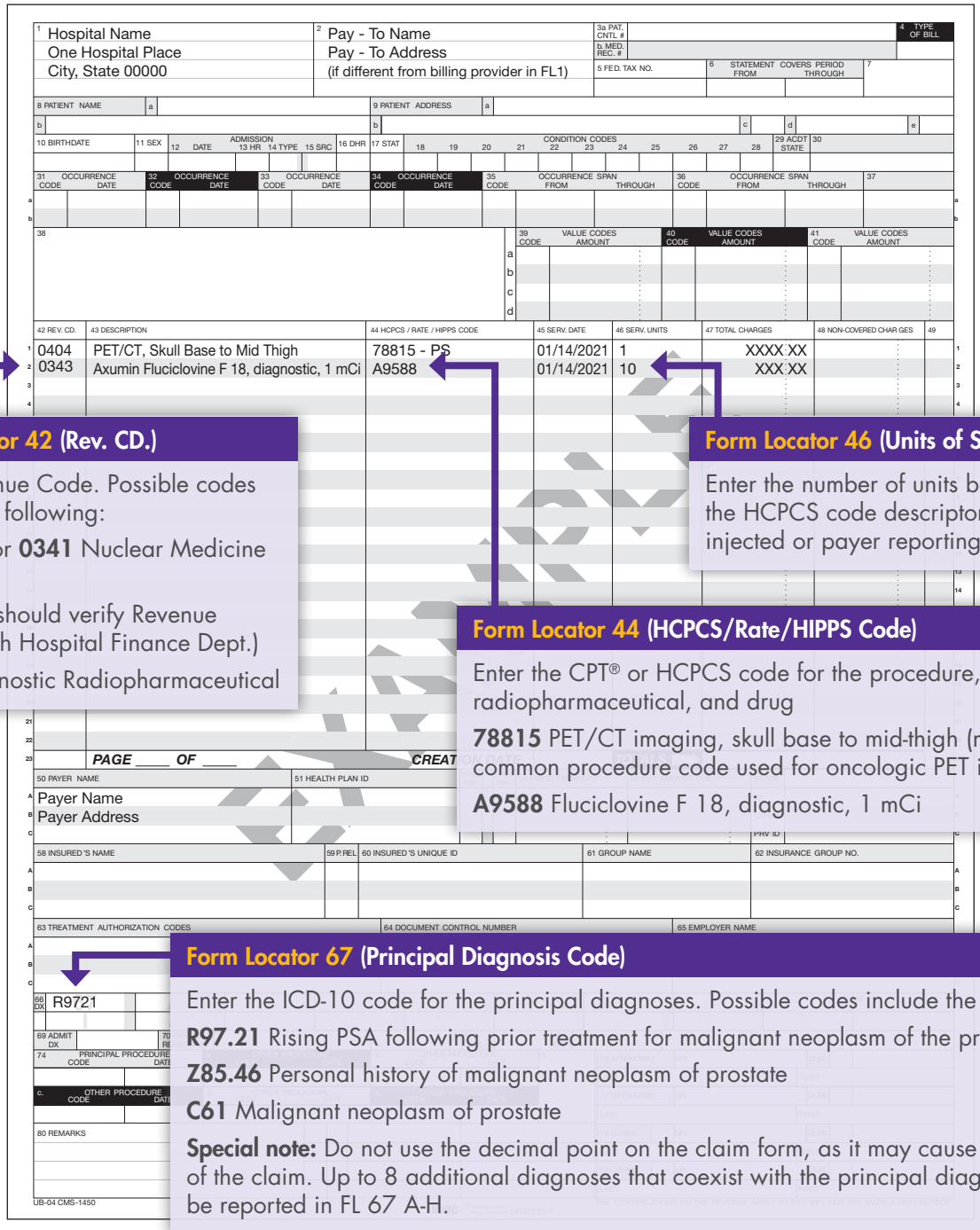
AXUMIN®
Fluciclovine F 18 Injection

Sample Hospital Setting Billing UB-04



Form Locator 42 (Rev. CD.)

Enter Revenue Code. Possible codes include the following:

0308 PET or **0341** Nuclear Medicine Diagnostic

(providers should verify Revenue Coding with Hospital Finance Dept.)

0343 Diagnostic Radiopharmaceutical

Form Locator 46 (Units of Service)

Enter the number of units based on the HCPCS code descriptor/# mCi injected or payer reporting instructions

Form Locator 44 (HCPCS/Rate/HIPPS Code)

Enter the CPT® or HCPCS code for the procedure, radiopharmaceutical, and drug

78815 PET/CT imaging, skull base to mid-thigh (most common procedure code used for oncologic PET imaging)

A9588 Fluciclovine F 18, diagnostic, 1 mCi

Form Locator 67 (Principal Diagnosis Code)

Enter the ICD-10 code for the principal diagnoses. Possible codes include the following:

R97.21 Rising PSA following prior treatment for malignant neoplasm of the prostate

Z85.46 Personal history of malignant neoplasm of prostate

C61 Malignant neoplasm of prostate

Special note: Do not use the decimal point on the claim form, as it may cause rejection of the claim. Up to 8 additional diagnoses that coexist with the principal diagnosis can be reported in FL 67 A-H.

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'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.

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.

BLUE EARTH DIAGNOSTICS
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