What is Clozapine?

Clozapine is the only FDA-approved medication for treatment-resistant schizophrenia. People are determined to have treatment-resistant schizophrenia when the first two antipsychotic medications they take fail to reduce their psychotic symptoms. Like other anti-psychotics, clozapine works by rebalancing dopamine, a neurotransmitter, and other chemicals in a person's blood. Clozapine was FDA-approved in 1989 in the class atypical, antipsychotic.

Clozapine is limited by strict usage protocols and providers reluctant to jump through all the hoops required to prescribe it. Several advocacy organizations are asking the U.S. Food and Drug Administration (FDA) to loosen restrictions and spread awareness about the benefits of this medication.

What is REMS?

Early trials of clozapine showed a potential for a severe side effect called neutropenia; a blood condition that can make someone vulnerable to infections. Because of that, the FDA created a strict protocol for administering the medication through their Risk Evaluation and Mitigation Strategy (REMS) program. REMS requires:
• Weekly blood tests for the first six months of treatment
• Blood tests every two weeks for the second six months
• Monthly blood tests for the rest of a person’s life while they are taking clozapine

Is clozapine more dangerous than other anti-psychotic medications?

The risk of developing neutropenia because of exposure to clozapine is not any higher than the risk posed by other medications for which the FDA does not require a lifetime of blood tests, according to research.

Surveys of health care providers show a general discomfort with clozapine. The term clozaphobia is sometimes used to describe provider reticence, which is made worse by complex administrative barriers that clinicians must navigate in order to prescribe clozapine under the REMS. TAC’s Research Weekly includes further information: The Clozapine REMS - Treatment Advocacy Center.

Who is advocating to lessen restrictions related to clozapine use?

Advocates who want to see an expansion of clozapine usage argue that the REMS are harmful for patients whose lives could be saved if the FDA made the REMS requirements less demanding and more similar to the evidence-based clozapine monitoring policies of countries like the United Kingdom, the Netherlands, Denmark, New Zealand, and Romania. One of those groups is the Angry Moms, which is lobbying to FDA to loosen the REMS.

The National Shattering Silence Coalition is another organization lobbying for change in how clozapine is regulated. NSSC published an article by Robert S. Laitman, M.D., a psychiatrist who specializes in clozapine usage: Why Choose Clozapine First for Schizophrenia - National Shattering Silence Coalition.

Laitman’s website includes information about his lived experience as father to a son with paranoid schizophrenia: teamdanielrunningforrecovery.org. He promotes clozapine to decrease mortality from suicide and other complications of schizophrenia. His book is Meaningful Recovery from Schizophrenia and Serious Mental Illness with Clozapine: Hope & Help.

How can I find a provider willing to prescribe clozapine?

Another organization spreading awareness about clozapine is the Comprehensive Understanding via Research and Education into Schizophrenia (CureSZ) Foundation. CureSZ provides an interactive map to help people find a provider in their area who will prescribe clozapine, which is also referred to by its brand name, Clozaril.
Disclaimer: The information in this article is not intended to taken as medical advice. A medication management provider should be consulted if this medication is being considered as a treatment option.