June 30, 2026

VIA ELECTRONIC SUBMISSION

USP Healthcare Safety & Quality Expert Committee
U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

RE: USP Medicare Model Guidelines V.10.0

Dear USP Healthcare Safety & Quality Expert Committee:

The undersigned organizations appreciate the opportunity to submit comments on the United States Pharmacopeia's (USP) proposed Medicare Model Guidelines V.10.0 (the "MMG V.10.0"). Together, our organizations are committed to improving the diagnosis and clinical management of Alzheimer's disease and related neurodegenerative diseases and ensuring access to safe, effective, patient-centered care.

For MMG V.10.0, our organizations urge USP to create a new class within the "Antidementia Agents" Category for "Disease Modifying Therapies" to distinguish FDA-approved treatment options that target the underlying disease from those approved for symptomatic treatment. These therapies are currently listed in a general, catch-all "Antidementia Agents, Other" class.

Disease-modifying therapies (DMTs) for Alzheimer's disease represent a monumental shift from merely managing symptoms to directly altering the disease's underlying biology. These treatments—primarily monoclonal antibodies (mAbs)—target toxic amyloid-beta proteins in the brain to slow cognitive and functional decline. In 18-month phase 3 trials of early AD, anti-amyloid mAbs slowed cognitive and functional decline by roughly 25–30% versus placebo on composite measures (e.g., CDR-SB, ADAS-Cog, functional scales).

In 2023, lecanemab gained FDA approval after clinical trials definitively showed it slowed cognitive decline and improved daily functioning in adults with early-stage Alzheimer's. In 2024, donanemab became the latest FDA-approved anti-amyloid therapy, demonstrating the ability to clear plaques and slow disease progression.

In addition, in late August 2025, the FDA approved a subcutaneous (SC) injection for maintenance dosing of lecanemab, further improving patient access and administration options. **With a self-administered, subcutaneous option under Part D now available, the need for USP to distinguish DMTs from symptomatic treatments has only grown more critical. Although the USP-Drug Classification lists mAbs in a separate "Disease Modifying Therapies" class, SC lecanemab is currently listed as a proposed addition to the "Antidementia Agents, Other" class for the MMG V.10.0, inappropriately grouping it with symptomatic agents. We urge USP to add a separate class in the MMG to align with the USP-DC and ensure the MMG V.10.0 clearly distinguishes DMTs from agents used for symptomatic treatment.**

Part D eligible DMTs, including SC lecanemab, aren't just a convenience upgrade — they play a vital role in expanding access to disease modification for people with early Alzheimer's disease. IV formulations of existing mAbs are clinically effective, but the delivery model is so

resource-intensive that it limits access, affordability, and real-world benefit. SC lecanemab fundamentally changes that equation, as would additional Part D eligible DMTs for Alzheimer's disease and other neurodegenerative disorders. IV DMTs requires infusion centers, nurses trained in mAb administration, 1–2 hour visits every few weeks, transportation and caregiver support, and scheduling capacity in already overloaded neurology systems. These constraints mean that only a fraction of eligible early-stage AD patients can realistically start therapy, even in major academic centers.

Part D eligible DMTs change the infrastructure requirements. There is no infusion chair needed. Drugs can be administered in a short clinic visit or even through at-home administration. There is far less staffing burden, rural and underserved areas can participate, and faster ramp-up of new treatment programs. In practical terms, Part D eligible DMTs will help to transform a specialized, high-resource therapy into something that can be delivered in standard outpatient or home settings, which is the only way to reach the millions of people with early Alzheimer's disease.

Adding this class to the MMG V.10.0 has implications well beyond SC lecanemab too. There are several DMTs in the pipeline for Alzheimer's disease as well as related neurodegenerative disorders, including subcutaneous and oral formulations. **These drugs may be available for patients well before 2031.** If the USP does not act now to establish this class for 2028, these drugs will be mistakenly grouped into the "Antidementia Agents, Other" catch-all class with symptomatic therapies, which will be detrimental for patient access. Introducing this class now would send a clear signal to drug sponsors, clinicians, and insurers that USP recognizes and prioritizes the clinical distinctiveness of DMTs.

For individuals living with Alzheimer's disease and related neurodegenerative disorders, **timeliness is not a luxury**—it determines the availability and magnitude of benefit. These first generation mAbs – and DMTs under development, including drugs for non-Alzheimer's causes of cognitive impairment – work best when started in early stages of disease, i.e., mild cognitive impairment (MCI) or mild dementia. **A three-year delay in creating this class likely would cost individuals living with early Alzheimer's disease their only opportunity to receive Part D DMTs.** By the time 2031 arrives, they will have progressed to a moderate stage of disease when they are no longer eligible for these early-stage treatments. While we understand that USP does not typically create a class with only one drug currently available, we understand there are exceptions (e.g., one drug in "NMDA Receptor Antagonist" class under "Antidementia Agents" category in the proposed MMG V.10.0). Given the enormous unmet needs of this community where delayed treatment equates to forgone treatment, we urge USP to adopt an exception to the typical standards.

Part D DMTs will also accelerate initiation because more sites can offer treatment, there is no infusion-center queue, and there are simpler scheduling and fewer logistical hurdles. Such delivery systems will also be less expensive for the Medicare program and out-of-pocket costs for families, in terms of infusion fees, facility charges, transportation costs, caregiver time off work, and higher administration overhead.

Without a distinct DMT class in the MMG V.10.0, these therapies will be evaluated by formularies alongside symptomatic agents, potentially resulting in formulary exclusion despite their fundamentally different mechanism, intent, and clinical value. When the distinction is not made between DMTs and symptomatic treatments, plans could adopt step therapy protocols that require patients to progress through symptomatic treatments prior to receiving a DMTs. This

means a loss of time and opportunity to delay decline. Fail-first coverage policies could mean that the patient progresses to moderate AD, at which point they will no longer be eligible for treatment with a DMT.

Bottom line

Creating a new class for “Disease Modifying Therapies” is not a minor formulation change — it is the key determinant of whether existing and future therapies in this class become accessible to typical early-stage AD patients, affordable for health systems and families, timely enough to preserve meaningful cognitive function, and sustainable as a long-term disease-modifying treatment.

We appreciate USP’s stewardship in helping CMS to ensure the Medicare Model Guidelines continue to support safe, clinically appropriate, and affordable access to high-quality care for those in need.

Please contact Scott Frey, SVP of Public Policy and Government Affairs at the Alliance for Aging Research, at sfrey@agingresearch.org, with any questions. Thank you again for the opportunity to comment.

Sincerely,

Alliance for Aging Research

LEAD Coalition (Leaders Engaged on Alzheimer’s Disease)

Partnership to Fight Chronic Disease

Voices of Alzheimer’s