

Blue Earth Diagnostics, Inc. Medical Affairs

<p>PROSTATE BED Prostatectomy</p>	<table border="1"> <tr> <td>No focal uptake</td> <td>Likely benign</td> </tr> <tr> <td>Focal uptake between blood pool and bone marrow</td> <td>Follow-up recommended</td> </tr> <tr> <td>Focal uptake equal to or greater than bone marrow</td> <td>Likely malignant</td> </tr> </table>	No focal uptake	Likely benign	Focal uptake between blood pool and bone marrow	Follow-up recommended	Focal uptake equal to or greater than bone marrow	Likely malignant	<ul style="list-style-type: none"> Uptake on anatomical correlate < 1cm, significantly greater than blood pool (i.e., close to bone marrow), may also be considered suspicious for malignancy. 										
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<p>SEMINAL VESICLES</p>	<ul style="list-style-type: none"> In seminal vesicles, with or without prostate, symmetric bilateral uptake similar to blood pool is likely physiologic. Asymmetric seminal vesicle uptake between blood pool and marrow (or greater) may increase the suspicion for malignancy; consider pelvis MRI for further characterization. 																	
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BONE	<ul style="list-style-type: none"> • Focal uptake clearly visualised on Maximum Intensity Projection (MIP) or PET-only images, can be considered suspicious for cancer. • A bone abnormality visualized on CT (e.g. sclerosis without uptake) may still represent a metastasis.
LIVER	<ul style="list-style-type: none"> • Due to normal physiologic activity in the liver, metastases may be obscured, and appropriate PET display windowing must be used (upper window level > normal liver). • Uptake in liver greater than normal liver tissue is considered suspicious for malignancy.
BLADDER	<ul style="list-style-type: none"> • Mild (similar to blood pool) symmetric bladder wall activity is typically benign. • Asymmetric significant uptake may represent malignancy and should be further evaluated.

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.

Responsibility for the accurate interpretation of Axumin® PET/CT images rests with the nuclear medicine physician or radiologist supervising the PET/CT imaging facility. The information summarized here is not intended to substitute for the independent medical judgement of the physician(s) responsible for the individual patient's management, nor is it a guarantee of any specific clinical results.

For further information, please see the current version of the Axumin® (fluciclovine F 18) Imaging and Interpretation Manual available from Blue Diagnostics, Inc. Medical Information Hotline at:

1-855-AXUMIN1 (298-6461) or medinfo@blueearthdx.com

Full Axumin prescribing information is available at: www.axumin.com