

Helpful Tips

PRIOR AUTHORIZATIONS | PREDETERMINATION | APPEALS

Information current as of January 2, 2021.

Important information

This resource is provided to support patient access to Axumin as prescribed. 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.

Prior authorizations

A process used to determine if a prescriber's procedure, service, or medication will be covered. This process does not guarantee payment. A prior authorization is not predetermined by a health plan.

› Collect all pertinent information

- Patient information
- Site information
- All items required by the health plan

› Electronic submission can reduce complexity of manual claims

› May be conducted via the telephone for certain payers

› Authorizations may be done for the following:

- A9588 (Fluciclovine F 18, diagnostic, 1 mCi)
- 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)
- 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)

› Provider must have appropriate documentation readily available

- Letter of medical necessity
- Patient records
- Information on the procedure, medication, etc
- Make note of any authorization number (eg, may request in writing from payer)
- Reverify authorization if granted to ensure patient is still eligible under plan and payer
- Make sure to follow all criteria set forth by the payer

(NOTE: Verify benefits, eligibility, coverage, and requirements for prior authorization with payer.)

Predetermination

Determination of the reimbursement amount from a third party before a healthcare service is performed. It does not guarantee payment.

› Collect all pertinent information

› Electronic submission can reduce complexity of manual claims

› Insight may be gained on reimbursement (payment) for Axumin and PET scan

› May be able to gain insight into contract limitations with payer

(NOTE: Many of the steps above would be used with a predetermination.)

Please see Axumin Important Safety Information on back.

Approval: Axumin and PET

- › Ready to facilitate
- › Make sure to have all approval documentation available—received from payer
- › Submit for reimbursement
- › Upon request, payer may clarify whether prior authorization will be required for each patient or if one prior authorization is sufficient for all patients

(NOTE: Unless predetermination is required by payer.)

Denial: Axumin or PET or both

APPEAL PROCESS

PAPER/ELECTRONIC

- › Make sure to use proper form
- › Follow exact criteria of payer
- › Include physician notes
- › Physician notes should document the use of product/scan
- › May use “Template Appeal Letter” or “Letter of Medical Necessity” provided by Blue Earth Diagnostics
- › Incorporate correct information per the denial remark code on the explanation of benefits
- › Submit in a timely manner and through proper channels provided by payer

PEER TO PEER

- › Contact payer and schedule a peer to peer
- › Make sure to ask for an individual well versed in radiopharmaceuticals
- › Request notification of assigned payer individual a week prior to scheduled appointment
- › If possible, send a few documents to assigned payer individual before call
- › Make sure to have all documentation ready
 - Denial explanation of benefits
 - Reason for use of Axumin, PET, and/or both
 - Documentation supporting medical necessity

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 ≤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.