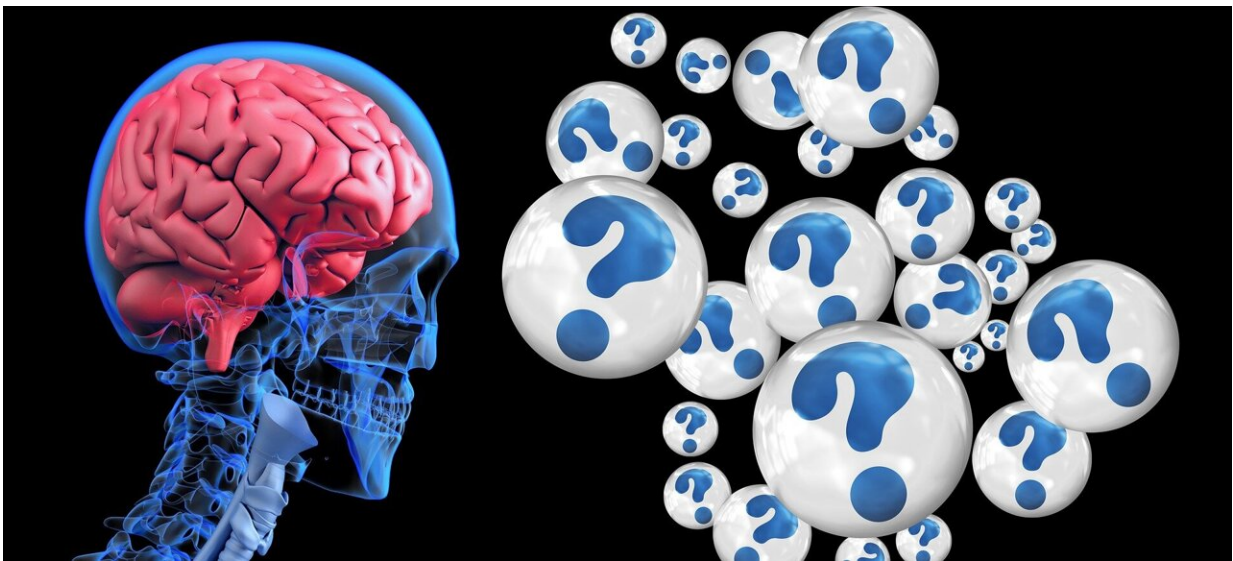


New Alzheimer's drug shines light on need for assessments to head off 'a tsunami of cognitive afflictions'

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Two stories dominated Alzheimer's news this year: The FDA's approval of Leqembi, the first drug to slow progression of the disease, and a surprising study showing that mild cognitive impairment is wildly underdiagnosed.

"For [mild cognitive impairment](#), or MCI, caused by Alzheimer's disease, the earlier you treat the better your outcomes," says Soeren Mattke,

director of the Brain Health Observatory at USC Dornsife's Center for Economic and Social Research. "This means even though the disease may be slowly progressing, every day counts."

Mattke led a [recently published study](#) that suggests that of the 8 million Americans who have MCI, more than 90% don't know it.

"The obstacles beyond lack of early detection are many. We have written a lot about limited capacity for Alzheimer's specialists and PET scanners to determine eligibility for those treatments, if patients actually get referred in a timely manner.

"Medicare Part B, which pays for physician-administered drugs, has a 20% co-payment without upper limit, i.e., around \$5,000 per year just for the drug. Higher income individuals typically buy Medigap insurance to cover those co-pays, but middle-income ones tend to forgo that because of the cost of these policies. For low-income individuals, who are eligible for Medicare and Medicaid, Medicaid covers the co-pays, but physicians might not accept them because of arcane Medicaid payment rules.

"Then there is the problem of a drug that requires bi-weekly IV administration. The burden on caregivers is substantial, even for early-stage Alzheimer's patients."

Cognitive screening must become part of routine care

In a recent opinion piece in [MedPage Today](#), Julie Zissimopoulos, a professor in the USC Sol Price School of Public Policy and co-director of the Aging and Cognition Program at the USC Schaeffer Center for Health Policy & Economics, writes that important pieces of the diagnosis and treatment puzzle are missing.

"The amyloids need to be cleared before they can ravage the brain, which puts greater emphasis on cognitive screening to find individuals most at risk.

"Just over one-third of older Americans report being assessed for cognitive issues. Medicare requires that a comprehensive cognitive assessment be included in each enrollee's annual wellness visit, but only a quarter of those who have a wellness appointment report undergoing a formal cognitive screening.

"This situation must change if the country hopes to acquire the basic information needed to forestall a tsunami of cognitive afflictions."

Weighing risks versus potential for small benefit

In its approval of Leqembi, the FDA included its strongest warning label—called a boxed warning—about potential side effects of brain swelling and bleeding, noting that they can lead to seizures and death.

"You've got small benefits and a certain risk for [serious adverse events](#), and that has to be balanced," said Lon Schneider, a professor of psychiatry at the USC Leonard Davis School of Gerontology and director of the USC State of California Alzheimer's Disease Center, who said he will prescribe Leqembi to carefully evaluated patients. "If its efficacy were greater, we would not be talking about adverse events as much because we would see a clear benefit.

"I think many people will see this and say it's not worth the effort, it's not worth twice-a-month infusions. Others might consider that any [clinical benefit](#) may be worth the risk."

Pharmacists can identify causes of reversible

cognitive 'slippage'

"Accurate diagnosis is extremely important. Leqembi has only been approved in Alzheimer's disease alone. Dementia often presents as a mixture of Alzheimer's and vascular disease. Leqembi was not studied in that mixed patient group to my knowledge. Adverse reactions are more likely," said Tatyana Gurvich, an associate professor of clinical pharmacy at the USC Mann School of Pharmacy and Pharmaceutical Sciences.

"One of the reversible causes of cognitive slippage are high risk medications such as those with an anticholinergic profile as well as some sedative hypnotic meds. Pharmacists should be working together with prescribers to deprescribe those meds so that a more accurate diagnosis is made.

"If Leqembi is being considered, a careful medication review by a geriatric clinical pharmacist can be helpful to eliminate high risk medications, which contribute to cognitive decline as well as those medications and supplements which increase the risk of bleeding and other adverse events."

A new Medicare proposal would cover training for family caregivers

A dementia diagnosis doesn't come with an instruction book for [family members](#), but a new Medicare proposal would cover training for informal caregivers. The expectation is that Medicare will start paying for caregiver training next year, and caregivers should start asking for it then, according to KFF Health News. About 42 million Americans provided unpaid care to people 50 and older in 2020, according to an [AARP report](#).

"This is a long-overdue recognition of the role of informal caregivers, who are an important part of the health care delivery system," said Donna Benton, a research associate professor of gerontology at USC Leonard Davis and director of the USC Family Caregiver Support Center.

"When possible, training should take place in a person's home rather than at a health care institution. All too often, recommendations caregivers get from health professionals aren't easy to implement at home and need to be adjusted."

'We have turned a corner'

Paul Aisen, founding director of USC's Alzheimer's Therapeutic Research Institute, said that with Leqembi slowing clinical progression of the disease, Alzheimer's research has turned a corner. However, the illness may need to be attacked from multiple directions.

"Controversy will continue. How important is the 27% slowing of progression seen with (Leqembi)," Aisen wrote in the *Journal of Prevention of Alzheimer's Disease*.

"For greater benefit in symptomatic Alzheimer's disease, a combination therapy approach may be required. Other strategies abound, from anti-tau therapies to neuroprotective, vascular, anti-inflammatory, and neuroendocrine approaches ...

"We must continue to rigorously pursue the most plausible approaches. Rapid progress will require collaboration and sharing of data and methodologies, and the generous participation of representative populations in our trials."

Provided by University of Southern California

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