Medicare is treating people with Alzheimer's differently- here's how

Voices of Alzheimer's

In the very near future, the U.S. Food and Drug Administration (FDA) is expected to grant full (or so-called traditional approval) to a new treatment for Alzheimer's – marking a first in history.

A panel of expert FDA advisers already unanimously agreed that clinical research studies of the Alzheimer's drug lecanemab confirm clinical benefits for patients. Clinical trial research showed a moderate slowing of cognitive and functional decline for people in early-stage cases of the disease, equating to months or years of added time engaging with loved ones and living independently for people living with Alzheimer's.

What you need to know:

With the recent unanimous vote of an FDA Advisory Committee confirming lecanemab's benefit to patients, the treatment is expected to receive "traditional" (rather than accelerated) FDA approval by mid-July of 2023. Once approved by the FDA, the Centers for Medicare and Medicaid Services (CMS) will finally need to decide whether to stop discriminating against people with Alzheimer's and allow Medicare to broadly cover access to the drug for the millions of Americans living with early Alzheimer's who have no other options.

Up to now, in what experts describe as a first for Medicare, CMS has refused to broadly cover drugs for Alzheimer's approved under the FDA's accelerated approval process. (The agency continues to refuse to cover diagnostic tools for Alzheimer's, like PET scans.)

What we're asking: treat people with Alzheimer's the same as everyone else.

Ahead of a decision by CMS, we demand that Medicare treat coverage for the diagnosis and treatment of Alzheimer's the same way it provides coverage for any other diseases or conditions. Currently, there are unprecedented barriers to access to medical care for the Alzheimer's community that add up to a pattern of discrimination. Medicare has the opportunity to do the right thing - the thing they do for all other FDA-approved drugs for all other diseases - and this is what that looks like:

First, the FDA determines if a treatment is safe and effective.

The functions, duties, and decisions of the FDA and CMS are defined by their respective areas of responsibility. For the FDA, U.S. policy tasks the agency with evaluating the safety and efficacy of medicines before their introduction to the marketplace. These determinations are the FDA's responsibility because, unlike CMS, the FDA has the scientific expertise to decide whether a drug works and is safe to use.

The FDA employs a comprehensive evaluation procedure to confirm that drugs are both safe and effective prior to approval, as well as diligent monitoring of patient outcomes after they are made available. This process includes data analysis and expert evaluation of clinical trial results to ascertain that the benefits of a treatment outweigh any potential adverse effects.

Only after years of rigorous scientific clinical trials and expert evaluation does the FDA consider approval.

After FDA approval, CMS decides if drugs are “reasonable and necessary” for Medicare patients.

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In all cases except for Alzheimer’s, CMS covers drugs at least as described on the FDA-approved label.

CMS has a coverage decision option called Coverage with Evidence Development (CED), which is reserved for when the agency makes a coverage determination for a treatment for which the evidence of being “reasonable and necessary” remains uncertain. Under a CED, CMS requires the generation of additional evidence to address sources of uncertainty and secure ongoing coverage.

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CMS has never before required Coverage with Evidence Development for the on-label use of a drug that received traditional FDA approval.

The FDA's rigorous traditional approval process ensures that by the time CMS makes a coverage determination, evidence for the on-label use of a drug is proven. As such, Medicare coverage for the on-label use of a drug that receives traditional FDA approval should not need CED.

CED requirements for FDA-approved Alzheimer's drugs do not serve to gather evidence towards the "reasonable and necessary" standard but will instead limit access to the millions of Americans in need of treatment.

We are not asking for special treatment, only to be treated the same as everyone else.

Every day, up to 3,200 Americans progress from mild to moderate Alzheimer's disease, where new treatments may no longer help them.

So far, CMS has required Coverage with Evidence Development for Alzheimer's treatments approved under the FDA's Accelerated Approval Process and for access to the amyloid PET scans that are critical to diagnosing Alzheimer's disease. The CED requirements have made treatment and diagnosis inaccessible to people living with the disease, wasting a valuable window of time when treatments can help.

Our only ask is that CMS does what it has always done: treat people with Alzheimer's with the same consideration as people living with any other diseases or conditions – deserving of treatment and support to live better, healthier lives for as long as possible.

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