The Aduhelm Saga and Medicare (continued)

March 1, 2022

MarketWatch Blog by Alicia H. Munnell

Alicia H. Munnell is a columnist for ***MarketWatch*** and director of the Center for Retirement Research at Boston College.

How Aduhelm presented Medicare officials with a real challenge

Aduhelm, a drug developed recently by Biogen, has raised enormously important issues for Medicare. Biogen's initial proposed price for Aduhelm was $56,000 per patient per year. Because Aduhelm is administered intravenously by physicians, it would be covered under Medicare Part B. (Medicare Part D covers retail prescription drugs.) While, to date, Medicare has covered virtually all drugs approved by the Food and Drug Administration (FDA), officials issued **a draft decision** in January 2022 to limit coverage of Aduhelm to those in clinical trials. The basis for their decision was concerns about whether the benefits of the drug outweighed the safety risks. The final decision is expected by April.

The story started with the **FDA approval of Aduhelm** in June 2021. The drug is the first new treatment for Alzheimer's in almost 20 years, the first aimed at treating the source of the disease rather than targeting the symptoms, and the need for a cure is compelling. On the other hand, three years ago, **Biogen halted** two late-stage clinical trials after experts concluded that the

drug would not slow cognitive decline and functional impairment. Subsequently, the company released **additional data** from the trials, asserting that one of the trials showed that a high dose of the drug could be effective in slowing cognitive decline.

The FDA approved the drug using the "**accelerated approval**" pathway, which is intended to provide earlier access to potentially valuable therapies when uncertainties exist about their ultimate benefit. In the case of Aduhelm, the drug had a clear impact on a "surrogate endpoint" – the removal of plaque – which the FDA concluded was reasonably likely to produce a "clinical benefit" – the slowing of cognitive decline.

The backlash was immediate. Three of the agency's outside advisors quit over the decision; a watchdog agency is investigating the approval process; and many prominent providers – Cleveland Clinic, Mt. Sinai, Mass General Brigham, and the Department of Veterans Affairs – have declined to adopt Aduhelm. Internationally, the European Union's drug regulator recommended against approving the drug, and leading Canadian Alzheimer's research organizations said adoption "cannot be justified."

In some ways, the debate over Aduhelm reflects the medical debate among doctors and researchers over what causes Alzheimer's. Aduhelm reduces a protein (amyloid) that clumps in the brain of people with Alzheimer's, but many specialists say that extensive research has shown that reducing the protein does not slow cognitive decline. Moreover, the drug can cause serious side effects such as headaches, dizziness, falls, and brain bleeds.

Aduhelm is also expensive. Biogen originally priced the drug at $56,000 per year, as noted, but cut the price to $28,200 in December 2021 after weak sales. Patients receive the drug in monthly infusions and also require

regular MRI scans to monitor for dangerous side effects such as brain swelling and bleeding. About half of Medicare's 14.5-percent premium increase for 2022 was attributable to the anticipated costs of covering Aduhelm.

In the wake of the controversy, Medicare opened a National Coverage Determination (NDC) process. The process involved a review of the clinical evidence to determine whether the drug is "reasonable and necessary for the diagnosis and treatment of an illness." That is, is the evidence adequate to ensure that the drug will improve outcomes? Cost is not included as a factor in the assessment. The determination was that the risks exceeded the benefits and that the coverage of Aduhelm would be limited to randomized clinical trials, with some patients getting placebos. The trials must be approved by Medicare or supported by the National Institutes of Health, conducted in a hospital-based outpatient setting, and cover a diverse population. This decision will limit treatment to a few thousand individuals over the next 3-5 years.

But what would it have meant for Medicare if the trials had shown Aduhelm to be effective?

This saga concludes with next week's post!