



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# European Medicines Agency recommends approval of first radiopharmaceutical for PET imaging of $\beta$ -amyloid neuritic plaque density

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Amyvid (florbetapir  $^{18}\text{F}$ ) as a diagnostic agent in patients who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.

Amyvid is a radiopharmaceutical agent used in positron emission tomography (PET) imaging in the brains of adults. It can highlight amyloid protein plaques in the brain, and assist in the diagnosis of AD.

Alzheimer's disease is the most common cause of dementia in the elderly, affecting up to 5.1 million people in the European Union. Accurate diagnosis of AD has been hampered to date by the lack of diagnostic tests. The current gold standard for confirming a clinical diagnosis of AD is post-mortem autopsy.

### Benefits of PET imaging using Amyvid

PET imaging using Amyvid can provide useful information on neuritic plaque density in the brains of patients who are being tested for cognitive decline. Following intravenous injection, the radioactive agent Amyvid binds to  $\beta$ -amyloid in the brain.  $\beta$ -amyloid protein is present in the brains of people with AD and other cognitive disorders.

Importantly, a negative Amyvid PET scan can rule out the presence of AD, and is expected to reduce the frequency of false positive diagnosis. However, a positive Amyvid scan is consistent with, but does not independently establish, the diagnosis of AD since  $\beta$ -amyloid neuritic plaque deposition may also be present in the brain of asymptomatic elderly and some neurodegenerative dementias, including Parkinson's disease dementia and Lewy body dementia.

Common adverse reactions include headache and taste alterations.

Given the public health burden of AD, there is great interest in the qualification of biomarkers allowing the study of AD earlier in the disease process, and investigating whether the use of potentially disease-modifying agents can alter the long-term course of the illness and prevent the neurodegenerative cascade associated with the disease.



## Notes

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1. This press release, together with all related documents, is available on the Agency's website.
2. More information about the qualification of biomarkers is available here:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000319.jsp&mid=WCOb01ac0580022bb0](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000319.jsp&mid=WCOb01ac0580022bb0)
3. More information on the work of the European Medicines Agency can be found on its website:  
[www.ema.europa.eu](http://www.ema.europa.eu)

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