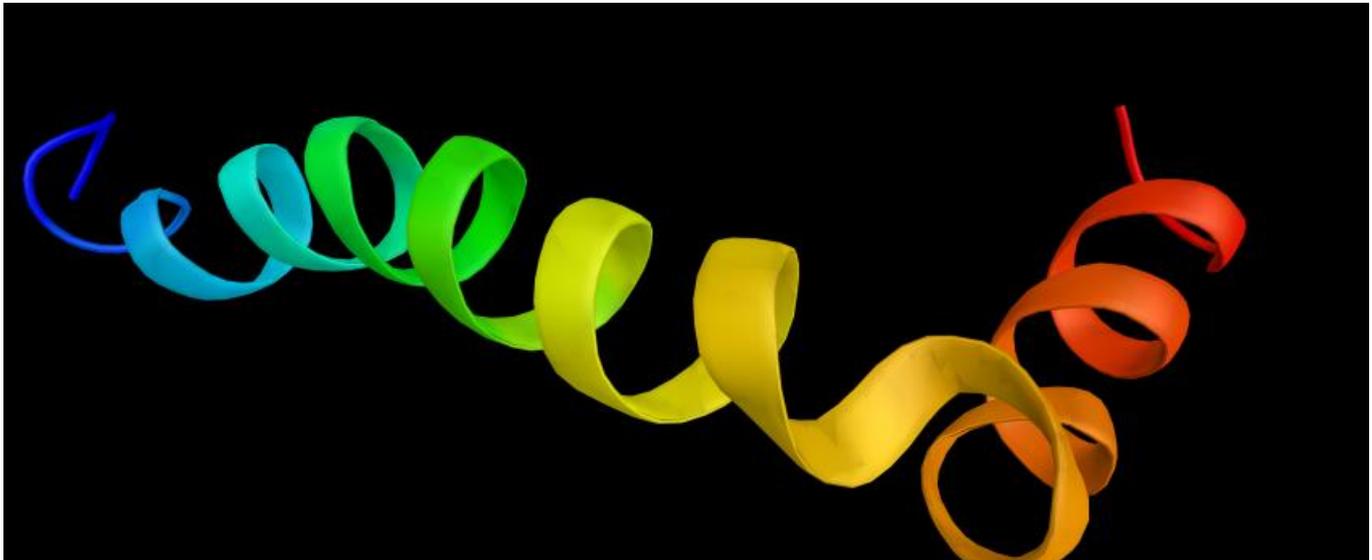


Aduhelm approval amplifies amyloid assays



[Elizabeth Cairns](#)



Biogen needs blood tests for amyloid beta to progress quickly - and several are in the pipeline.

The label granted to Aduhelm with yesterday's accelerated approval was broad: Biogen's anti-amyloid MAb is indicated, quite simply, [for the treatment of Alzheimer's disease](#). But many industry watchers expect the product to be used only in patients exhibiting amyloid pathology, not least because of the \$56,000 per year price tag.

This creates a golden opportunity for the few companies that have developed blood tests to screen patients for amyloid. The private group C2N Diagnostics is the leader here, being the only company with a marketed blood test for amyloid beta. But Quanterix, which is mostly focused on testing for a different Alzheimer's biomarker, closed up 11% yesterday.

The gold-standard for diagnosing amyloid plaques is Pet imaging of the patient's brain. This is time-consuming and expensive, and demand already exists for tests that can pick up amyloid in other ways.

Speaking on a conference call today, Alisha Alaimo, president of Biogen's US organisation, said that the decision of whether to test patients for amyloid "has been left to the judgement of the prescribing physician". This testing is not routine, she said, and there is currently no reimbursed test for amyloid.

Cerebrospinal fluid tests have been available for some time, with PerkinElmer, for instance, offering tests for two forms of the substance: the 40-residue peptide amyloid beta (1-40), which is the most abundant isoform in the brain, and the 42-residue amyloid beta (1-42), which is increased with certain forms of Alzheimer's. Roche offers a CSF test for the 1-40 isoform.

Biogen said yesterday that along with its partner Eisai it has set up a program with Labcorp and Mayo Clinic Laboratories to [boost access to CSF diagnostic laboratory testing](#). But CSF sampling involves a spinal tap and is not suitable for all patients - and is not much cheaper than Pet imaging.

On today's call the company admitted that it would need broad reimbursement of both CSF testing and Pet imaging for Aduhelm sales to really take off.

Blood tests are not only cheaper and more pleasant than either of the alternatives, they are also vastly more scalable and easily conducted. Biogen's chief executive, Michel Vounatsos, said: "I want to believe that soon we'll have also a blood diagnostic, and this will make things much easier."

A new frontier

In fact a blood test for amyloid beta already exists. C2N's PrecivityAD is available on a commercial basis as a lab-developed test, and is used to recruit amyloid-positive patients into clinical trials of pharmaceutical agents that act on the amyloid pathway, as well as to aid doctors in their diagnosis of the disease ([A new market beckons for Alzheimer's blood tests](#), April 19, 2021).

Selected tests for amyloid beta			
Company	Test	Sample	Availability
C2N diagnostics	PrecivityAD - tests for amyloid beta 42/40 ratio and the apolipoprotein E proteotype	Blood	On sale to aid in Alzheimer's diagnosis
ADx Neurosciences	Amyblood - tests for amyloid beta (1-40) and (1-42)	Blood	In development
Quanterix	Simoa A β 40 Advantage Kit	Blood	On sale for research only
Quanterix	Simoa A β 42 Advantage Kit	Blood	On sale for research only
Perkinelmer	Beta-amyloid (1-40) Elisa	CSF	On sale to aid in Alzheimer's diagnosis
Perkinelmer	Beta-amyloid (1-42) Elisa	CSF	On sale to aid in Alzheimer's diagnosis
Roche	Elecsys β -Amyloid(1-42) CSF	CSF	On sale for research only
Quanterix	Neurology 3-Plex A assay - tests for tau, amyloid beta (1-40) and (1-42)	CSF	On sale for research only

Source: Company websites.

It seems unlikely that a relatively obscure private group will remain the only provider of an amyloid blood test for long. Larger groups might begin to mull a bid for C2N. And other companies will be keen to get into the amyloid blood testing arena.

One possibility is Quanterix, which has developed a plasma assay for tau, the other main Alzheimer's biomarker. The test is currently used to aid research into Alzheimer's and to identify suitable patients for trials of anti-tau projects, but it could see huge demand if [agents acting on the tau pathway](#), such as Lilly's zagotenemab, follow Aduhelm onto the market.

Quanterix has a CSF test and a couple of blood tests for amyloid, but these may only be used for research into the disease. Leerink analysts believe that the tests have the potential to screen for patients eligible to receive Biogen's drug, though they add that such an indication would require further studies. Intriguingly, Quanterix told the analysts that Biogen is one of its leading customers.

Any company pursuing an amyloid blood or CSF test as some sort of companion diagnostic to Aduhelm would be well advised to put the assay on an officially approved footing, not least because this would be necessary for obtaining reimbursement. C2N is known to be working towards FDA approval for PrecivityAD, and Biogen will be hoping that others follow.