

For Immediate Release

Media Contact: Edwina Blackwell Clark
edblackwellclark@alz.org

Draft Medicare Coverage Decision Adds Barriers to Accessing New Alzheimer's Drug

When Shelley Goshorn and Vance Seagle moved back to the Greater Cincinnati area three years ago, they couldn't find an Aducanumab clinical trial in the area that he could transfer to.

Seagle had been on the Alzheimer's drug since around 2015, except for the year or so that Biogen, the maker of the newly approved FDA drug Aducanumab/Aduhelm, halted the trials.

So, for 18 months they flew monthly back to Las Vegas to allow Seagle to get the treatment that Goshorn said is instrumental in Seagle having some recollection of who he is.

Today, they drive to Indianapolis monthly to continue treatments there in a clinical trial. His time in the trial ends in June and while Seagle has Medicare, Goshorn said she is worried because of the restrictions Medicare has placed on coverage of the drug in its draft coverage decision.

"I don't have \$28,000 a year to pay for it so we are really not sure what is going to happen," Goshorn said. "The difference between being on the drug and not being on the drug is he knows who he is when he is on the drug. He knows who I am, and he knows his dogs, and he knows he is at home. He's still him," she said.

On January 11, The Centers for Medicare & Medicaid Services proposed that Medicare would only cover FDA-approved drugs, like Aduhelm, that target amyloid for the treatment of Alzheimer's disease if individuals are enrolled in qualifying clinical trials.

The Alzheimer's Association said the draft decision not only severely limits access to Aduhelm, but also any future FDA-approved treatments targeting amyloid in those living with Alzheimer's disease. Eric VanVlymen, Regional Leader for the Alzheimer's Association in Ohio said, "We are concerned that access to treatments would now only be available to a privileged few — those who live near research institutions or can afford to pay out-of-pocket and 'skip the steps' imposed by this decision. What about the 220,000 Ohioans living with Alzheimer's disease? All Americans living with Alzheimer's disease are entitled to therapies, just as people with conditions like cancer, heart disease and HIV/AIDS," he said.

Requiring people to participate in a clinical trial also adds time to gain access to an approved treatment – something many Alzheimer's caregivers feel that their loved ones do not have.

"The drug doesn't work for everybody. I understand that," Goshorn said. "But if it's your wife, your husband and you are watching that person and they at least are still present in being a person, (with the drug) you want that. If not, it's over," Goshorn said.

Dr. Babak Tousi, head of the clinical trials program at the Cleveland Clinic Lou Ruvo Center for Brain Health, said the problem with requiring clinical trial participation so that Medicare covers the costs is that "if something is approved and we're offering them participation in a clinical trial, some participants of the trial will receive non-active medication (placebo)."

He said adding in more trials just makes things longer. "I am concerned. Whatever this draft is I hope it can be optimized in a clearer way," he said.

At The Ohio State University Wexner Medical Center's Center for Cognitive and Memory Disorders, Dr. Douglas Scharre, Director, said they are currently giving Aducanumab infusions to 16 patients. Three of them participated in an earlier clinical trial with the drug.

Currently he has patients where Medicare is picking up the cost. But with the current draft coverage decision, "If they limit the use to clinical trials, I am wondering what they will do with the patients already taking the treatment. Just have them stop if they have no funds to cover the costs? Since we are a research site, we could probably offer them a study where they could get the medication. Other places will not have that option," Dr. Scharre said.

Since 2011, there have been seven clinical studies using Aducanumab in Ohio, according to clinicaltrials.gov. Currently one study is active at the Wexner Medical Center and Cleveland Clinic to evaluate the safety of Aducanumab in patients like Seagle, who have participated previously in other Aducanumab studies. One study in Dayton is evaluating another drug being tested, Donanemab, to Aducanumab and another study in Centerville, Ohio has not started recruiting yet. A few other sites in the state are providing the Aducanumab infusions.

Dr. Rhonna Shatz, medical director of the University of Cincinnati Memory Disorders Center, said, while UC Health announced in June it would be among three sites in Ohio to provide the new Alzheimer's treatment, the Center has yet to treat anyone. After the announcement, her practice talked to about 50 people, she said and approximately 10 people went through their screening process. Of the number of patients her practice has screened, only two individuals have met the criteria "but the issue of payment is a problem so it's kind of in limbo," she said.

Pamela Mizer is one of Dr. Scharre's patients. She and her husband live in New Philadelphia, Ohio and drive about 1.5 hours to New Albany, Ohio to receive the monthly Aducanumab infusions. She started in July, after the FDA approved the drug. "Some days I seem to be clearer and other days, forget about it I can't focus," she said. Her husband Charles said he feels fortunate to have access to the drug treatment. "We

have not paid anything. When we get our statement from Medicare, it is not there," he said.

The uncertainty over coverage just adds to caregivers' worries. Goshorn said, "to watch someone who deserves better just sit in a chair and turn into a vegetable when there is something that can be done, that's not right....They pay for all other kinds of things that aren't nearly as important as this disease. It is the ravage of our generation. Wait until so many more people have it," she said.