

## Dear Rep. Mayberry,

Thank you for the opportunity to share our views with the Alzheimer Advisory Council. I'm sorry we are both out of town and unable to attend your meeting. Below are our thoughts and please feel free to contact me with any questions you or other members may have.

Arkansas Blue Cross Blue Shield (ABCBS) understands and supports the concerns of the search for an effective therapy which might stop or even reverse the ravages of Alzheimer's disease. However, the medical policy committee at ABCBS finds insufficient evidence of meaningful clinical effectiveness and more importantly a lack of medical safety for both FDA approved drugs directed only at beta-amyloid inhibition. This is why ABCBS cannot justify coverage (an evidentiary summary is available on request).

The committee finds both **aducanumab [Aduhelm]** (with a checkered history of FDA-approval resulting in a Congressional investigation of the approval process) and the more recently approved **lecanemab (Lequembi)** have no evidence of stopping or reversing this devastating disease. It also finds minimal to no evidence of clinical effectiveness in slowing progression while also having substantial toxicity in people with early mild Alzheimer's dementia, the population most in need of benefit.

ABCBS Medical Policy Committee agrees with the editorial of the American Academy of Family Physicians that finds the use of **Aduhelm**:

"provides no meaningful benefit only creates false hope for these patients and caregivers. Given its high cost, we cannot afford to prescribe a "cure" that has been shown to improve only a biomarker (amyloid deposition on positron emission tomography) rather than a clinically meaningful patientoriented outcome." Am Fam Physician. 2022;105(4):353-354.

https://www.aafp.org/pubs/afp/issues/2022/0400/p353.html.

For Lequembi, a recent respected editorial noted:

"Leqembi cannot repair cognitive damage, reverse the course of the disease or stop it from getting worse. But data from a large clinical trial suggests that the drug — administered every two weeks as an intravenous infusion — may slow decline by about five months over about 18 months for people with mild symptoms.

Still, some Alzheimer's experts have said it is unclear from the medical evidence whether Leqembi's ability to delay erosion of memory and cognition would be enough to be noticeable or meaningful for patients and their families. And while most cases of brain swelling and bleeding have been mild or moderate and have resolved, there have been some serious cases." [NYT Belluck July 2023].

In consideration, an expert in Alzheimer's treatment noted:

"The risks are very vivid," said Dr. Jason Karlawish, a co-director of the University of Pennsylvania's Penn Memory Center, "Within the first few months, you may have small bleeds or swelling in your brain, which may or may not be symptomatic and if not detected in time can cause disability."

"In contrast," Dr. Karlawish continued, "the benefits of slowing are subtle. You're not going to experience the perception of changes in your cognition or function in the same amount of time."

ABCBS advocates for prevention of Alzheimer's disease utilizing often-overlooked precautions and interventions that play a crucial role in preventing dementias such as Alzheimer's. These include:

--identify and control hypertension

--moderate use of alcohol

- --quit smoking and tobacco use
- --balanced diets which emphasize phosphatidylcholine containing foods
- --adequate and effective sleep
- --avoidance of chronic drug use in medications associate with Alzheimer's disease
- --controlling inflammatory conditions
- --adequate vitamin D levels
- --regular aerobic exercise
- --significant social and mental engagement
- --addressing hearing impairment
- --minimizing diabetic risk
- --avoidance of head injuries
- --adequate brain oxygenation [treatment of significant obstructive sleep apnea]

The effectiveness of prevention-based strategies has been shown in studies such as the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability, commonly known as FINGER. The landmark trial involving more than 1,200 people has significantly outperformed any drug trial to date by tackling dementia prevention from multiple angles, ranging from nutrition and physical activity to mental and social stimulation.

"After two years, the group assigned to the prevention strategies did 25% better than the control group on an assessment of overall cognitive performance. Specifically, participants showed improvements in executive functioning and processing speed, key cognitive functions often affected early in Alzheimer's disease. They also experienced broader health benefits; the side effects of prevention are often positive rather than negative." [LAT, June 2023]

https://www.latimes.com/opinion/story/2023-06-11/alzheimers-drugs-lecanemab-healthcare-prevention-research.

While continued research and development of drug interventions that truly make a difference in meaningful Alzheimer's disease outcomes remains a crucial goal, the emphasis and implementation of

programs already at Arkansans' disposal could preserve memory, maintain individual function, and assure longer horizons for independent living and enhanced quality plus quantity of life.

ABCBS supports those programs with proven benefit in slowing or preventing dementia rather than accepting expensive and potentially unsafe drugs with inadequate evidence of preventing, stopping, or reversing Alzheimer's dementia. We are hopeful that truly effective and safe drugs will be developed in the near future.

Sincerely,

## **Max Greenwood**

Vice President Government and Media Relations

and

Mike Martin

Michael R. Martin MD FACP

Corporate Medical Director for Policy Development