1 TITLE PAGE

Axumin® (fluciclovine F 18) Imaging & Interpretation Manual (Prostate Cancer)
Blue Earth Diagnostics, Inc. US Corporate Headquarters Blue Earth Diagnostics Inc. 25 Burlington Mall Road, Suite 206 Burlington, MA USA 01803 1-855-AXUMIN1 (1-855-298-6461) medinfo@blueearthdx.com Please see Axumin full Prescribing Information accompanying this Manual and available at www.axumin.com
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Approval _____ _____

Signature (Name and Title) Date

This Manual is provided to you as a background resource to help familiarize you with techniques for the safe and effective usage of Axumin. The responsibility for the accurate and timely acquisition and interpretation of images using Axumin PET scanning rests with the nuclear medicine physician or radiologist supervising the PET imaging facility. The Axumin Imaging and Interpretation Manual is not intended to substitute for the independent medical judgment of the physician(s) responsible for the individual patient's management, nor is it a guarantee of any specific clinical results.

2 TABLE OF CONTENTS

3 Indication and Important Safety Information

3.1 Indication

Axumin® (fluciclovine F18) injection is a radioactive diagnostic agent 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.

3.1.1 Patient Selection Considerations: Suspected Prostate Cancer Recurrence

Although definitions of biochemical recurrence vary, position statements and guidelines from the American Urological Association and the National Comprehensive Cancer Network provide some recommendations:

- Post-prostatectomy: Detectable or rising PSA level ≥ 0.2 ng/mL that is confirmed with a second PSA level ≥ 0.2 ng/mL
- Post-radiotherapy: PSA rise by ≥ 2.0 ng/mL over nadir

In addition, if available, PSA doubling time (PSAdt) and pre-treatment Gleason Score can be considered, with a shorter PSAdt and higher Gleason Score potentially associated with a greater likelihood of recurrence.[1-3]

3.1.2 Detection Rate Varies by PSA Value at Time of Scan

PSA levels seem to have an impact on the detection rate of Axumin. In general, patients with negative scans had lower PSA levels than those with positive scans. The detection rate (number with positive scans/total scanned) for patients with a PSA value of less than or equal to 1.78 ng/mL (1st PSA quartile) was 15/25, of which 11 were histologically confirmed as positive. In the remaining three PSA quartiles, the detection rate was 71/74, of which 58 were histologically confirmed. Among the 25 patients in the first PSA quartile, there were 4 false positive scans and 1 false negative scan. For the 74 patients with PSA levels greater than 1.78 ng/mL, there were 13 false positive scans and no false negative scans. (Section 14; Axumin (fluciclovine F 18 injection); US Prescribing Information; August 2016).

3.2 Important Imaging Considerations

- Images should only be interpreted by readers trained in the interpretation of PET images with Axumin.
- 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.
- Axumin Image Interpretation Training, including the Suggested Interpretation Criteria described in this manual, is not intended to substitute for the independent medical judgment of the physician(s) responsible for the individual patient's management, nor is it a guarantee of any specific clinical results.
- The responsibility for the accurate and timely acquisition and interpretation of images using Axumin PET scanning rests with the nuclear medicine physician or radiologist supervising the PET imaging facility.

- 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

4 Imaging

4.1 Radiation Safety - Drug Handling

Axumin is a radioactive drug and should be handled with appropriate safety measures to minimize radiation exposure during administration. Use waterproof gloves and effective shielding, including syringe shields, when handling and administering Axumin.

4.2 PET instrumentation

PET instrumentation is grouped into the following categories:

4.2.1 PET/CT

Provided that the Axumin image acquisition guidelines and the image display and interpretation instructions (Sections 2.4 and 2.5; Axumin (fluciclovine F 18 injection); US Prescribing Information) are followed, clinical results comparable to those described in the US Prescribing Information (Section 14) can be expected.

Please contact Blue Earth Diagnostics Inc. Medical Affairs if you have any questions regarding the acquisition of Axumin images.

4.2.2 PET/MRI

Some institutions are gaining initial clinical experience of imaging Axumin on a PET/MRI scanner and at least one clinical study has been performed [4].

Please contact Blue Earth Diagnostics Inc. Medical Affairs if you have any questions regarding the use of Axumin on a PET/MRI scanner..

4.2.3 Not Recommended for Use with Axumin

- Dual-head coincidence cameras
- PET stand-alone cameras

4.3 Dose Preparation

- Inspect Axumin visually for particulate matter and discoloration before administration. Do not use the drug if the solution contains particulate matter or is discolored.
- Use aseptic technique and radiation shielding when withdrawing and administering Axumin.
- Calculate the necessary volume to administer based on calibration time and date, using a suitably calibrated instrument.
- The recommended administered activity is 370 MBq (10 mCi) administered as an intravenous bolus injection. Axumin may be diluted with Sodium Chloride Injection, 0.9%.
    - The adult effective dose resulting from the administration of the recommended activity of 370 MBq of Axumin is 8.2 mSv [5].
- The recommended maximum volume of injection of undiluted Axumin is 5mL. **Do not administer a volume of undiluted Axumin that is greater than 5mL.** This volume keeps the administration of all species and solvents within the limits generally recognized as safe.

4.4 Patient Preparation Prior to PET Imaging

- Advise the patient to avoid any significant exercise for at least one day prior to PET imaging.
    - If the patient has not avoided exercise, the bio-distribution (Section 4.6, Figure 1) may be altered and this should be taken into account during image interpretation.
- Advise patients not to eat or drink for at least **4 hours** (other than small amounts of water for taking medications) prior to administration of Axumin.
    - If the patient has not fasted, the bio-distribution (Section 4.6, Figure 1) may be altered and this should be taken into account during image interpretation.
- Patients should be encouraged to void approximately **30-60 minutes** *before* scanning.
    - This is to reduce the potential impact of early urinary excretion (in a minority of patients) into the bladder.
    - If the patient voids within 30-60 minutes prior to the start of the scan, there is the possibility of early appearance of bladder activity and this should be taken into account during image interpretation. This activity is usually generalised, but occasionally may be focal in nature (simulating the appearance of a nodule adjacent to the bladder wall), at least on the early images.

4.5 Dose Administration

- Administer the dose as an intravenous bolus injection whilst the patient is positioned in the PET/CT scanner
    - Injection into the right arm is suggested, when possible, as stasis in the left axillary vein may be misinterpreted as a metastatic lymph node (Virchow's node). If the right arm cannot be used, be aware of the possibility of image interpretation error.
- After the Axumin injection, administer an intravenous flush of sterile Sodium Chloride Injection, 0.9% to ensure full delivery of the dose.
- Dispose of any unused drug in a safe manner in compliance with applicable regulations.

4.6 Image Acquisition

- Position the patient supine with arms above the head.
    - If the patient cannot tolerate this position for the duration of the study, an alternate position for the patient's arms may be used.
- The CT should be acquired per site standards, however a small lesion seen on PET may be better characterized with a high-quality CT. A high quality CT acquisition for anatomic correlation and attenuation correction is recommended. Regardless of the CT technique used, a careful review of the CT image is necessary.
- The administration of intravenous CT contrast media is not required for the CT acquisition when using Axumin. However, if the use of intravenous CT contrast is standard of practice at a site, it is recommended that the contrast is administered after the completion of the Axumin PET scan. Oral contrast may be administered, if this is consistent with standard practice at a site.
- Begin PET scanning 3 to 5 minutes after completion of the Axumin injection moving in a caudal to cranial direction:
    - Following intravenous administration, the tumor-to-normal tissue contrast is highest between 4 and 10 minutes after injection, with a 61% reduction in mean tumor uptake at 90 minutes after injection (see Figure 1).

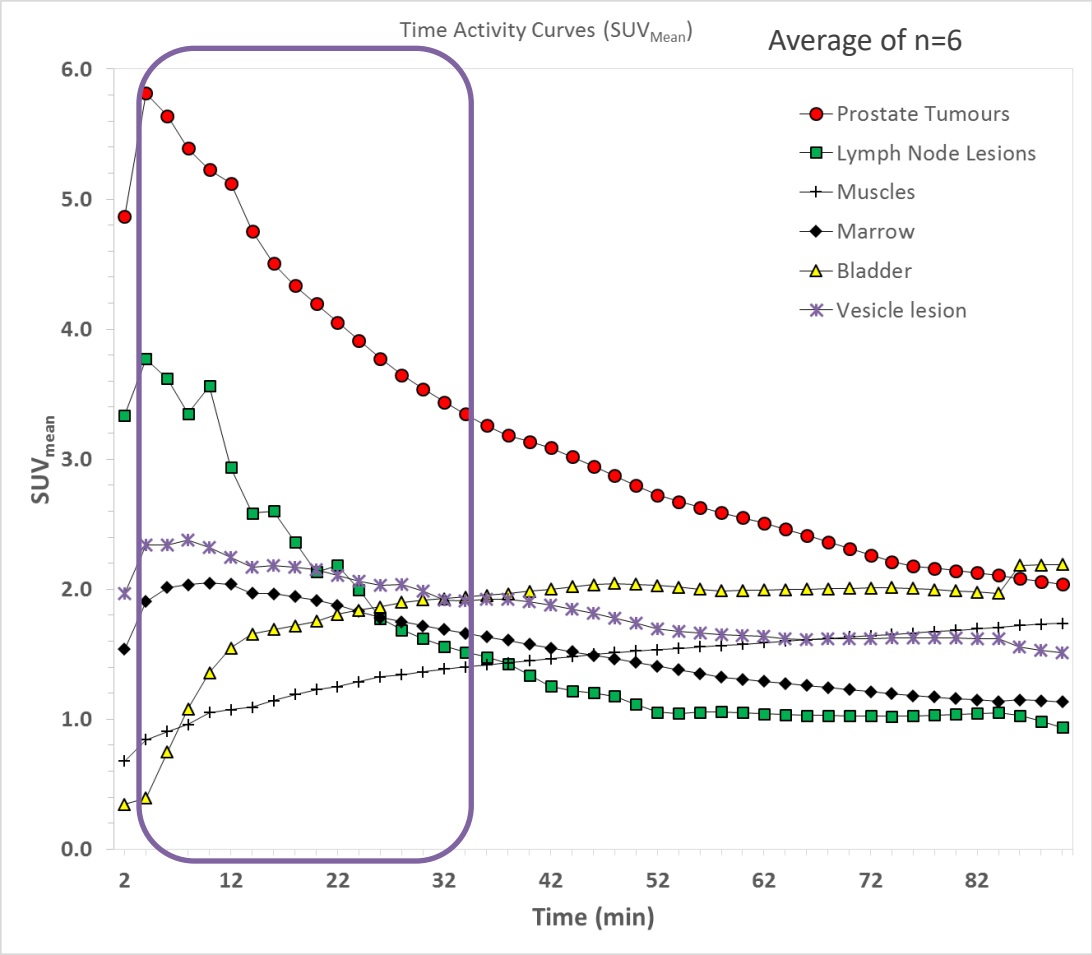

Figure 1 Time Activity Curves (SUV_{mean} vs Time; mean & interpolated data from 6 subjects; study GE148-001, Owenius et al, Internal Blue Earth Diagnostics Ltd. (Dec 2010) Report)

  - If scanning is started early, the bio-distribution may be altered (e.g.: increased blood pool) and this should be taken into account during image interpretation.
  - If scanning is started late, the bio-distribution may be altered (e.g.: increased muscle uptake) and this should be taken into account during image interpretation.
- It is recommended that image acquisition should start at the mid-thighs, just below the pelvis.
  - It is **very important** that the prostate bed is centrally positioned within the first bed position and, also, that the inguinal lymph nodes are included.
  - The coverage of imaging should extend to the base of the skull.
- Typical total scan time is between 20 to 30 minutes. The actual scan time is typically dependent on scanner type, scan length, and the time per bed position/bed speed (scanners with continuous bed motion).
- It is recommended to scan for **5 minutes per bed position over the pelvis** (i.e. pubic symphysis to iliac crest) to facilitate the localization of prostate cancer recurrence in sites typical for such recurrence.
  - However, acquisition time is scanner specific. The start time of the scan after injection (3-5 minutes, target 4 minutes) is more important.

- For the remaining bed positions (i.e. iliac crest to base of skull) 5 minutes per bed position is recommended, although this may be reduced to 3 minutes per bed position if the PET/CT allows this adjustment and the site is experienced with such image acquisition procedures.

4.7 Image Reconstruction

- The highest quality scanner at an institution should be used because of the potential impact of lesion size on image interpretation (Section 2.5; Axumin (fluciclovine F 18 injection; US Prescribing Information).
- Reconstruction algorithms should be based on the manufacturer's recommendations. Reconstruction modifications can best be achieved using the manufacturer's guidelines along with the institution's physician and physicist recommendations.
- If a scanner has time-of-flight (ToF), an iterative reconstruction algorithm using recovery resolution, a Bayesian penalized-likelihood reconstruction algorithm or other new reconstruction algorithm, it is recommended that these features be utilized.
    - However, if resolution recovery is utilized, the physician should be aware of the advantages and disadvantages. Resolution recovery may help with the detection of small lesions, but the size criteria for evaluation may change. For example, a 1 cm lymph node without resolution recovery may be equivalent to a 7 or 8 mm lymph node with resolution recovery.

4.8 Summary of the Axumin PET/CT Image Acquisition Protocol

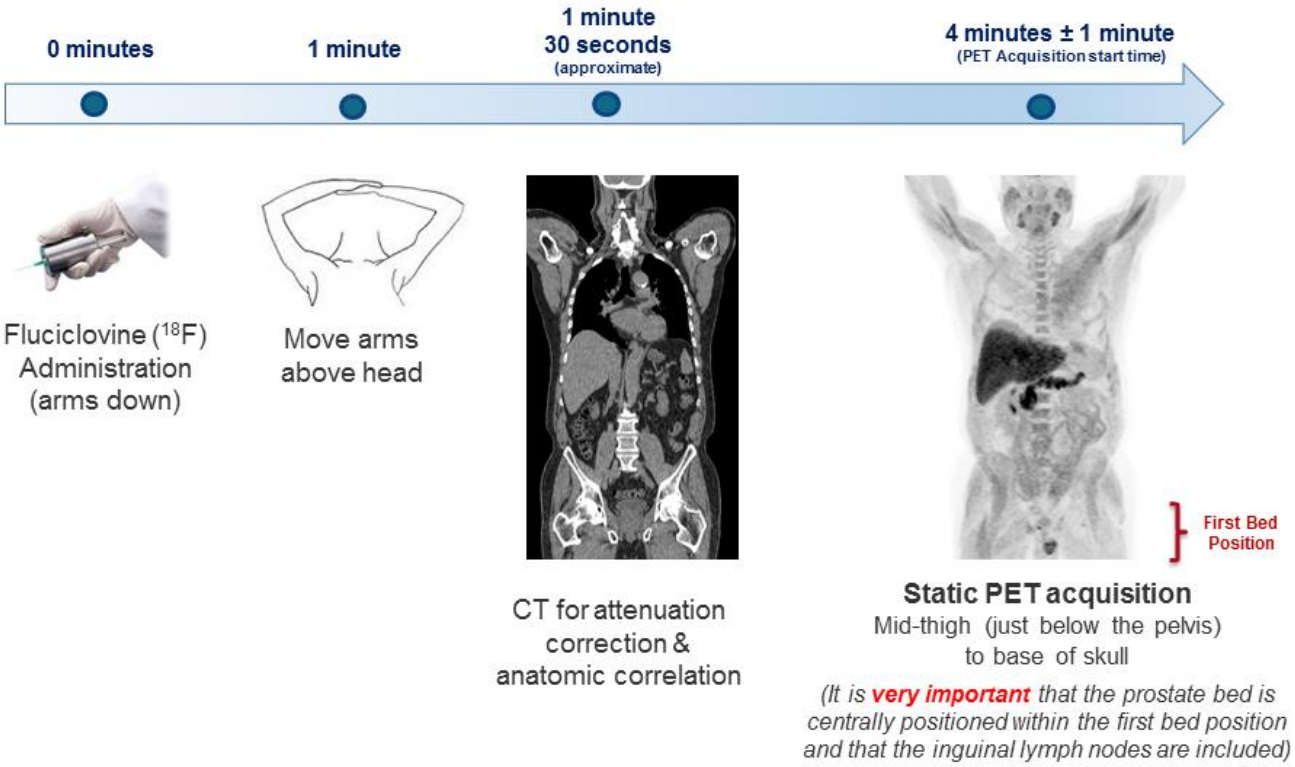

Figure 2: Graphical Summary of the Imaging Procedure

5 Read Methodology

- Localization of prostate cancer recurrence in sites typical for prostate cancer recurrence is based on Axumin uptake in comparison with tissue background (Section 2.5; Axumin (fluciclovine F 18 injection); US Prescribing Information).
- Imaging interpretation is predominantly qualitative, based on typical sites of recurrence of prostate cancer.
- General guidance is to report 'inside-out', i.e., assess central areas of focal uptake before assessing the periphery.
    - It is critically important for the reader to know the typical sites of metastases and recurrence of prostate cancers, as well as normal distribution of Axumin, normal variants and potential pitfalls.
    - When interpreting Axumin scans, the interpreting physician should be aware of the differences in biodistribution between other commonly used radiopharmaceuticals, particularly [^{18}F]-FDG, and Axumin.
- As with any imaging, full correlation with all available information (e.g. medical history, laboratory results, bone scans, CT & MRI scans) should occur and may improve the confidence level of interpretation of the PET scan.
- Tissue background is measured in blood pool or bone marrow
    - Volume of Interest for blood pool. Measure a volume that encompasses the lumen of the aorta or largest artery (~1cm) at or about the level of the lesion (**in the same bed position frame**).
    - Volume of Interest for bone marrow. Measure the largest volume that encompasses marrow in normal third lumbar vertebra (L3 or nearest adjacent normal vertebra if uptake in L3 is not physiological).
- Thresholds based on lymph node sizes (i.e. $<$ or $\geq$ 1 cm), referred to throughout the interpretation criteria, are based on the *maximum* dimension of the lymph node for the purpose of visual interpretation.
    - Nodal short axis or bi-dimensional measurements should still be reported per the interpreting reader's usual practice.
- SUV measurements should be normalized by body weight.
- The use of multiple orthogonal planes of view (for example: axial, sagittal, and coronal) is recommended. The Maximum Intensity Projection (MIP) may be useful for the detection of lesions in bone, as well as in lymph nodes.
- The use of color tables are a personal preference for the reader, based on the image review workstation and reader's experience.
- To ensure that all organs are being reviewed appropriately, the following PET window display guidelines are suggested.
    - Prostate.
        - View with a variety of PET and CT windows, start with pancreas and liver fairly intense.
    - Lymph nodes.
        - Window with lower upper-threshold SUV intensity. Consider optimizing setting for lesion detectability.
    - Liver.

- Review liver with similar windowing as brain in (^{18}F)-FDG, upper-threshold should be higher than SUV_{max} in normal liver.

- Bone.
  - Use the Maximum Intensity Projection (MIP) image
- Readers should be cognizant of the fact that the biodistribution is different to other commonly used radiopharmaceuticals, in particular [^{18}F]-FDG, and different windows are needed.
- The most appropriate windowing is typically scanner/workstation dependent and must be selected based on the clinical judgement and experience of the reader.

5.1 Prostate Bed

5.1.1 Prostatectomy

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

* Uptake not meeting threshold for malignancy (equivocal) may require follow-up and clinical correlation.

- Uptake on anatomical correlate < 1cm, significantly greater than blood pool (i.e., close to bone marrow), may also be considered suspicious for malignancy; MRI correlation is suggested.
  - If a lesion of this size does not meet this threshold it should be reported as such but requires follow-up and clinical correlation.
- Sagittal images are useful in the evaluation of the anastomotic site.

5.1.2 Non-Prostatectomy (intact prostate)/prior therapy

No focal uptake	Likely benign
Diffuse, focal, or multi-focal uptake between blood pool and bone marrow	Follow-up recommended*
Diffuse, focal, or multi-focal uptake equal to or greater than bone marrow	Likely malignant

* Uptake not meeting threshold for malignancy (equivocal) may require follow-up and clinical correlation.

- Uptake on anatomical correlate < 1cm, significantly greater than blood pool (i.e., close to bone marrow), may also be considered suspicious for malignancy; MRI correlation is suggested.
  - If a lesion of this size does not meet this threshold it should be reported as such but requires follow-up and clinical correlation.
- Focal uptake with calcification may indicate benign inflammation; MRI correlation is suggested.
- Anecdotally, median prostate lobe uptake (central base invaginating into bladder) has a higher false positivity.

5.2 Seminal vesicles

- In seminal vesicles, with or without the prostate present, 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 pelvic MRI for further characterization.

5.3 Lymph Nodes

5.3.1 Lymph nodes in a typical site of recurrence of prostate cancer, equal to or greater than 1cm (maximum dimension)

Uptake less than or equal to blood pool	Likely benign
Uptake between blood pool and bone marrow	Follow-up recommended*
Uptake equal to or greater than bone marrow	Likely malignant

* Uptake not meeting threshold for malignancy (equivocal) may require follow-up and clinical correlation.

- Uptake in lymph nodes ≥ 1 cm in a typical site of recurrence of prostate cancer should have a higher threshold for positivity relative to lymph nodes < 1cm. If a node ≥ 1cm does not meet this threshold of equal to or greater than bone marrow (including those approaching, but not reaching, bone marrow) it should be reported as such but requires follow-up and clinical correlation.

5.3.2 Lymph nodes in a typical site of recurrence of prostate cancer, less than 1cm (maximum dimension)

Uptake less than blood pool	Likely benign
Uptake greater than or equal to blood pool, but not close to bone marrow	Follow-up recommended*
Uptake *significantly* greater than blood pool, close to, equal to, or greater than bone marrow	Likely malignant

* Uptake not meeting threshold for malignancy (equivocal) may require follow-up and clinical correlation.

- Uptake in a lymph node < 1cm in a typical site of recurrence of prostate cancer has a lower threshold for positivity, which is considered significantly greater than blood pool (i.e. close to, equal to, or greater than marrow). If a node < 1cm does not meet this threshold it should be reported as such but requires follow-up and clinical correlation.

The following factors should be considered in evaluation of lymph nodes, especially for lymph nodes not meeting threshold for malignancy:

5.3.3 Lymph node location

- For atypical sites for recurrence (e.g., inguinal, hilar, and axillary nodes) mild symmetric uptake is considered physiologic uptake. But if the node is present within the context of other recurrent disease, particularly pelvic metastases, it may also be considered suspicious.
- Distal external iliac nodes may also be suspicious in isolation. Mild symmetric uptake may be considered physiologic uptake. But if the node is asymmetric or present within the context of other recurrent disease, it may also be considered suspicious.

- Note that the presence of nearby vascular grafts, orthopaedic hardware or recent invasive procedures could cause false positive uptake in these nodal groups.

5.3.4 Lymph node shape

- Round nodes are more suspicious than curvilinear nodes on CT

5.3.5 Lymph node grouping

- Depending on category, a group of nodes in a typical location is more suspicious than a solitary node, and in that case a single node with higher uptake than surrounding lymph nodes may still be suspicious even if not meeting the threshold for malignancy

5.3.6 Lymph node necrosis

- A metastatic necrotic node may not have increased Axumin uptake

5.4 Bone

- 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. Alternative imaging, for example, MRI, [^{18}F]-NaF PET/CT, SPECT/CT bone scan or standard bone scintigraphy should be considered.
- Due to normal physiologic heterogeneity of bone marrow, appropriate PET display windowing must be used.
- Increased uptake in bone may be seen in the setting of trauma (including compression fractures) or occasionally degenerative changes.
- Skeletal metastases which resemble Schmorl's nodes, but with uptake within them, have been described.
- Areas of normal bone marrow regeneration (e.g., pelvis and proximal femurs) may also show increased physiologic uptake; consider MRI if no clear CT correlate.

5.5 Liver

- 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.
- Lesions seen on CT or MRI with uptake less than normal liver (but higher than bone marrow) may represent malignant processes. This can be further evaluated with a multi-phase liver MRI or CT.

5.6 Bladder

- Mild (similar to blood pool) symmetric bladder wall activity is typically benign.
- Asymmetric significant uptake may represent malignancy and should be further evaluated.
- Accumulation of Axumin may simulate the appearance of a nodule adjacent to the bladder wall, particularly in the dependent portion of the bladder.

5.7 False positives

- Axumin uptake is not specific for prostate cancer and may occur with other types of cancer, prostatitis and benign prostatic hyperplasia.
- False-positive cases have also been described in association with an inflammatory response after cryotherapy, and radiation artefacts in patients previously treated with radiotherapy.
- Clinical correlation, which may include histopathological evaluation of the suspected recurrence site, should be considered where appropriate
- The PSA value may affect the diagnostic performance of Axumin PET.
- Physicians should be aware of potential for Axumin uptake in areas of benign pathology and other incidental cancers. These potential incidental findings with Axumin are outside of its indicated use for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence.

5.8 Sample Axumin (fluciclovine F-18) Interpretation Report

- A sample Axumin (fluciclovine F-18) Interpretation Report is included in the appendix (Section 7.1)

6 References

1. *Carroll P, Albertson PC, Greene K, et al. PSA testing for the pretreatment staging and posttreatment management of prostate cancer. 2013 revision. American Urological Association; www.auanet.org/education/guidelines/prostate-specific-antigen.cfm*
2. *NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer 2016, v3.2106*
3. *Goonewardene SS, Phull JS, Bahl A et al. Interpretations of PSA levels after radical therapy for prostate cancer. Trends in Urology & Men's Health 2014;July/August:30-34*
4. *Elschot M, Selnæs KM, Johansen H et al. The Effect of Including Bone in Dixon-Based Attenuation Correction for ^{18}F-Fluciclovine PET/MRI of Prostate Cancer. J Nucl Med 2018; 59:1913. (ClinicalTrials.gov identifier NCT02562131).*
5. *McParland B, Wall A, Johansson S et al. The clinical safety, biodistribution and internal radiation dosimetry of (^{18}F) fluciclovine in healthy adult volunteers. EJNMMI, 40:1256, 2013.*

6.1 Suggested Reading

- *Schuster DM, Nanni C, Fanti S, et al. Anti-1-amino-3-^{18}F-fluorocyclobutane-1-carboxylic acid: physiologic uptake patterns, incidental findings, and variants that may simulate disease. J Nucl Med 2014;55:1986-92*
- *Paño B, Sebastià,C, Buñesch L, et al. Pathways of lymphatic spread in male urogenital pelvic malignancies. RadioGraphics 2011;31:135–160*
- *Mattei, A, Fuechsel F, Dhar N, et al. The template of primary lymphatic landing sites of the prostate should be revisited: Results of a multi-modality mapping study. Eur Assoc Urol 2008;53:118-125*
- *Bach-Gansmo T, Nanni C, Nieh PT, et al. Multisite experience of the safety, detection rate and diagnostic performance of fluciclovine (^{18}F) positron emission tomography/computerized tomography imaging in the staging of biochemically recurrent prostate cancer. J Urol, 2017;197:676.*
- *Andriole GL, Kostakoglu L, Chau A et al (on behalf of the LOCATE study group). The impact of positron emission tomography with ^{18}F-fluciclovine on the management of patients with biochemical recurrence of prostate cancer: Results from the LOCATE trial. J Urol. 2019; 201:322-31.*

AXUMIN 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 the full Prescribing Information accompanying this Manual and available at www.axumin.com.

7 Appendices

7.1 Sample Axumin® (fluciclovine F-18) Interpretation Report

This resource can assist with providing appropriate information regarding your patient's Axumin (fluciclovine F18) scan. It is not a guide or instructions, nor is it intended to replace the independent medical judgment of the provider. Blue Earth Diagnostics does not provide nor imply any medical advice regarding patient care or patient management. It is the provider's responsibility to accurately complete and submit necessary information.

Patient:	**Exam Date:**
MRN:	**DOB:**
Referring Physician:	**FAX:**

Axumin® (Fluciclovine F 18) PET Scan

[Text in *italics* denotes suggested information to record]

DIAGNOSIS: *Consider including stage and state of prostate cancer*

EXAMINATION: *PET/CT or PET/MRI*

EQUIPMENT: *PET camera (make & model)*

AGENT: Fluciclovine F18

HISTORY: *Consider including the following: Clinical question; date of diagnosis; prior treatment (e.g. prostatectomy, radiation therapy, other locoregional treatment, hormonal therapy, chemotherapy, other systemic treatments); current treatment; current/recent PSA levels (showing suspicion of recurrence; PSA doubling Time (or comment if this is not available)); Gleason Score (initial); prior imaging/correlative studies, notable clinical symptoms (e.g. pain; loss of ROM).*

PROCEDURE: *Consider including the following: Administered activity; injection site (right or left); oral or i.v. contrast (if applicable); extravasation/tracer retention (if applicable); patient compliance with recommended scan preparation (i.e. exercise, fasting, voiding); time of injection*

ACQUISITION: *Consider including the following: Uptake time; axial extent of scan; minutes per bed position.*

FINDINGS: *Consider including the following: Any findings, with reference to the following regions: local recurrence; loco-regional recurrence; distant disease; focality, size and image slice number of any abnormal findings and describe abnormal uptake relative to blood pool and bone marrow; normal findings; muscle uptake; liver uptake; pancreas uptake; incidental findings; SUV_{max} (lesion); SUV_{mean} (background).*

Consider using terms like uptake, activity, avidity, or accumulation. Consider avoiding terms like "metabolic" or "hypermetabolism".

Consider including images/snapshots of findings.

IMPRESSION: *Consider recording an abbreviated summary of relevant findings and if possible, answer clinical question.*

RECOMMENDATIONS*: Consider including the following: additional testing, clinical correlation.*
