

BILLING AND CODING RESOURCE

Updated November 2023

The following information is presented 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. Individual coding decisions should be based upon diagnosis and treatment of individual patients. Eli Lilly and Company 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, coding, and payment policies. Please consult with your legal counsel or reimbursement specialist for any reimbursement or billing questions. For more information about Amyvid, please call Lilly Support Services at 1-800-LillyRx (1-800-545-5979).

INDICATION

Amyvid is indicated 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

EOS=end of synthesis; HCPCS=Healthcare Common Procedure Coding System; PSD=per-study dose.

How Supplied

Amyvid (Florbetapir F 18 Injection) for intravenous use is available in 50 mL and 100 mL multidose vials containing a clear, colorless solution at a strength of 500-1900 MBq/mL (13.5-51 mCi/mL) florbetapir F 18 at EOS. Each vial contains multiple doses and is enclosed in a shielded container to minimize external radiation exposure.¹ Imaging centers receive Amyvid in the form of a patient-ready dose. In billing HCPCS Level II terms, this is often referred to as a PSD.

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 last page and [Full Prescribing Information for Amyvid](#).



COVERAGE AND CODING

MEDICARE COVERAGE

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).² For Medicare Fee-for-Service, refer to the MAC for the location of service. For Medicare Advantage and commercial plans, refer to the plan provider for policy questions.

THIRD-PARTY PAYER COVERAGE

Insurance coverage may vary by plan. Please consult with the health plan or reimbursement specialist for any reimbursement or billing questions. For more information about Amyvid, please call Lilly Support Services at 1-800-LillyRx (1-800-545-5979).

CODING

The following codes may be used for patients insured by Medicare or third-party payers. Both the HCPCS A-code specific to Amyvid (A9586) and the appropriate CPT codes must be entered.³

Please note use of the following codes does not guarantee reimbursement.

SELECT IMPORTANT SAFETY INFORMATION

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%)

Please see Important Safety Information on last page and [Full Prescribing Information for Amyvid](#).

Hospital Outpatient and Independent Diagnostic Testing Facility Codes

CODES⁴

HCPCS: A9586

AND

CPT®: 78811

OR

CPT®: 78814

DESCRIPTION³

Florbetapir F 18, Diagnostic, Per Study Dose, Up to 10 mCi

PET Imaging; Limited Area (eg, Chest, Head/Neck)

PET Imaging With Concurrently Acquired CT for Attenuation Correction and Anatomical Localization Imaging; Limited Area (eg, Chest, Head/Neck)

NDC Code*

0002-1200-01

NDC Units

Units 1 "EACH"[†]

ICD-10-CM Diagnosis Codes^{5‡}

Code

Description

F03.90-F03.94

Unspecified dementia, unspecified severity

F03.A0-F03.C4

Unspecified dementia, mild/moderate/severe

G30.0-G30.9

Alzheimer's disease

*The NDCs listed in the Amyvid Prescribing Information are not commercially available and should not be used for billing and coding.

[†]Represents 10mCi dose.

[‡]The codes provided are not exhaustive and additional codes may apply. Listed codes may require a higher level of specificity when reporting for individual patients. Refer to specific payer or plan policies for additional information.

CPT=Current Procedural Terminology; CT=computed tomography; ICD=International Classification of Diseases; LCD=local coverage determination; PET=positron emission tomography.



SAMPLE CLAIM FORM CMS-1450 (UB-04)*

FL 42 AND 43: REVENUE CODES AND DESCRIPTION

Enter the revenue codes that correspond to HCPCS or CPT codes outlined in FL 44. Payers may vary on revenue code requirements for each procedure/service performed.

FL 44: PRODUCT AND PROCEDURE CODING

Enter the HCPCS and CPT code for the administration of Amyvid and the PET scan.

HCPCS:

A9586: Florbetapir F 18, diagnostic, per dose, up to 10 mCi

CPT:

78811: PET imaging; limited area (eg, chest, head/neck)

78814: PET imaging with concurrently acquired CT for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

FL 46: SERVICE UNITS

One (1) billable unit equals 1 per dose, 10 mCi or less.

FL 67: DIAGNOSIS CODES

Enter the appropriate ICD diagnosis code(s) that correspond(s) to the type and location of the disease with which the patient has been diagnosed.

FL 80: REMARKS

To support the review and payment of the claim, include additional information as required by respective payers. This may include NDC, total dosage, and date Amyvid was administered.

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

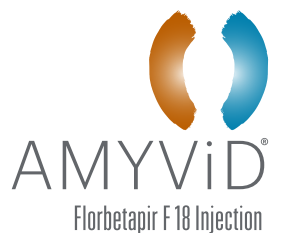
Please see Important Safety Information on last page and [Full Prescribing Information for Amyvid](#).

The image shows a sample CMS-1450 (UB-04) claim form. Several fields are highlighted with orange boxes and lines pointing to explanatory text on the left:

- 42 REV. CD.** and **43 DESCRIPTION**: Revenue codes and descriptions for services.
- 44 HCPCS / RATE / HIPPS CODE**: HCPCS codes and rates.
- 46 SERV. UNITS**: Service units for the procedure.
- 67**: ICD diagnosis codes.
- 80 REMARKS**: Additional information to support the claim.

The form includes various sections for patient information, insurance details, and provider information. A large 'SAMPLE' watermark is visible across the center of the form.

*For more information, please visit www.cms.gov.



SAMPLE CLAIM FORM CMS-1500*

BOX 19: ADDITIONAL CLAIM INFORMATION

To support the review and payment of the claim, include additional information as required by respective payers. This may include NDC, total dosage, and date Amyvid was administered.

BOX 21: DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the appropriate diagnosis code in lines A-L to identify the patient's diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity.

BOX 24D: PROCEDURES, SERVICES, OR SUPPLIES

Enter the HCPCS and CPT code for the administration of Amyvid and the PET scan.

HCPCS:

A9586: Florbetapir F 18, diagnostic, per dose, up to 10 mCi

CPT:

78811: PET imaging; limited area (eg, chest, head/neck)

78814: PET imaging with concurrently acquired CT for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

BOX 24E: DIAGNOSIS POINTER

Enter the diagnosis code reference letter, as shown in Box 21, to relate the date of service and the procedures performed to the primary diagnosis.

BOX 24G: DAYS OR UNITS

One (1) billable unit equals 1 per dose, up to 10 mCi or less.

SELECT IMPORTANT SAFETY INFORMATION

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%)

Please see Important Safety Information on last page and [Full Prescribing Information for Amyvid](#).

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM DD YY) SEX (M F)

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self Spouse Child Other)

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) (MM DD YY) QUAL.

15. OTHER DATE (MM DD YY) QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a. NPI

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM DD YY TO MM DD YY)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? (YES NO \$ CHARGES)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. |

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From MM DD YY To MM DD YY) B. PLACE OF SERVICE (EMG CPT/HCPCS) C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSON Family Plan I. ID, QUAL. J. RENDERING PROVIDER ID, #

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) (YES NO)

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

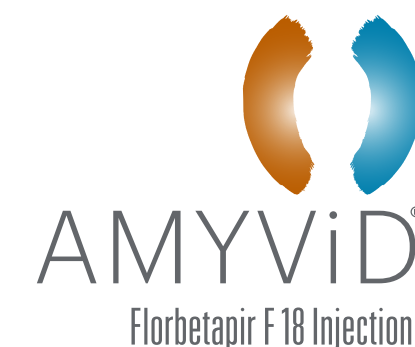
33. BILLING PROVIDER INFO & PH # ()

SIGNED DATE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

*For more information, please visit www.nucc.org and www.cms.gov.





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

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 healthcare 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%)

AM HCP ISI 14SEP2022

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

References: **1.** Amyvid (florbetapir F 18 injection). Prescribing Information. Lilly USA, LLC. **2.** 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> **3.** CMS.gov. HCPCS Quarterly Update. July 2023. Updated July 11, 2023. Accessed August 17, 2023. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update> **4.** Centers for Medicare & Medicaid Services. Billing and coding: independent diagnostic testing facility (IDTF) (A57807). Accessed August 3, 2023. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57807> **5.** Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries. Accessed July 31, 2023. https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2020/icd10cm_tabular_2020.pdf

Amyvid® is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates. All other trademarks are the property of their respective owners.
PP-AM-US-0427 11/2023 © Lilly USA, LLC 2023. All rights reserved.