



Pharmacy Grand Rounds

200 First Street SW
Rochester, Minnesota 55905
<https://ce.mayo.edu/pharmacy-grandrounds2021>

Life in the Fast Lane: Aducanumab and the Accelerated FDA Approval Process

Session Date: 01/18/2022

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

The recent FDA approval of aducanumab was met with a high degree of controversy from the medical community. The monoclonal antibody offers the first novel pharmacological mechanism targeting Alzheimer's disease since 2003, yet, in the setting of dubious results from the ENGAGE and EMERGE trials, aducanumab was found to have unsatisfactory evidence to warrant approval per a 2020 FDA advisory committee vote. Despite this, the FDA approved the medication in June 2021 with the consequent impact: advisory committee resignation by several members, a federal investigation of the interactions between Biogen and FDA staff, and healthcare professional uncertainty regarding formulation and treatment appropriateness.

This activity will focus on reviewing the pharmacology of aducanumab, assessment of the literature pertaining to aducanumab's approval, examining the FDA accelerated approval process, and finally evaluating the ethical and financial considerations that contributed to the complexity of aducanumab's approval.

Learning Objectives

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

1. Describe the pharmacology of aducanumab
2. Summarize the clinical literature and approval process for aducanumab
3. Discuss stewardship considerations of aducanumab

Faculty Information

Joseph C. Osborne II, PharmD
PGY-2 Health-System Pharmacy Administration Resident
Mayo Clinic Hospital - Rochester, MN

Joe received a Doctor of Pharmacy degree from Ferris State University in Big Rapids, MI. He is a current PGY-2 Health-System Pharmacy Administration Resident at Mayo Clinic Hospital – Rochester with practice interests including pharmacy operations administration, pharmacy practice advancement, and stewardship of healthcare resources.



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): JA0000238-0000-22-139-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 Interprofessional Continuing Education, Mayo Clinic College of Medicine and Science (Mayo Clinic School of CPD) must ensure balance, independence, objectivity and scientific rigor in its educational activities. Course Director(s), Planning Committee Members, Faculty, and all others who are in a position to control the content of this educational activity are required to disclose all relevant financial relationships with any commercial interest related to the subject matter of the educational activity. Safeguards against commercial bias have been put in place. Faculty also will disclose any off label and/or investigational use of pharmaceuticals or instruments discussed in their presentation. Disclosure of these relevant financial relationships will be published in activity materials so those participants in the activity may formulate their own judgments regarding the presentation.

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

The faculty report the following relationships:

- Joseph C. Osborne II, PharmD
 - Declares no financial relationship(s) pertinent to this session
 - Declares off-label use of medications will not be discussed during this presentation

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

- Jennifer Elmer, DNP, APRN, CCNS
- Michael Huckabee, MPAS, PA-C, PhD
- Sarah Jane Kotval, BSW
- Wayne Nicholson, MD, PharmD, BCPS
- Garrett Schramm, PharmD, FCCP

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.**