

Neurologists' group issues guidance to families on controversial Alzheimer's drug

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Neurologists must make sure Alzheimer's patients and their families

understand that the controversial drug aducanumab does not restore mental function, the American Academy of Neurology (AAN) said in new position statement that includes ethical guidelines.

"Aducanumab is not a cure for Alzheimer's disease, yet since it has been approved by the [U.S. Food and Drug Administration], patients are asking their doctors if this is an option for them," said statement author Dr. Winston Chiong, an associate professor at the University of California San Francisco and member of the AAN's Ethics, Law and Humanities Committee.

"This is a high-cost [drug](#) that was approved by the FDA without convincing evidence of benefits and with known harms, so the purpose of this position statement is to offer ethical guidance on how neurologists can help patients make informed decisions about this treatment," Chiong said in an AAN news release.

The U.S. Food and Drug Administration approved [aducanumab](#) (brand name: Aduhelm) based on two studies that were both stopped early because the drug showed no benefits for patients. The statement explained that a later analysis of data from one of those studies suggested a small benefit, while the other still showed no benefit.

The statement noted that while aducanumab reduces the [beta-amyloid plaques](#) in the brain that are markers of Alzheimer's, it's unclear whether that provides any meaningful benefits to patients.

There isn't sufficient evidence to offer the drug to patients with moderate or advanced dementia, or to those without evidence of beta-amyloid in the brain, according to the position statement published Nov. 17 in the journal *Neurology*.

It also said the drug carries a risk of brain inflammation and brain

bleeds, which occurred in a third of patients in the studies who received the dose approved by the FDA.

The statement said neurologists must inform patients and families about the drug's potential risks of and the need for more frequent monitoring with MRI scans.

Another issue is the lack of racial and [ethnic diversity](#) in the clinical trials of aducanumab. Patients in racial and ethnic minorities need to be told about the lack of safety and effectiveness data for them, the statement said.

In addition, it warned that pricing and insurance coverage of the drug may cause financial harm to patients and their families.

Aducanumab is priced at \$56,000 a year. But the costs of infusing the drug, repeated imaging and [medical management](#) may push annual costs to more than \$100,000. Medicare generally covers 80%, so patients and families must be told that the full cost of treatment may not be covered, the statement advised.

The statement said another concern is that availability of aducanumab may lead to lower patient enrollment in clinical trials of more effective treatments.

More information: The U.S. National Institute on Aging has more about [Alzheimer's disease treatment](#).

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