



October 7, 2021

Administrator Chiquita Brooks-LaSure  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: ACHP Recommendations on Recent FDA Approval of Aduhelm**

Dear Administrator Brooks-LaSure:

The Alliance of Community Health Plans (ACHP) appreciates the Administration's willingness to engage industry partners regarding the recently FDA-approved Alzheimer's drug, Aduhelm. ACHP shares concerns raised by many stakeholders regarding the lack of clinical evidence demonstrating value of the drug, use of beta-amyloid plaques as a surrogate endpoint and patient safety. This is in addition to concerns regarding impact on overall affordability for the U.S. healthcare system.

ACHP represents the nation's top-performing non-profit health plans improving affordability and outcomes in the health care system. ACHP member companies are provider-aligned health organizations that provide high-quality coverage and care to more than 24 million Americans across 36 states and D.C. They are leading the industry in practical, proven reforms around primary care delivery, value-based payment and data-driven systems improvement.

ACHP recommends the Administration take these immediate actions as it considers coverage for Aduhelm:

1. **Issue guidance to the Independent Review Entity (IRE) Maximus with standards in reviewing appeals of Aduhelm coverage.** As CMS determines whether Medicare will establish a national coverage policy for monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease, the IRE should be provided with interim guidance to ensure national consistency. Without the yet-to-be established local or national coverage determinations, patients, providers and health plans need consistency to make appropriate coverage determinations. ACHP member plans have already experienced instances of inconsistent determinations from the IRE resulting from the lack of CMS guidance.

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- 2. Do not include Aduhelm appeals in Medicare Advantage star rating measurement.** Since the FDA approved Aduhelm with few population restrictions, health plans will need to institute utilization management methods to protect appropriate use and premium dollars. This broadly approved use for the drug means a significantly larger pool of beneficiaries potentially filing appeals. In the event of an appeal, ACHP maintains that this should not be included in the MA star rating appeals measure calculation. The lack of certainty surrounding coverage of this drug, its high cost and under-evaluated effectiveness make it inappropriate to include in quality measures. Health plans and the consumers they serve should not be penalized for lack of coverage guidance.

We appreciate the opportunity for engagement with you and members of your team. Please contact Michael Bagel, ACHP Director of Public Policy, at [mbagel@achp.org](mailto:mbagel@achp.org) or (202) 897-6121 with any questions.

Sincerely,

A handwritten signature in blue ink that reads "Ceci Connolly". The signature is written in a cursive, flowing style.

Ceci Connolly  
President and CEO, ACHP