

AXUMIN[®]

Fluciclovine F 18 Injection

PRIOR AUTHORIZATIONS •
PRE-DETERMINATION •
APPEALS •

Important Information: This resource is provided as educational support to assist health care professionals and the patients they serve. Health care professionals may choose to use these “Easy Tip” check tools to assist in their access to Axumin[®] (fluciclovine F 18) injection. This is not a guide or instructions. It is in conjunction to the “Frequently Asked Questions” located on www.axumin.com and other resources. The provider has the responsibility to ensure correct prior authorization, appeal and denial policies are followed. Providers must ensure they accurately complete and submit necessary information to payers.

PRIOR AUTHORIZATIONS

A process used to determine if a prescribe procedure, service, or medication will be covered. It is intended to act as a safety and cost savings measure. This process does not guarantee payment. A prior authorization is not pre-determined by a health plan.

✓ Collect all pertinent information

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

✓ Electronic version reduces complexity of manual claims

✓ May be conducted via the telephone

✓ Authorizations may be done for the following:

- A9588 (fluciclovine F18, diagnostic, 1mCi)
- 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)

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

✓ 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)
- Re-verify authorization if granted to ensure patient is still eligible under plan and payer
- Make sure to follow all criteria set forth by the payer

PRE-DETERMINATION

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

✓ May be required by the payer

✓ Electronic submissions may be more beneficial than manual submission

✓ 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 pre-determination)

Please see AXUMIN Important Safety Information on page 3.

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APPROVAL: AXUMIN AND PET

- ✓ Ready to facilitate
- ✓ Make sure to have all approval documentation available—received from payer
- ✓ Submit for reimbursement
- ✓ May chose to request if prior authorization will be required for all patients or if one prior authorization will be enough for the payer.

(NOTE: Unless pre-determination 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 reflect use of product/scan**
- ✓ May use "Template Appeal Letter" or "Letter of Medical Necessity" provided by Blue Earth Diagnostics
- ✓ Make sure to 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 payer assigned individual before call (May be provided by Blue Earth Diagnostics)
- ✓ Make sure to have all documentation ready
 - Denial Explanation of Benefits
 - Reason for use of Axumin, PET and/or both
- ✓ May be beneficial to explain Axumin is a "new" radiopharmaceutical with Pass-Through Status
- ✓ May be beneficial to mention Original Medicare has A9588 listed on Fee Schedule

Please see AXUMIN Important Safety Information on page 3.
Full Axumin Prescribing Information is available at www.axumin.com.

For more information please visit either www.axumin.com or contact the Axumin Reimbursement Hotline at 1-855-AXUMIN1 (1-855-298-6461)

Information current as of
September 5, 2017

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.

REIMBURSEMENT DISCLAIMER:

The information in 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.

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