



## Biogen To Offer Continuity of Care Plan for U.S. Patients Currently Treated with ADUHELM® (aducanumab-avwa)

April 28, 2022

Biogen is announcing plans to help patients in the U.S. currently on ADUHELM avoid any treatment interruptions following the final national coverage determination by Centers for Medicare & Medicaid Services (CMS) that could result in a loss of coverage for Medicare beneficiaries.

All U.S. patients who began treatment on or before April 7, 2022 are now eligible to receive ADUHELM at no cost for the duration of their treatment or for the duration of the program. The plan is effective immediately. In addition, patients who are already enrolled in Biogen's Free Drug Program will automatically continue in the program and continue to receive the medicine at no cost. Biogen's program does not cover diagnostics and other potential fees associated with treatment administration and monitoring.

"One of our immediate priorities following the NCD decision is to support patients on therapy who were uncertain whether they could receive their next infusion," said Alisha Alaimo, President of Biogen's U.S. Organization. "This program allows eligible patients continued access to ADUHELM and aims to help them avoid long-term interruptions in their care."

On April 7, CMS issued a final national coverage determination that limited access to ADUHELM for Medicare beneficiaries to only those enrolled in FDA or National Institutes of Health (NIH) approved clinical trials. For those already on ADUHELM, this meant a potential halt in their treatment plans.

Patients who are currently taking ADUHELM and have questions can contact Biogen Support Services at 1-833-425-9360.

### About ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use

ADUHELM is indicated for the treatment of Alzheimer's disease. ADUHELM should be started in patients with mild cognitive impairment or mild dementia stage of disease, the population studied in clinical trials. There are no data on risks or benefits for patients in other stages of Alzheimer's. ADUHELM is approved under accelerated approval based on reduction in amyloid plaques as seen in patients treated with ADUHELM. Continued approval of ADUHELM may require verification of clinical benefit in a confirmatory study.

ADUHELM is a monoclonal antibody directed against amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. The accelerated approval of ADUHELM has been granted based on data from clinical trials showing the effect of ADUHELM on reducing amyloid beta plaques, a surrogate biomarker that is reasonably likely to predict clinical benefit, in this case a reduction in clinical decline.

ADUHELM can cause serious side effects including: Amyloid Related Imaging Abnormalities or "ARIA". ARIA is a common side effect that does not usually cause any symptoms but can be serious. Although most people do not have symptoms, some people may have symptoms such as: headache, confusion, dizziness, vision changes and nausea. The patient's healthcare provider will do magnetic resonance imaging (MRI) scans before and during treatment with ADUHELM to check for ARIA. ADUHELM can also cause serious allergic reactions. The most common side effects of ADUHELM include: swelling in areas of the brain, with or without small spots of bleeding in the brain or on the surface of the brain (ARIA); headache; and fall. Patients should call their healthcare provider for medical advice about side effects.

From 2017 to March 13, 2022, Biogen and Eisai jointly collaborated on the development, commercialization and manufacturing of ADUHELM. Effective March 14, 2022, Biogen has sole decision-making authority over the development, commercialization and manufacturing of ADUHELM. In 2022 the parties will continue in a global profit/loss sharing arrangement subject to a cap on Eisai's expenses for 2022. Eisai will be entitled to a tiered royalty on net sales of ADUHELM as of January 1, 2023.

Please click here for [full Prescribing Information](#), including [Medication Guide](#), for ADUHELM.

### About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, \$250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on our website at [www.biogen.com](http://www.biogen.com). To learn more, please visit [www.biogen.com](http://www.biogen.com) and follow Biogen on social media – [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

### Biogen Safe Harbor

This statement contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential clinical effects of ADUHELM; the potential benefits, safety and efficacy of ADUHELM; the treatment of Alzheimer's disease; clinical development programs, clinical trials and data readouts and presentations; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; the occurrence of adverse

safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; difficulties in obtaining and maintaining adequate coverage, pricing and reimbursement for our products; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks associated with current and potential future healthcare reforms; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

###

**MEDIA CONTACT(S):**

**Biogen**

Ashleigh Koss

+ 1 908 205 2572

[public.affairs@biogen.com](mailto:public.affairs@biogen.com)

**INVESTOR CONTACT(S):**

**Biogen**

Mike Hencke

+1 781 464 2442

[IR@biogen.com](mailto:IR@biogen.com)