CAPITOL STREET

June 1, 2023

Medicare Likely to Cover Alzheimer's Upon Full Approval

CMS-Facilitated Patient Registry Required

Relevant Companies

Our Take & Next Up

CMS's new coverage policy will not go into effect until an anti-amyloid drug receives full FDA approval later this summer. We believe full FDA approval is likely for Leqembi (BIIB) by July 6 and CMS notes "other registries may become available in the coming weeks and months" which could provide faster access to Leqembi under the registry CED policy. Donanemab full FDA approval is also likely within the year.

A national registry is burdensome, and takes time to learn how to use, particularly in rural areas, for small providers. We do not see that much that is new here, as we anticipated a registry requirement from the agency. Over time, the registry requirement will likely be removed. Slower uptake of the medicines may ensue, despite the significant unmet need addressed by Leqembi/donanemab.

Key Points

The timing is no coincidence & CMS is touting the news as a positive for patients, despite the lack of much new news. With next week's FDA Advisory Committee (June 9), CMS announced plans on how it will cover anti-amyloid monoclonal antibodies (LLY, BIIB, Eisai), the new class of Alzheimer's disease treatments. The coverage policy will take effect only after full FDA approval of Leqembi later this summer and will apply to any products in the class that also receives full FDA approval in the future. Link to announcement here.

CMS has faced significant public pressure to address AD treatment access. Lawmakers from both parties have been vocal about their concerns on access to anti-amyloid treatments in recent Congressional hearings. In a recent House Ways and Means hearing, Health subcommittee Chair Rep. Buchanan (R-FL) voiced his criticism of the CED. In April, Rep. Eshoo (D-CA), ranking member of the House Energy and Commerce health subcommittee, questioned CMS Administrator Chiquita Brooks-LaSure on anti-amyloid treatment access and how CMS plans to structure a registry. While Brooks-LaSure reassured lawmakers on access, CMS has not yet provided details on a registry infrastructure.

CMS will provide Part B coverage for monoclonal antibodies (mAbs) in treating Alzheimer's disease, but will require a patient registry for data collection purposes. Part B coverage will be provided to those who meet the clinical diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia.

A national "CMS facilitated portal" will be required, which likely will be burdensome for the agency and time-consuming for physicians. Coverage is under the condition that patients will be seen by physicians who will report patient data as well as any label requirements set by the FDA. CMS plans to roll out a nationwide, CMS-facilitated portal for data collection and may also collect data from private organizations that plan to open their own patient registries.

Patient registries have been used before by CMS, largely for cardiovascular therapies. A registry records "real world" data pertaining to the usage of a specific biopharmaceutical or drug. For CMS, a registry can provide data for determining drug and technology efficacy, financial stakes, and final coverage determination. Information for a registry is most typically reported directly from the patient or the patient's physician to a private research organization or to a relevant provider organization.

CED dashboard. In total, four CED ("coverage with evidence development") requirements have been dropped to provide full coverage after positive evidence was provided by data collection. Conversely, two NCDs have been revoked and coverage was deferred to local coverage determinations due to poor evidence.

CMS's announcement references the Transcatheter Aortic Valve Replacement (TAVR) CED which requires providers and hospitals to participate in a prospective, national, audited registry (TVT registry). The registry was created through a collaboration Society of Thoracic Surgeons (STS) and American College of Cardiology Foundation's (ACCF) and compiled patient information including procedure, treatments, outcomes, demographics.

CMS's coverage framework is much broader than the prior Coverage with Evidence Development (CED), but data requirements remain in place. A reminder, the initial CED requirement restricted access to only seniors in approved clinical trials, which meant most weren't likely to receive treatment. The CED restriction was a result of Aduhelm's (BIIB) limited clinical benefit and the controversy surrounding its accelerated approval which ran contrary to the FDA's own advisers. In December 2022, the Alzheimer's Association, a patient advocacy group, asked for removal of the CED restriction, but was denied by CMS earlier this year. CMS is unlikely to remove the CED upon FDA approval of Leqembi, but the agency is being more flexible as a response to both public and lawmaker pressure on improving access to Alzheimer's disease treatments.

FDA is likely to give full FDA approval to Leqembi (BIIB, Eisai) this summer. Anti-amyloid drugs represent a new class of treatments that could significantly impact the standard of care for Alzheimer's disease. FDA will

convene the Peripheral and Central Nervous System Advisory Committee on June 9th to discuss Leqembi, which received accelerated approval in January. If approved, Leqembi will be the first of its class to receive full FDA approval. Under CMS's current coverage policy, if FDA grants traditional approval to other drugs in this class, they would also be eligible for registry coverage. After reporting positive Phase 3 data for donanemab (LLY) in May, LLY was expected to file for full FDA approval in Q2. We expect progress on the donanemab FDA filing to be reported in LLY's Q2 earnings in July.

Ipsita Smolinski

Managing Director | Capitol Street

ipsita@capitol-street.com

900 19th Street, NW 6th Fl
Washington DC 20006

202.250.3741

www.capitol-street.com
