

CAPITOL STREET

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Leqembi Does Not Meet Significant Cost for MA

MA Plans Required to Assume mAb Costs for Alzheimer's Disease

Relevant Companies



Humana.



Lilly

aetnaCVSHealth.

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On August 17, 2023, CMS provided significant cost determination for Medicare coverage of monoclonal antibodies (mAbs) for the treatment of Alzheimer's Disease (access memo [here](#)).

»» Our Take & Next Up

This is in line with expectations as MA plans (UNH, HUM, CVS, ELV, Others) have discussed mAbs likely not exceeding CMS's significant cost threshold. Plans may be relieved that costs are not anticipated to be high. Several noted feeling comfortable with what they have priced for 2024 on CMS coverage for Leqembi (BIIB/Eisai). Rollout of the drug is commencing, as health systems develop patient selection protocol; prominent neurology clinics and academic medical centers are restricting access at first, while learning to manage a new national registry required for Medicare coverage. Plans are likely more concerned about GLP-1s (diabetes, obesity – Ozempic, Wegovy, Mounjaro). The class has demonstrated efficacy, priced at about \$12,000 - \$15,000 per patient per year (oftentimes taken for years to maintain weight loss, with potential side effects). Currently Medicare statute does *not* allow for the coverage of anti-obesity medications, as we watch for legislation that flips the switch for future CMS coverage.

»» Key Points

CMS determined that the cost of coverage under National Coverage Determination (NCD) does not meet the significant cost coverage. This means that MA plans are required to assume the costs and cover anti-amyloid monoclonal antibody treatments for Alzheimer's. This also means that MA organizations are now required to provide coverage for the NCD and assume risk for the cost of the drugs. Humana stated on its Q2 earnings call that based on cost estimates, plans would have to

hit about a \$1 PMPM expense to tip the “significant cost policy” and expectations across the industry were that there would *not* be this level of spend. Per CMS, the threshold is roughly \$200,000 per year or \$1 PMPM.

As a reminder, on July 6, the FDA granted full approval of Leqembi (Eisai/Biogen) 100 mg/mL injection for intravenous use. The drug is expected to cost \$26,500 per year, and Medicare has indicated that it will cover 80% of the cost of medication. Medicare will cover the drug but a national registry is required for patient data collection (CMS), which can be burdensome for rural or small providers.

For precedent, CAR T-cell therapy for certain types of cancer was considered a “significant cost” for contract years 2019 and 2020 ([here](#)). As a result, FFS Medicare reimbursed CAR T-cell therapy for beneficiaries enrolled in MA plans when the coverage criteria in the NCD was met. In 2021, MCOs took over the provider reimbursement of CAR T-cell therapy for MA members from the Medicare FFS system. In 2021 it was estimated that the therapy cost more than \$370,000 for a single infusion.

At least five major US health systems will offer Leqembi over the next few months and a recent study ([here](#)) found that <1 in 10 patients may be prescribed Leqembi. Clinical trials selected the most robust patients with the fewest comorbidities to reduce the risk of adverse reactions or complications, and some clinicians may use the trial criteria as a “reasonable guidepost” when deciding which patients make the best candidates for the drugs. The study looked at 237 older adults that met the FDA’s criteria for Leqembi and found that, excluding people with comorbidities, only 19 people (8%) would be eligible for Leqembi. Some specifics around centers providing access ([here](#)):

- Before July 6 full approval, Duke University Health System started 16 patients on Leqembi who are paying for the drug out of pocket.
- Neurologists at the University Penn hospital said clinical rollout will start this month.
- Neurologists at the Mayo Clinic Rochester, Minnesota, Chicago’s Northwestern Memorial and LA’s Cedars-Sinai all said they plan to roll out the drug in the next few months.
- UHealth-the University of Miami Health System recently completed protocols for the treatment, which must be reviewed and adopted by colleagues in other departments.

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