

Updates on the Clozapine REMS Program: An Important Relic or Fool's Gold of Safety?

Session Date: 03/21/2023

Session Time: 11:00 – 11:45 AM (CST)

Target Audience

This continuing education (CE) session was planned to meet the needs of professional staff who deal with the selection and monitoring of medication(s) as part of their patient care duties, including pharmacists, RNs, APRNs, PAs, MDs.

Activity Overview

Clozapine was FDA approved over 30 years ago. It is the only medication with proven benefit in treatment resistant schizophrenia with additional FDA approval for the reduction of suicidality in patients with schizophrenia or schizoaffective disorder. It has many off-label benefits such as use in bipolar disorder, treatment-emergent tardive dyskinesia, and Parkinson's related psychosis. However, major barriers in the United States continue to prevent the more widespread use of clozapine. One of the most notable barriers is the clozapine REMS program. Evidence suggests that the FDA REMS requirements for hematologic monitoring are too robust and there may be ability to safely loosen requirements. Also, the past motto of the REMS program, "No Blood, No Drug" has undoubtedly cast a shadow over more important monitoring parameters of clozapine management. There is an urgent need to remove barriers created by REMS and establish consistent practices throughout the US in order to expand use of this life saving medication.

Learning Objectives

At the conclusion of this knowledge-based CE session, participants should be able to:

1. List the therapeutic benefits of clozapine
2. Describe the risk of clozapine-induced neutropenia throughout treatment
3. Describe critical non-neutropenia related adverse event associated with clozapine

Faculty Information

Jonathan G. Leung, PharmD, BCPS, BCPP
Pharmacist
Mayo Clinic Hospital - Rochester, MN

Dr. Leung is a board-certified psychiatric pharmacist with a clinical practice in various outpatient psychiatric areas at Mayo Clinic - Rochester, including the Clozapine Clinic and Long-Acting Injectable Clinic. He has published numerous papers that focus on improving the safety of clozapine and promoting clozapine use in appropriate populations.



Approved Provider Statement



JOINT ACCREDITATION™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity is planned and implemented by Mayo Clinic College of Medicine and Science. Mayo Clinic College of Medicine and Science is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

Credit Statements

AMA

Mayo Clinic College of Medicine and Science designates this live activity for a maximum of 0.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ACPE



ACPE Universal Activity Number (UAN): JA0000238-0000-23-007-L01-P

Mayo Clinic College of Medicine and Science designates this educational activity for a maximum of 0.75 ACPE Knowledge-based contact hours. Participants should claim only the credit commensurate with the extent of their participation in the activity

ANCC

Mayo Clinic College of Medicine and Science designates this activity for a maximum of 0.75 ANCC contact hours. Nurses should claim only the credit commensurate with the extent of their participation in the activity.

AAPA



Mayo Clinic College of Medicine and Science has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. This activity is designated for 0.75 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation.

Educational Format and CE Requirements

This CE session is available as a live presentation, including live webcast.

Participants must complete the following to record attendance and obtain CE credit:

1. Attend the entire session.
2. Text the session code to 507-200-3010 within 48 hours of the live presentation to record attendance.
 - a. This number is only used for receiving text messages related to tracking attendance
 - b. Employees are encouraged to create a contact in their mobile phone, as the same number is used to record attendance for every session
3. Complete the online evaluation for the respective session within 2 weeks of live presentation.

Pharmacist CE credit is electronically transferred to the National Association of Boards of Pharmacy CPE Monitor. To track CE, please go to [NABP CPE Monitor](#).

Non-pharmacist attendees can print out a record of attendance at ce.mayo.edu after completing the evaluation and claiming credit.

Live attendance: Rochester, Saint Mary's Campus, ALF_MN_459

Live virtual attendance via [Zoom link](#)

Disclosure Summary

As a provider accredited by Joint Accreditation for Interprofessional Continuing Education, Mayo Clinic College of Medicine and Science must ensure balance, independence, objectivity and scientific rigor in its educational activities. All who are in a position to control the content are required to disclose all financial relationships with any ineligible company. Faculty will also identify any off-label and/or investigational use of pharmaceuticals or instruments discussed in their content for FDA compliance.

Listed below are individuals with control of the content of this program:

The faculty report the following relationships:

- Jonathan G. Leung, PharmD, BCPS, BCPP
 - Declares no financial relationship(s) pertinent to this session
 - Declares off-label use of medications will be discussed during this presentation: clozapine

Course Director and Planning Committee Members declare no relevant financial relationship(s) pertinent to this session. Members include:

- Jennifer Elmer, DNP, APRN, CCNS
- Andrew Herber, PA-C
- Sarah Jane Kotval, BSW
- Scott Nei, PharmD, BCPS, BCCCP, FCCM, FMSHP
- Wayne Nicholson, MD, PharmD, BCPS
- Garrett Schramm, PharmD, FASHP, FCCP

All relevant financial relationships have been mitigated.

For additional disclosure information regarding Mayo Clinic School of Continuous Professional Development accreditation review committee members visit ce.mayo.edu, About Us, Disclosures - or -

<https://ce.mayo.edu/content/disclosures>

System and Technical Requirements

For participants viewing the webcast, sessions are delivered via Mayo Clinic intranet web browser and Adobe® PDF. For participants viewing outside the Mayo Clinic firewall, a VPN connection is required for remote access. Recommended web browser includes Google Chrome. This session is planned and coordinated by **the Department of Pharmacy, Mayo Clinic.**