

CMS announces final Medicare national coverage determination for Aduhelm[™] (aducanumab)

- On April 7, 2022, the Centers for Medicare and Medicaid Services (CMS) announced the final National Coverage Determination (NCD) policy for Medicare coverage of Aduhelm (aducanumab).
- The NCD policy states that Aduhelm will be provided under Medicare coverage only for patients participating in CMS-approved clinical studies when used as part of a CMS approved clinical trial.
 - This policy goes into effect immediately and also applies to any future FDA-approved monoclonal antibodies directed against amyloid for use in treating Alzheimer's disease (AD).
- CMS acknowledges that Alzheimer's disease affects many Medicare beneficiaries. However, CMS noted Aduhelm has not demonstrated a clinically meaningful improvement in health outcomes (i.e., cognition and function) for patients with Alzheimer's disease. Additionally, CMS noted Aduhelm has been associated with safety concerns including amyloid-related imaging abnormalities (ARIA) that can lead to bleeding or edema in the brain. CMS believes the guidance provides a pathway to Medicare coverage while additional evidence is developed.
- Aduhelm was approved by the Food and Drug Administration in June 2021.
- At least three other anti-amyloid monoclonal antibodies (gantenerumab, donanemab, and lecanemab) are in late-stage clinical trials and could launch in 2023. OptumRx will continue to monitor emerging clinical data on Aduhelm as well as other pipeline drugs for Alzheimer's disease and then inform our clients of further recommendations.