



This resource is provided to assist health care providers and the patients they serve. This is not a guide or instructions. The processes outlined here do not guarantee payment. Providers must use independent medical judgment in determining whether an Axumin PET scan is appropriate for the patient. The provider has the responsibility to ensure correct prior authorization, appeal, and denial policies are followed.

Axumin is covered by Medicare for the FDA-approved indication only:

Axumin is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

IS THIS PATIENT APPROPRIATE FOR AXUMIN IMAGING?

- Patient has prior history of prostate cancer
- Patient was treated for prostate cancer
- Patient has rising PSA after reaching a nadir
- All of the above documented in physician’s notes & on file at imaging center

DO I HAVE WHAT I NEED TO SCHEDULE THE PATIENT?

- Physician order for Axumin PET scan
- Patient’s insurance information and prior authorization number, if available
- If performing authorization, documentation of:
 - Medical necessity
 - Patient history
 - Information on Axumin PET scans

CODING FOR AXUMIN PET SCANS:

HCPCS Code for Axumin (fluciclovine F 18) injection

A9588	Fluciclovine F 18, diagnostic, 1 milliCurie (mCi)*
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*Unit alert: Axumin is provided in 10 mCi doses. When submitting claims, be sure to enter the correct number of units.

HCPCS Code for Axumin (fluciclovine F 18) injection

78811	Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)
78815	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

ICD-10 Codes Currently Covered by Medicare

C61	Malignant Neoplasm of Prostate
Z85.46	Personal History of Malignant Neoplasm of Prostate
R97.21	Rising PSA Following Treatment for Malignant Neoplasm of the Prostate

Disclaimer: This document contains factual information and is not intended to be legal or coding advice. Blue Earth does not guarantee coverage or reimbursement for Axumin. The existence of billing codes does not guarantee coverage and payment. Payer policies vary and may change without notice. It is the provider’s responsibility to determine and submit accurate information on claims. This includes submitting proper codes, modifiers, charges, and invoices for the services that were rendered. It is the provider’s responsibility to ensure that all information on a claim is accurate. It is the provider’s responsibility to check with the payer to determine whether the information contained on the claim is accurate. It is the responsibility of the provider to document the medical necessity of Axumin in the medical record.

AXUMIN®

Fluciclovine F 18 Injection

INDICATION

Axumin® (fluciclovine F 18) injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

IMPORTANT SAFETY INFORMATION

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation, is recommended.
- Hypersensitivity reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in $\leq 1\%$ of subjects during clinical studies with Axumin. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full Axumin prescribing information is available at www.Axumin.com.

