PREPARING A COVERAGE AUTHORIZATION APPEALS LETTER

AMYVID®
Florbetapir F 18 Injection

The following information is presented as a guide for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Eli Lilly and Company, with the use of the information contained herein, does not guarantee success in obtaining insurance payments. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. Lilly Support Services™ for Amyvid® is here to support you and your patients. If you have any questions, please call 1-800-LillyRx (1-800-545-5979).

If the patient's initial claim or Coverage Authorization Request Letter is denied by the patient's health plan, the payer may require a Coverage Authorization Appeals Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing a Coverage Authorization Appeals Letter**, provides information to healthcare providers (HCPs) when appealing a coverage authorization decision for a patient's plan. Included on the following page is a list of considerations that can be followed when creating a Coverage Authorization Appeals Letter. In addition, a sample letter is included in this document and features information that many plans require to process a coverage authorization appeal. **Follow the patient's plan requirements when requesting Amyvid.**

A **Coverage Authorization Appeals Letter** originates from the prescribing HCP.* It should be submitted with 2 additional items: the patient's medical records and a Letter of Medical Necessity. Also see **Composing a Letter of Medical Necessity** for more information.

*For Medicare beneficiaries, specific requirements must be met for the HCP to be considered a legal representative of the patient in an appeal. To download the form, please visit https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf.

INDICATION

Amyvid is a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.

A negative Amyvid scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Amyvid scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Amyvid is an adjunct to other diagnostic evaluations.

LIMITATIONS OF USE:

- A positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder
- Safety and effectiveness of Amyvid have not been established for:
  - Predicting development of dementia or other neurologic condition
  - Monitoring responses to therapies

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

SELECT IMPORTANT SAFETY INFORMATION

Risk for Image Misinterpretation and Other Errors

- Errors may occur in the Amyvid estimation of brain neuritic plaque density during image interpretation
- Image interpretation should be performed independently of the patient's clinical information. The use of clinical information in the interpretation of Amyvid images has not been evaluated and may lead to errors. Other errors may be due to extensive brain atrophy that limits the ability to distinguish gray and white matter on the Amyvid scan as well as motion artifacts that distort the image
- Amyvid scan results are indicative of the brain neuritic amyloid plaque content only at the time of image acquisition and a negative scan result does not preclude the development of brain amyloid in the future

Please see Important Safety Information on Page 4 and click for full Prescribing Information for Amyvid.

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In 2023, the Centers for Medicare & Medicaid Services (CMS) removed the national coverage determination (NCD) for beta amyloid PET (§220.6.20). This ends the requirement of coverage with evidence development (CED) for beta amyloid PET imaging. Removal of the NCD from §220.6.20 permits Medicare coverage determinations to be made by Medicare Administrative Contractors (MACs).[1] In the case that a MAC or health plan denies coverage, the following considerations may help when appealing this decision.

COVERAGE AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. Include the patient's full name, date of birth, plan identification number, and case identification number, if applicable.
2. Add the prescribing HCP's National Provider Identifier (NPI) number and specialty.
3. Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter.
4. Provide a copy of the patient's records with the patient's history and other relevant clinical information, which may include but is not limited to:
   - Signs of cognitive decline and relevant ICD-10 diagnosis code(s) as appropriate
   - Blood work
   - Magnetic Resonance Imaging (MRI), if applicable
   - Cognitive assessment with one or more validated tools, including date, type, and score. For example:
     - Clinical Dementia Rating (CDR) Scale
     - Mini-Mental State Examination (MMSE) score
     - Montreal Cognitive Assessment (MoCA)
     - Other cognitive tests and associated scores
   - Functional assessments with one or more validated tools, including date, type, and score. (For example: the Functional Activities Questionnaire (FAQ) score or other functional tests and associated scores).
5. Explain why the plan's preferred diagnostic tool and/or denial rationale(s) are not appropriate for the patient.
6. Note the severity of the patient's symptoms. Please include any co-morbidities, treatments, and all relevant information.
7. Provide the clinical rationale for needing an Amyvid scan, and how determining amyloid status could serve as an adjunct to other diagnostic evaluations. Information about Amyvid is available in the **Prescribing Information** and/or clinical peer-reviewed literature, such as the results of the IDEAS Study (*JAMA*. 2019;321(13):1286-1294), SNMMI guidelines (*J Nucl Med*. 2016;57(8):1316-1322), or Shea YF, et al (*J Alzheimers Dis.* 2018;66(4):1599-1608).
8. Summarize your recommendation at the end of the letter.
9. Include a Letter of Medical Necessity.

PET=positron emission tomography; SNMMI=Society of Nuclear Medicine and Molecular Imaging.

Reference: 1. CMS.gov. Beta amyloid positron emission tomography in dementia and neurodegenerative disease (CAG-00431R). Accessed October 13, 2023. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=308

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PREPARING A COVERAGE AUTHORIZATION APPEALS LETTER

HCPs CAN UTILIZE THIS SAMPLE LETTER TO APPEAL A COVERAGE DENIAL FOR AMYVID

[Date]
[Prior Authorization/Appeals Department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]
[Case Identification Number]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of radiopharmaceuticals. We are requesting that you reassess your recent denial of Amyvid (florbetapir F18 injection) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Amyvid is the appropriate diagnostic tool for this patient. In support of our recommendation for utilizing Amyvid, we have provided an overview of the patient's relevant clinical history below.

Patient's history, condition with diagnosis codes, and symptoms*:

[Provide clinical rationale for this diagnostic; this information may be found in the Amyvid Prescribing Information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis without more information that Amyvid PET scan would provide.]

Please feel free to contact me, **[HCP's name]**, at **[office phone number]**, for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]
[Email]

[Patient's name and signature]
Encl: Medical records
Clinical trial information

Patient must have cognitive impairment per the indication for Amyvid. Amyvid is a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.

Note: this is an overview only. Please see the full indication on the next page.

When appealing a denial, consider providing statements indicating why these requirements may not be appropriate for the patient. This may include possible consequences of delays in diagnosis and how more information could lead to deciding on the appropriate course of treatment for patients with cognitive decline.

*Include patient's medical records and supporting documentation.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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Radiation Risk

- Amyvid, similar to other radiopharmaceuticals, 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

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%), and injection site reaction (0.5%)

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Please see full Prescribing Information for Amyvid.

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