



FDA approves updated label for Lilly's Amyvid (florbetapir F 18 injection) to support diagnosis of Alzheimer's disease in patients

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INDIANAPOLIS, JUNE 25, 2025 – Eli Lilly and Company (NYSE: LLY) announced that the U.S. FDA has approved a label update for Amyvid (florbetapir F 18 injection) for intravenous use. Amyvid is used for brain imaging to estimate amyloid plaque density in patients with cognitive impairment being evaluated for Alzheimer's disease and other causes of cognitive decline.

The label update includes the following:

- Revises how Amyvid can be used to estimate plaque density in patients being evaluated for Alzheimer's disease and other causes of cognitive decline and in patients who are potential candidates for amyloid-targeting therapy.
- Provides a new indication for the selection of patients for amyloid-targeting therapy.
- Quantification of amyloid plaque levels can be used in conjunction with the visual interpretation.
- Updates the clinical studies section of the label to note that amyloid beta positron emission tomography (PET) scans have been used to assess reduction of plaque in some clinical trials of amyloid-targeting therapies as also described in the prescribing information of the therapeutic products.

Amyloid is a protein produced naturally in the body that can clump together to create amyloid plaques. The excessive buildup of amyloid plaques in the brain may lead to memory and thinking issues associated with Alzheimer's disease ¹ – and is the target of approved medicines. Amyvid binds to amyloid plaques, which can be detected using positron emission tomography (PET) scan images of the brain and can help confirm or identify presence of excessive amyloid plaque levels to aid in the diagnosis of Alzheimer's disease when paired with other diagnostic evaluations. ²

"Nearly 80% of Americans would prefer to know if they have an Alzheimer's diagnosis before their memory and thinking symptoms disrupt daily life ³, highlighting the importance of advanced diagnostic tools like amyloid PET and blood biomarker testing," said Mark Mintun, M.D., group vice president, Neuroscience Research & Development, Lilly. "The modernization of Amyvid's label is a significant step in advancing Alzheimer's care, enabling physicians to help patients make informed decisions, being evaluated for or to aid in the selection of patients who are indicated for amyloid-targeting therapy."

In patients being evaluated for Alzheimer's disease and other cognitive issues who haven't been treated with an amyloid-targeting therapy ²:

- A negative scan means there are few or no amyloid plaques, making Alzheimer's disease less likely.
- A positive scan shows moderate to frequent amyloid plaques, indicating a higher chance of Alzheimer's disease.

Refer to Indication and Important Safety Information below.

Amyloid PET, including Amyvid, is broadly covered by both Medicare and other insurance plans. Coverage details do vary by plan, so it is important that healthcare providers check with the patient's individual plan for coverage details.

About Amyvid

Amyvid is a radioactive diagnostic agent tagged with a radioisotope called fluorine-18. Once Amyvid is injected into a vein, it travels through the bloodstream and into the brain, binding to amyloid plaques. Amyvid produces a positron signal, which is detected by a PET scanner and used to create a brain image. A radiologist, who should have successfully completed Amyvid reader training, then interprets the image to evaluate it for the presence or absence of significant amyloid plaques (i.e., moderate to frequent levels of neuritic plaques) in the brain. This information is reported back to the referring physician, who then determines the next steps in the evaluation and management of the patient. Because Amyvid loses over half of its radioactivity every two hours, Amyvid must be distributed directly from a radiopharmacy to the imaging centers where it will be administered within several hours. Errors may occur in the estimation of plaque density during image interpretation.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

Amyvid is a radioactive diagnostic drug indicated for positron emission tomography (PET) of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment for:

- Evaluation of Alzheimer's disease (AD) and other causes of cognitive decline.
- Selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products.

IMPORTANT SAFETY INFORMATION

Risk for Image Misinterpretation and Other Errors

- Errors may occur in the estimation of brain amyloid beta neuritic plaque density during Amyvid image interpretation.
- The use of clinical information in the interpretation of Amyvid images has not been evaluated and may lead to an inaccurate assessment. Extensive brain atrophy as well as motion artifacts that distort the image may limit the ability to distinguish gray and white matter on an Amyvid scan.

Perform image interpretation independently of the patient's clinical information. For cases where there is uncertainty as to the location of cortical signal, use co-registered anatomical imaging to improve localization of signal.

Radiation Risk

- Amyvid contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

The **most common adverse reactions** reported in clinical trials were headache (1.8%), musculoskeletal pain (0.7%), blood pressure increased (0.7%), nausea (0.7%), fatigue (0.5%), injection site reaction (0.5%), anxiety (0.4%), back pain (0.4%), claustrophobia (0.4%), dizziness (0.4%), feeling cold (0.4%), insomnia (0.4%) and neck pain (0.4%).

Amyvid (florbetapir F 18 injection) for intravenous use is supplied in multidose vials containing 500-1900 MBq/mL.

[Please see Full Prescribing Information for Amyvid.](#)

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About Lilly

Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit [Lilly.com](https://www.lilly.com) and [Lilly.com/news](https://www.lilly.com/news), or follow us on [Facebook](#), [Instagram](#) and [LinkedIn](#). P-LLY

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Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Amyvid (florbetapir F 18 injection) and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. For discussion of risks and uncertainties, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

References

1. Porsteinsson AP, Isaacson RS, Knox S, et al. Diagnosis of early Alzheimer's disease: clinical practice in 2021. *J Prev Alzheimer's Dis.* 2021;8:371-386.
2. Amyvid (florbetapir F 18 injection). *Prescribing Information.* Lilly USA, LLC.
3. Alzheimer's Association. *Alzheimer's Disease Facts and Figures. Alzheimer's Disease and Dementia. Published 2025.* <https://www.alz.org/alzheimers-dementia/facts-figures>