The Medicare National Coverage Determination and Future of Alzheimer's Treatments

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Aduhelm

Aduhelm is **an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.**

- Targets Mild Cognitive Impairment (MCI) due to Alzheimer's disease and mild (early) Alzheimer's dementia.
- Approved by the FDA under the accelerated approval pathway in June 2021.
- Administered intravenously through an IV infusion.
- Important to monitor for Amyloid Related Imaging Abnormalities (ARIA) to ensure patient safety.

Medicare NCD

- Monoclonal antibodies directed against amyloid that are approved by FDA for the treatment of AD based upon evidence of efficacy from a change in a surrogate endpoint (e.g., amyloid reduction) considered as reasonably likely to predict clinical benefit **may be covered in a randomized controlled trial conducted** under an investigational new drug (IND) application or may be covered in CMS approved prospective comparative studies, including registries.
- Treatments are also covered when furnished in accordance with FDA-approved and National Institutes of Health (NIH)-supported trials.
- Outside of these criteria, this class of drugs is considered nationally non-covered.

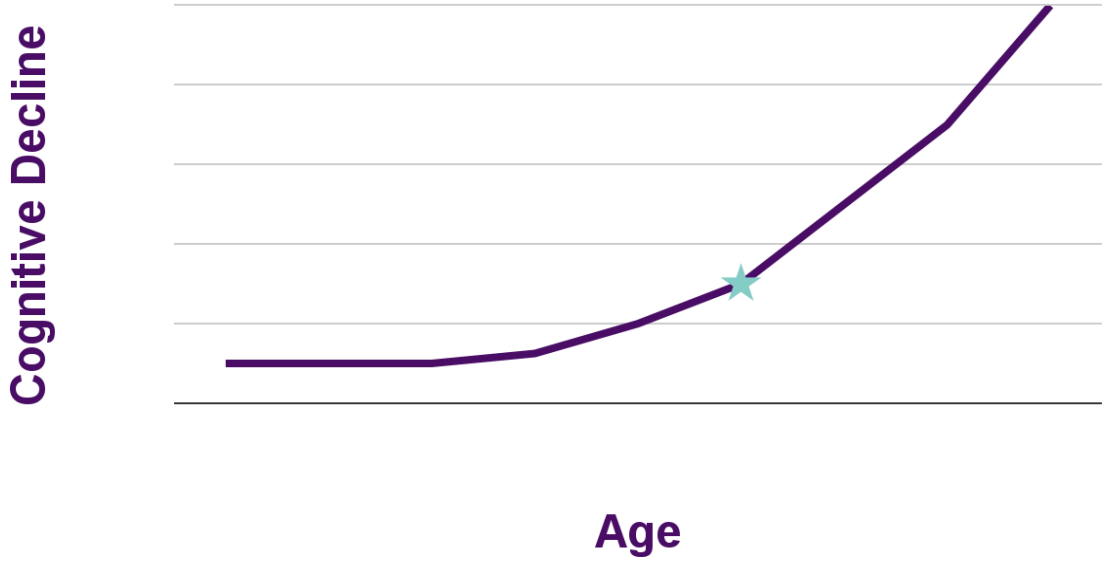
NCD Impact on Medicaid

- State Medicaid programs are **required** to cover Aduhelm when used for a medically accepted indication since:
  - Manufacturer of Aduhelm has entered into and has in effect a Medicaid drug rebate agreement; and
  - Aduhelm satisfies the definition of a covered outpatient drug as set forth in section 1927(k)(2) of the Social Security Act.
- State programs could, however, subject Aduhelm to utilization management techniques (i.e. prior authorization), and medical necessity criteria.
- However, when Aduhelm or other drugs included in the NCD are non-covered under the terms of the NCD, they are Part D drugs, and by law, **Medicaid cannot pay for Part D drugs for full-benefit dually eligible individuals.**

NCD and Future Treatments

- NCD takes a class approach, similar to other NCDs, in order to create a predictable pathway to national coverage that applies to every drug in this anti-amyloid mAb class.
- At this time, CMS believes a FDA determination of a drug/biologic that demonstrates efficacy from a direct measure of clinical benefit is *promising* but does not meet the 1862(a)(1)(A) reasonable and necessary statute.
- The final NCD also provides coverage for anti-amyloid mAbs that have FDA approval based upon evidence of efficacy from a direct measure of clinical benefit.

Age vs. Cognitive Decline Without Treatment



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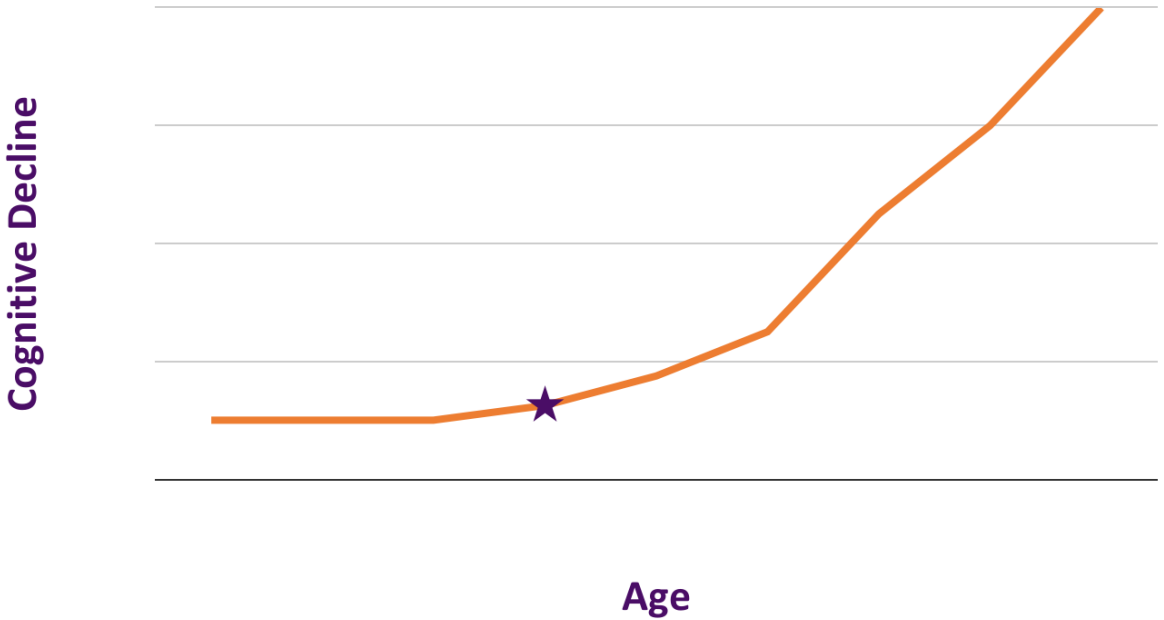
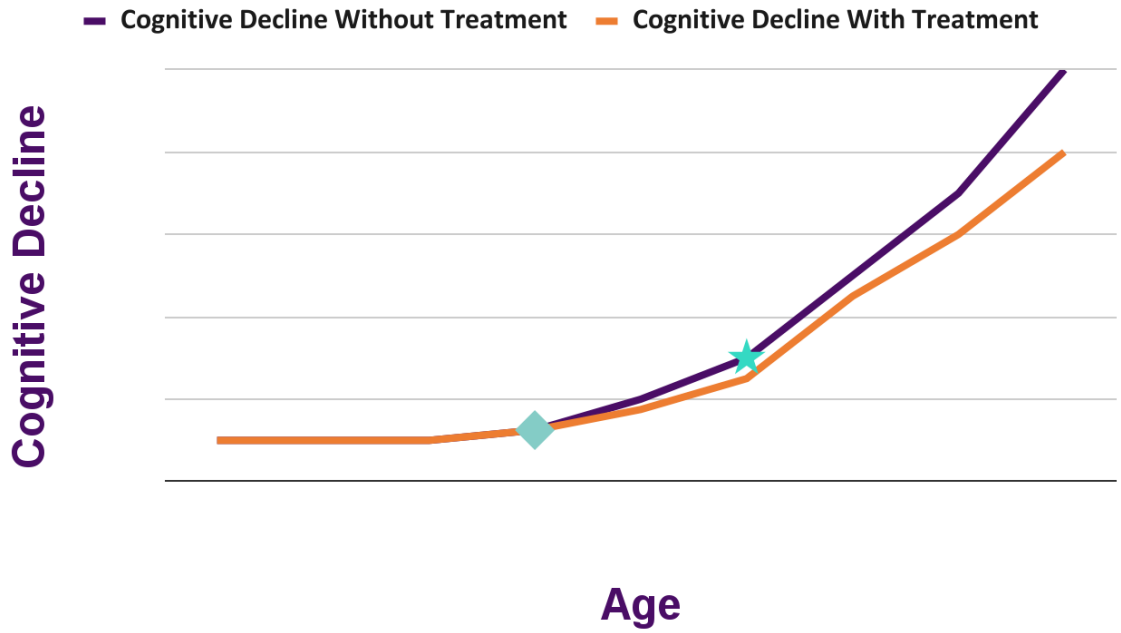


Age vs. Cognitive Decline



Potential Impact on State Policy

- Genetic Testing and Diagnosis Protections
- Testing - PET, MRI, CSF and future testing
- Drug Delivery - Clinical Settings
- Monitoring - MRI
- Coverage
  - Medicare
  - Medicaid
  - Private Insurance
  - State Employee Health Plans

Questions?