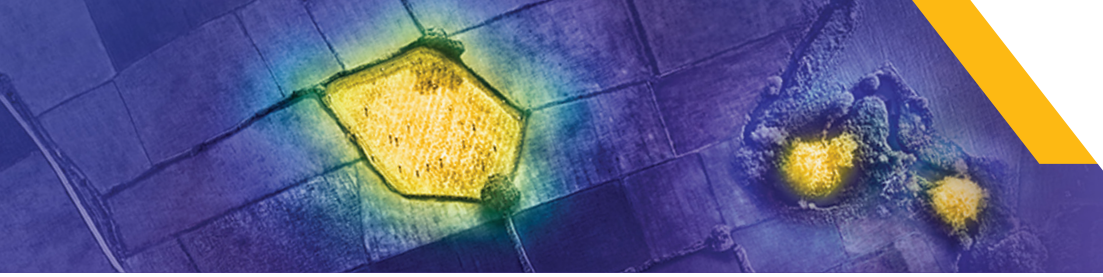

AXUMIN®
Fluciclovine F 18 Injection

Axumin PET Imaging Program Implementation Checklist

A proactive approach regarding reimbursement can help your patients successfully obtain coverage for Axumin as prescribed. The checklist below outlines key potential steps to help facilitate coverage if you determine Axumin is appropriate for your patient. Please review individual insurer requirements, as the specific steps may vary based on the patient's insurer.

- ✓ Confirm/add PET or PET/CT procedure codes and Axumin HCPCS code A9588 to charge master (hospitals only)
- ✓ Confirm both current APC and revenue codes for PET scanning are set up in charge master (hospitals only)
- ✓ Submit form 855B to add Axumin HCPCS code A9588 (IDTF only)
  https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf
- ✓ Obtain local MAC oncologic PET coverage policy and coding instructions for restaging/recurrence of prostate cancer
- ✓ Obtain oncologic PET coverage policies from commercial payers and Medicare Advantage plans
- ✓ Obtain publicly available RBM coverage criteria for oncologic imaging
- ✓ Review commercial payer contracts and submit contract addendum to add separate reimbursement for Axumin, fluciclovine F 18 HCPCS Level II code A9588 to current contract. Please note, such contract addenda may take 60 days or more to process
- ✓ Check with private payers to confirm code sets for oncologic PET are included in privileging criteria
- ✓ Credentialing—you may need to update your office/practice profile with your payers

- ✓ If you have questions, your Blue Earth Diagnostics field reimbursement specialist is available to provide a reimbursement training overview. This training will provide information relevant to departments including, but not limited to:
  - › Scheduling department
  - › Benefit investigation
  - › Prior authorization
  - › Charge master
  - › Finance department
  - › Billing and patient financial services
  - › Third-party billing company (if utilizing)
  - › Prostate cancer nurse navigators

- ✓ Topics for this training session will include:
  - › Review of Axumin Reimbursement Resource Guide
  - › Review of publicly available local MAC and private payer coverage policies
  - › Review of publicly available RBM coverage criteria and prior-authorization requirements
  - › Q&A session

This resource is provided to help patients access Axumin as prescribed by their healthcare providers. 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 of the patient's insurer are followed.

Abbreviations: APC, ambulatory payment classification; HCPCS, Healthcare Common Procedure Coding System; IDTF, independent diagnostic testing facility; MAC, Medicare Administrative Contractor; RBM, radiology benefits manager.

Please see Axumin Important Safety Information on back.

Axumin PET Imaging Program Implementation Checklist

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 ≤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.

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