components of white blood cells). If you have a lower ANC level than is recommended, you and your prescriber have the option to continue treatment with clozapine: as long as you're not having any symptoms that are concerning, and you're doing well in treatment.
- The program continues to allow people with benign ethnic neutropenia, or BEN, to use clozapine as a treatment option. People with BEN and their prescribers may also choose to continue treatment if they have ANC levels that are below recommendations: as long as there are no concerning symptoms and treatment is working well.

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Benign Ethnic Neutropenia (BEN) is a condition found in people of African, Middle Eastern, and non-Caucasian descent. People with BEN have lower white blood cell levels, possibly due to genetics. In the past, these lower levels prevented them from having clozapine as a medication option. Since 2015, people with BEN have been able to safely include clozapine in their treatment plan.

Medical Self-Advocacy for Those Taking Clozapine

Although you don't need to do anything to enroll yourself into the new Clozapine REMS Program, there are some things that you can do to help prevent any potential interruption in your treatment.

- **Talk with Your Clozapine Prescriber:**
 - Ask if they have enrolled in the new program yet, and if they have enrolled you also. Share with them that the new system started on November 15, 2021, and they have 37 days to complete everyone's enrollment.
 - Share with them the website link for the [SMI Adviser & NAMI Clozapine REMS Program Update Guide for Prescribers and Pharmacists](#).
- **Talk with Your Pharmacist:**
 - Ask if the pharmacy and its staff are enrolled in the new program. Share with them the same information you gave your prescriber:
 - ❖ The new system started on November 15, 2021, and they must complete enrollment within 37 days.
 - ❖ The link for [SMI Adviser & NAMI Clozapine REMS Program Update Guide for Prescribers and Pharmacists](#).
 - If they are unable to fill your prescription after the deadline, you may still be able to find a pharmacy in your area that is [certified to dispense clozapine](#).
- **Ask Questions:**
 - Will I have enough medication in the coming months?
 - Are there potential delays in treatment or medication access that I should be prepared for? If so, how should I prepare?
- **Talk with Your Family and Peers:**
 - Share information about these changes and create a plan to manage any unexpected delays in treatment or medication access.
 - Create a plan for everyone to follow in the event of an emergency.
- **Continue Monitoring Your Health:**
 - Make sure you continue having blood work done on the schedule required for your treatment plan.
 - Tell your doctor right away if you experience any unusual symptoms, infection, or pain.
 - Take care of your health with physical activity, good nutrition, and social support.

You can find additional information on the [Patient Information](#) page of the Clozapine REMS website.

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Frequently Asked Questions

How can I be sure my medication prescription is not interrupted?

Make sure your lab work is up to date and ask if your prescriber and pharmacy are enrolled in the new system. This a first step to ensure your prescription is not interrupted.

What happens if I must go into the hospital?

If the pharmacy in the hospital is enrolled in the new system, there will be no interruption in your clozapine prescription. Your prescriber will need to ensure that an outpatient pharmacy can fill any order after discharge.

Is there an easier way to have blood tests done, instead of going to an office or a lab?

There are remote blood monitoring devices that you can use at home. Talk to your treatment providers about a specific device for ANC monitoring and if it's eligible to be covered through insurance or Medicare.

Your local NAMI is here to support you — You Are Not Alone.

Additional Resources

- [A Guide for Patients and Caregivers: What you Need to Know about Clozapine and Neutropenia.](#)
- NAMI provides [information on clozapine for patients and families](#), as well as [support groups](#) for individuals with mental health conditions, and their families.
- The [Clozapine Center of Excellence](#) from [SMI Adviser](#) offers education and resources for clinicians, patients and families.

References

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