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**DATE:** August 17, 2023

**TO:** All Medicare Advantage Organizations, Part D Plan Sponsors, 1876 Cost Plans and Programs of All-Inclusive Care for the Elderly (PACE)

**SUBJECT:** Significant Cost Determination for Medicare Coverage of Monoclonal Antibodies for the Treatment of Alzheimer's Disease

On April 7, 2022, CMS issued the “Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease” National Coverage Determination (NCD 200.3). This NCD outlines Medicare coverage policy for monoclonal antibodies that target amyloid (or plaque) for the treatment of Alzheimer's disease. Under NCD 200.3, Medicare covers monoclonal antibodies that the Food and Drug Administration (FDA) has not yet determined to have shown a clinical benefit (or that receive an accelerated FDA approval), in the case of FDA or National Institutes of Health (NIH) approved trials. The NCD also provides Medicare coverage for monoclonal antibodies that receive traditional approval from the FDA under coverage with evidence development. Any physician administering monoclonal antibodies that receive traditional approved by the FDA must submit data to at least one registry-based study. On July 6, 2023, the FDA granted the first traditional approval of an amyloid-targeting monoclonal antibody to Leqembi (lecanemab).

If CMS determines that an NCD meets the criteria for “significant cost” under § 422.109 of Title 42 of the Code of Federal Regulations, Medicare Advantage (MA) organizations are not required to assume risk for the costs of that service or benefit until the contract year for which MA payments are appropriately adjusted in the rate book to account for the cost of the NCD. If CMS determines that an NCD does not meet the “significant cost” criteria, MA organizations are required to provide coverage for the NCD and assume risk for the costs of that service as of the effective date stated in the NCD.

CMS has determined that the cost of coverage under NCD 200.3 does not meet the significant cost threshold. Therefore, MA plans are required to assume the costs and cover anti-amyloid monoclonal antibody treatments for Alzheimer’s following the coverage criteria set forth under NCD 200.3. Consistent with procedures under Traditional Medicare, MA plans must collect the applicable registry trial number on each claim or encounter for monoclonal antibodies that receive traditional approval from the FDA.

For more information on the NCD and related information see

<https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval>.

Information on available registries for physicians can be found at: <https://www.cms.gov/medicare/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad>, and clinicians will be able to choose in which registry to participate.