

Understanding Payer Evidentiary Needs for Alzheimer's Disease Monoclonal Antibody Treatments

July 14, 2021

10:00 AM-3:45 PM

Roundtable Objective:

Important progress in clinical research and innovative Alzheimer's Disease monoclonal antibody (AD mAb) drug development has been made over the last decade, and potentially transformative treatments may be on the horizon. However, the opportunity to treat patients with this new class of therapies will be accompanied by questions related to patient access, treatment costs, and long-term data collection on patient outcomes.

This multistakeholder roundtable will explore the issues associated with the use of these AD mAb treatments that are important to the payer communities. Specifically, sessions will focus on the broader therapeutic class landscape, how payer groups envision continuing evidence development efforts in a postmarket setting, and ideas for working together to track utilization and patient outcomes. This roundtable will not focus on the approval process or approval requirements for any mAb therapy.

10:00 a.m. Welcome and Framing the Issues

- Mark McClellan, Duke-Margolis Center for Health Policy

10:20 a.m. Session I: Current Landscape of mAb Development for AD and Potential Implications for Coverage and Access (110 minutes)

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Objective: This session will feature a review of emerging mAb treatments for Alzheimer's Disease and follow-up discussion on the implications of the arrival of these therapies in the context of coverage and access.

Framing Comments:

Jeff Cummings, University of Nevada Las Vegas

Mark Mintun, Eli Lilly

Sheila Selzer, Roche/Genentech

Ivana Rubino, Biogen

Lynn Kramer, Eisai

Questions to Consider:

- What are potentially achievable outcomes that payers will look for in AD mAb treatments? Based on currently available information about the drug class, as well as your own organizations' early review of this information, what are the highest priority questions where more evidence would be needed to inform coverage decisions? Specific questions to consider include:
 - For which populations might these treatments offer the greatest impact or value?

- What are the most effective ways to improve understanding of the relationship between the treatment's surrogate endpoints and cognitive outcome endpoints? The relationship between the cognitive outcomes to other measures of value, such as quality of life, independence and reduced supportive care costs and caregiver burden?
- What are the expectations associated with differing durations of treatment?
- What are the most effective and efficient care models for mAb treatment, including diagnosis, monitoring, and management of treatment complications?
- What coverage and payment decisions might be appropriate for these treatments?
 - How will payers treat populations included in clinical trials versus less-studied populations when making coverage determinations? Would coverage differ by population group?
 - What additional evidence described previously would affect payers' willingness to cover these drugs?
- What are payers' pricing and payment expectations with regard to the AD mAb drug class? What is the expected pricing dynamic when there are several similar drugs in this space?
 - How might past experiences in the context of pricing and competition help inform this discussion, for example, the approval of multiple PCSK9 drugs for lowering cholesterol and the competition that impacted hepatitis C treatment prices?

Open Discussion

12:10 p.m. Lunch Break (30 mins)

12:40 p.m. Session II: Opportunities for Generating Clinical Evidence for Promising AD mAb Treatments (90 mins)

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Objective: In this session, participants will discuss types of premarket and postmarket data and evidence that may be useful in the context of coverage and reimbursement decisions for AD mAb therapies.

Framing Comments:

Maria Carrillo, The Alzheimer's Association
George Vradenburg, UsAgainstAlzheimer's
Joe Johnston, Eli Lilly
Jennifer Whitely, Roche/Genentech
Chris Leibman, Biogen
Amir Tahami, Eisai

Questions to Consider:

- Will the pivotal trials underway now or the planned Phase 4 (postmarket) studies provide substantial insights into the key evidence questions?
- What are near-term ways to augment these studies to fill key evidence gaps?
- Can these key evidence questions be addressed through observational real-world studies (e.g., registries), or are randomized studies needed?
- What potentially feasible further postmarket studies are most important to consider now – for both early-stage and later-stage patients?
- Are there any learnings to leverage from our collective experience with registries, practical platform trials, and other postmarket evidence initiatives?
- What should CMS consider in terms of an evidence development (e.g., CED) approach for these therapies? How might these studies be designed and executed given the existing coverage issues and challenges associated with creating a randomized controlled trial for the treatment?

Open Discussion

2:10 p.m. Break (20 mins)

2:30 p.m. Session III: Looking Forward (60 mins)

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Objective: In this session, participants will discuss additional scientific, finance, and collaboration opportunities important when considering the availability of new AD mAb therapies.

Lead Discussants:

Steve Miller, Cigna

Kate Goodrich, Humana

Questions to Consider:

- How can stakeholders work together to address these questions in both premarket and postmarket studies?
- Would additional public-private collaboration help address these questions?
- What potential payment models could address the health care spending and evidence concerns associated with these therapies?

Open Discussion

3:30 p.m. Closing Remarks

Mark McClellan, Duke-Margolis Center for Health Policy

3:45 p.m. Adjournment

Funding for this roundtable was made possible by the US Food and Drug Administration through grant U19FD006602. Views expressed in the written materials and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.