



September 27, 2013

Lilly Disappointed in Medicare Decision to Deny Appropriate Patient Access to Beta-Amyloid Imaging Agents, Including Amyvid™ (Florbetapir F 18 Injection), Despite Support From Experts, Patients and the Alzheimer's Disease Community

Company Remains Committed to Alzheimer's Disease Research and Development to Bring Innovative New Products to Patients Who Need Them Most

INDIANAPOLIS, Sept. 27, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) is disappointed that the Centers for Medicare & Medicaid Services (CMS) has denied patient access to beta-amyloid imaging agents, such as Amyvid™ (Florbetapir F 18 Injection). This final decision is not only contrary to expert opinion and published Appropriate Use Criteria previously recommended by the Alzheimer's Association and the Society of Nuclear Medicine and Molecular Imaging, but contradicts the statutory authority CMS has over coverage determinations for diagnostics. Denying appropriate patient access is also in conflict with the administration's National Alzheimer's Project Act.¹ CMS participated in creating this plan aimed at developing new and innovative ways to diagnose, support and treat patients suffering from Alzheimer's Disease¹—yet the same agency is challenging the value of the only technology approved by the Food and Drug Administration (FDA) for estimating beta-amyloid neuritic plaque density in the living brain, which can aid in helping doctors make a more informed diagnosis.²

Amyvid is a beta-amyloid imaging agent for use in adults with thinking or memory problems who are being assessed for Alzheimer's Disease or other causes of these symptoms. Amyvid is used by doctors in combination with other tests. A positive Amyvid scan does not diagnose Alzheimer's Disease or other thinking or memory disorders. Amyvid is not approved to predict the development of dementia or other brain conditions in the future or for monitoring the effectiveness of treatments. Amyvid for intravenous use is supplied in 10 mL, 30 mL, or 50 mL multidose vials containing 500-1900 MBq/mL Florbetapir F 18.²

"Coverage with Evidence Development as proposed by CMS does not provide patients appropriate access to these amyloid imaging brain scans. Instead, it creates additional complexity for the broader community in determining the best path forward for patients," said Eric Dozier, senior director, Alzheimer's Business Division, Eli Lilly and Company. "As we continue to review the final decision memo, we will be evaluating all available options to ensure patients and physicians can gain access to this innovative diagnostic tool as soon as possible."

About Alzheimer's Disease

Alzheimer's Disease, a fatal illness, is the most common form of dementia, accounting for 60 to 80 percent of dementia cases.³ It continues to be one of the most significant health challenges facing the United States, with an estimated 5.2 million Americans already suffering from the disease—5.0 million of whom are aged 65 and over.³ Alzheimer's Disease is one of many possible causes of cognitive impairment, which can make diagnosis challenging.^{3,4} In fact, it is estimated that up to one in five patients clinically diagnosed with probable Alzheimer's Disease during life do not exhibit Alzheimer's Disease pathology upon autopsy.^{5,6} If it is determined that Alzheimer's Disease is not the cause of a patient's cognitive impairment, their doctor can avoid or discontinue unnecessary or potentially harmful treatments and investigate other possible causes.^{7,8,9}

About Amyvid²

Amyvid is a radioactive diagnostic agent that is injected into the bloodstream, where it crosses the blood-brain barrier and selectively binds to amyloid plaques. The fluorine 18 (F 18) isotope produces a positron signal, which is detected by a PET scanner. Doctors who read Amyvid PET scans should complete a comprehensive training program available through live events or online at AmyvidTraining.com.

For more information about Amyvid, please see Prescribing Information at <http://pi.lilly.com/us/amyvid-uspi.pdf>.

INDICATIONS AND USAGE²:

Amyvid is approved for use in adults with thinking or memory problems who are being assessed for Alzheimer's Disease (AD) or other causes of these symptoms. Amyvid is used by doctors in combination with other tests.

Amyvid is used with a positron emission tomography (PET) scanner to show whether high levels of plaques, which are a buildup of a protein called beta-amyloid, are in the brain.

A negative Amyvid scan means that there are few to no plaques in the brain and makes it unlikely that AD is the cause of symptoms at the time of the scan.

A positive Amyvid scan means that the amount of plaque in the brain is similar to the amount seen in people with AD. This amount of plaque may also be seen in people with other conditions of the brain that cause thinking or memory problems, as well as in older people with normal thinking and memory.

A positive Amyvid scan does not diagnose AD or other thinking or memory disorders. Amyvid is not approved to predict the development of dementia or other brain conditions in the future or for monitoring the effectiveness of treatments.

IMPORTANT SAFETY INFORMATION²:

What is the most important information I should know about Amyvid?

- **Risk for Misreading Scans and Other Errors**

Errors may happen when Amyvid scan images are read. In clinical studies, a scan read as negative, when it was actually positive, accounted for most of these errors. An Amyvid scan only indicates whether beta-amyloid plaques, which are a buildup of proteins in the brain, are present at the time of the scan. Even if the scan is negative, it is possible to develop plaques in the future

- **Radiation Risk**

Amyvid, like other radioactive diagnostic agents, adds to overall, long-term combined radiation exposure. Long-term combined radiation exposure may increase risk of cancer

What are the most common side effects of Amyvid?

- Headache
- Muscle or joint pain
- Tiredness
- Nausea

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/safety/medwatch or call **1-800-FDA-1088**.

What should I tell my doctor before taking Amyvid?

- Tell your doctor if you are pregnant or breast-feeding
- Tell your doctor about any prescription or over-the-counter medicines you are taking

Amyvid is available by prescription only.

See [Prescribing Information](#).

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About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers—through medicines and information—for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains certain forward-looking statements about Amyvid™ (Florbetapir F 18 Injection), a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline. This release reflects Lilly's current beliefs; however, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that Amyvid will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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- ¹ National Plan to Address Alzheimer's Disease: 2013 Update. US Department of Health and Human Services Web site. <http://aspe.hhs.gov/daltcp/napa/NatlPlan2013.shtml>. Updated June 14, 2013. Accessed September 26, 2013.
- ² Amyvid [package insert]. Indianapolis, IN: Lilly USA, LLC; 2012.
- ³ Alzheimer's Association. 2013 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2013;9(2):208—245.
- ⁴ Balasa M, Gelpi E, Antonell A, et al; for the Neurological Tissue Bank/University of Barcelona/Hospital Clínic NTB/UB/HC Collaborative Group. Clinical features and APOE genotype of pathologically proven early-onset Alzheimer disease. *Neurology*. 2011;76(20):1720—1725.
- ⁵ Lim A, Tsuang D, Kukull W, et al. Clinico-neuropathological correlation of Alzheimer's disease in a community-based case series. *J Am Geriatr Soc*. 1999;47(5):564—569.
- ⁶ Petrovitch H, White LR, Ross GW, et al. Accuracy of clinical criteria for AD in the Honolulu-Asia Aging Study, a population-based study. *Neurology*. 2001;57(2):226—234.
- ⁷ Alzheimer's Association. 2011 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2011;7(2):208—244.
- ⁸ Boise L, Neal MB, Kaye J. Dementia assessment in primary care: results from a study in three managed care systems. *J Gerontol A Biol Sci Med Sci*. 2004;59(6):621—626.
- ⁹ Mendez MF, Shapira JS, McMurtray A, et al. Preliminary findings: behavioral worsening on donepezil in patients with frontotemporal dementia. *Am J Geriatr Psychiatry*. 2007;15(1):84—87.

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