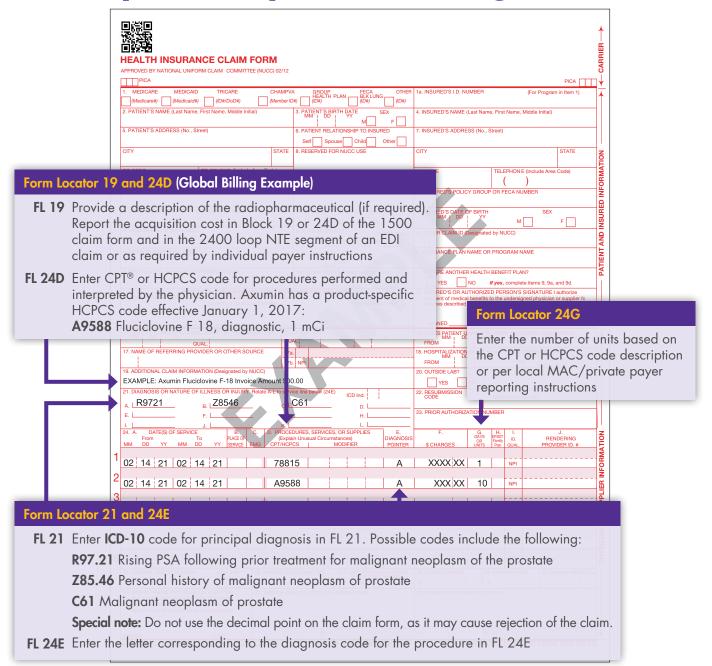


Sample Physician Billing Global Nonhospital Outpatient Setting CMS-1500



Blue Earth Diagnostics, Inc. cannot guarantee coverage or reimbursement for Axumin. The existence of billing codes does not guarantee coverage and payment. Payer policies may change without notice. It is the provider's responsibility to determine and submit accurate information on claims. This includes submitting paper 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 to document the medical necessity of Axumin in the medical record.

Abbreviations: CPT, current procedural terminology; HCPCS, Healthcare Common Procedure Coding System.

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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.

