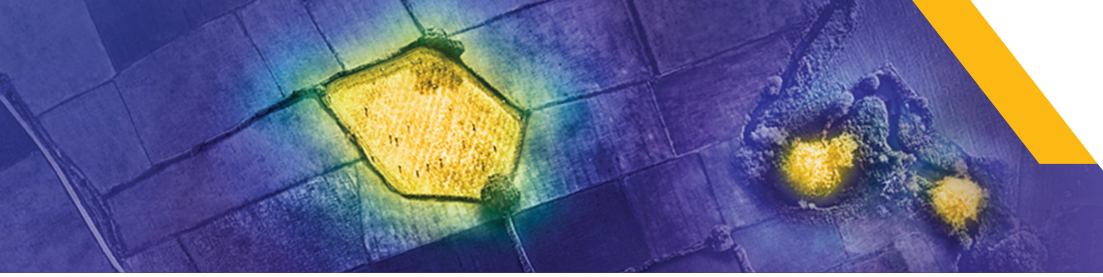

AXUMIN®
Fluciclovine F 18 Injection

Axumin Coding Information Sheet

Information current as of January 2, 2021.

What is the HCPCS code for Axumin?

Axumin has a product-specific Healthcare Common Procedure Coding System (HCPCS) code, effective January 1, 2017. For claims with dates of service on or after January 1, 2017, the following HCPCS code should be used:

HCPCS code	HCPCS descriptor
A9588	Fluciclovine F 18, diagnostic, 1 mCi

Which PET procedure codes would be used on Axumin claims?

The Current Procedural Terminology (CPT®) codes for PET imaging are 78811- 78816. Providers should choose the code that accurately describes the procedure performed and is supported by documentation in the medical record. Based on the Axumin Prescribing Information, it is expected that the following 2 CPT codes will be commonly used for Axumin PET or PET/CT imaging of patients with recurrent prostate cancer:

CPT code	CPT descriptor
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78815	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh

Is a modifier necessary for billing?

Medicare requires oncologic PET imaging be billed using either the PI or PS modifier. The PS modifier is appropriate for PET imaging of recurrent prostate cancer, as recurrence occurs after the completion of initial treatment.

PI – Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing. Short descriptor: PET tumor init tx strat

PS – Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent antitumor strategy. Short descriptor: PET tumor subsq tx strategy

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1833CP.pdf

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.

Please see Axumin Important Safety Information on back.

Axumin Coding Information Sheet

AXUMIN®
Fluciclovine F 18 Injection

Does Axumin have pass-through payment in the hospital setting?

No, Axumin's transitional pass-through period for Original Medicare beneficiary scans performed in the hospital outpatient department ended on December 31, 2019. For Medicare hospital outpatients, payment for the PET diagnostic radiopharmaceuticals are bundled with the procedure payment after the transitional pass-through period. As of January 1, 2020, Axumin will be bundled with the procedure payment.

It is essential that hospitals appropriately and accurately determine codes for items and services and apply appropriate charges, even when the payment is bundled. For example, diagnostic radiopharmaceuticals are packaged but still should be coded and billed in order for the cost to be accurately represented in the claims data.

Which ICD-10 codes may be used on Axumin claims?

ICD-10 code	ICD-10 descriptor
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

The above codes are representative. Providers should choose the code(s) that accurately describes the diagnoses.

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- 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 ≤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.

Please see accompanying full Axumin Prescribing Information, also available at www.axumin.com.

This document contains factual information and is not intended to be legal or coding advice. Blue Earth Diagnostics does not guarantee coverage or reimbursement for Axumin. The information provided in this document is based upon current, general coding practices. The existence of billing codes does not guarantee coverage and payment. Payer policies vary and may change without notice. It is the providers' responsibility to determine and submit accurate information on claims. This includes submitting such as proper codes, modifiers, charges, and invoices for the services that were rendered. The coding on claims should reflect medical necessity and be consistent with the documentation in the patient's medical record.

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BEDPRC21-0079A 9/21