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February 9, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard, MD 21244
Attn: CAG-00460N

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its new Proposed Decision Memorandum, *Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease*, published on January 11, 2022. We appreciate the opportunity to leverage our members' expertise in offering feedback.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's 7,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Coverage of anti-amyloid monoclonal antibodies

CMS Propsal
CMS proposes to cover the treatment class of anti-amyloid monoclonal antibodies (mABs), including Aduhelm, under its Coverage with Evidence Development (CED) pathway. Specifically, CMS will limit Medicare coverage for this class of therapies to Medicare beneficiaries participating in CMS-approved randomized clinical trials that satisfy specified coverage criteria, as well as trials supported by the National Institutes of Health.

AMCP Response
AMCP supports CMS' decision to cover FDA approved mABs directed against amyloid for the treatment of Alzheimer's disease under the CED pathway and encourages CMS to finalize the draft decision without an expansion of coverage. Alzheimer's disease (AD) and related dementia is a devastating illness currently without an effective treatment, and it is imperative that potential treatments meet the highest standards of clinical evidence. However, the current clinical evidence does not support broad coverage of Aduhelm at this time. The conflicting data from clinical trials on anti-amyloid mABs requires, at a

minimum, additional research into safety and efficacy before beginning broad coverage. A report released by the Institute for Clinical and Economic Research (ICER) concluded "the evidence is *insufficient* to conclude that the clinical benefits of [Aduhelm] outweighs its harms or, indeed, reduces progression of AD in patients with mild AD or [mild cognitive impairment]."[1] These safety and efficacy concerns are widely held by the medical community, with many hospital networks and provider groups declining to prescribe Aduhelm on the basis of its risks and low evidence of improvement for Alzheimer's patients.

AMCP believes that the price of Aduhelm, the only Food & Drug Administration-approved anti-amyloid mAB, is misaligned with the potential clinical value provided by the treatment. ICER notes that "the uncertainty in effectiveness of [Aduhelm] percolates through to a wide range in potential cost-effectiveness estimates" but concludes that the cost of the treatment "is not in reasonable alignment with its clinical benefits, even under a scenario with optimistic assumptions regarding treatment effectiveness."[2] Medicare has a responsibility to promote the wise and efficient use of its resources to provide the highest quality care to the highest number of beneficiaries possible. CMS estimated in 2021 that broad coverage of Aduhelm would be responsible for approximately half of the 14.5% increase in monthly Medicare Part B premiums from $148.50 to $170.10 per month,[3] although Aduhelm's manufacturer has since reduced the price. Also of concern is that the subsequent decrease in cost is inadequate to prevent Medicare Advantage beneficiaries from reaching the annual out-of-pocket limit, an average of $5,153 in 2022, if they receive treatment with Aduhelm. Given the substantial risk of potentially fatal side effects, the absence of clear evidence of clinical benefit, and the high price tag of the treatment even considering recent price reductions, AMCP believes that this drug is not a responsible use of limited healthcare dollars.

Further, AMCP is concerned about the burden Aduhelm and any subsequently approved anti-amyloid mABs may impose upon state Medicaid programs. Under current rules, for the dual-eligible population, Medicare is typically the primary payer and Medicaid assists by covering an individual's cost sharing (in the case of Part B, 20%). As a consequence of the proposed CED policy, Medicaid will now become the primary payer for this significant population. Medicaid is a vital program for many vulnerable Americans. To avoid a potentially destabilizing effect on state Medicaid budgets, AMCP encourages CMS to use available and appropriate resources to reduce this burden. The National Association of Medicaid Directors (NAMD) published a letter in August 2021 estimating that no or limited Medicare coverage of Aduhelm would "increase total state and federal Medicaid spending on the therapy by roughly 250% nationally," with some states seeing increases "as high as 500%."[4] AMCP echoes NAMD's

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[1] : Lin GA, Whittington MD, Synnott PG, McKenna A, Campbell J, Pearson SD, Rind DM. Aducanumab for Alzheimer's Disease: Effectiveness and Value; Final Evidence Report and Meeting Summary. Institute for Clinical and Economic Review, August 5, 2021. https://icer.org/assessment/alzheimers-disease-2021/.

[2] Id.

[3] CMS Announces 2022 Medicare Part Premiums. Centers for Medicare and Medicaid Services. November 12, 2021. https://www.cms.gov/newsroom/press-releases/cms-announces-2022-medicare-part-b-premiums#:~:text=The%20increase%20in%20the%20standard,2021%20Medicare%20Part%20B%20monthly.

[4] Letter from the National Association of Medicaid Directors to Administrator Brooks-LaSure. National Association of Medicaid Directors. August 11, 2021. https://medicaiddirectors.org/wp-content/uploads/2021/08/NAMD-Alzheimers-Medicare-NCD-comments.pdf

recommendations to either allow state Medicaid programs to apply the same CED criteria as Medicare or add Aduhelm to the list of drugs with restricted coverage under the Medicaid Drug Rebate program.[5]

Conclusion

AMCP appreciates the opportunity to comment on the Proposed Decision Memorandum, *Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease*. We are committed to serving as a valuable resource to CMS on improving access to prescription drugs at lower costs, reducing costs in the health care system, and coverage decisions for novel therapies. We support CMS' decision of coverage with evidence development and recommend no further expansion due to the uncertain clinical benefits, substantial risk of harmful side effects, and disruptive cost to the Medicare and Medicaid programs. However, we also urge CMS to remain flexible and act swiftly to revise its coverage determination if new evidence should emerge that clearly demonstrates the efficacy of anti-amyloid mAB treatments for patients with MCI or mild AD. If you have any questions regarding AMCP's comments or would like further information, please contact Jennifer Mathieu at 703.284.2654 or jmathieu@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

[5] Id. Section 1927(d)(3) of the Social Security Act permits CMS to designate certain drugs as "subject to clinical abuse or inappropriate abuse", allowing states to exclude such products from their formulary.