

The information contained in this template is provided by Blue Earth Diagnostics, Inc. to ensure communication of Axumin efficacy and safety information in accordance with applicable laws, rules, and regulations. This template is for facilities to use at their discretion. There is no requirement that any patient or healthcare provider use Axumin in exchange for this information.

[Imaging facility address/logo]

[Date]

Dear [Referring physician name],

Axumin® (fluciclovine F 18) Is Now Available at [Facility Name] for Use with PET/CT Scans to Detect and Localize Prostate Cancer Recurrence Across Local and Distant Sites

[Facility Name] now offers an imaging agent called Axumin that can be administered with a Positron Emission Tomography/Computed Tomography (PET/CT) scan for men with suspected recurrent prostate cancer. Axumin is FDA-approved in the United States for PET imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.¹ Axumin can help determine if prostate cancer has spread within the prostate or prostate bed or to other parts of the body.²

In a multicenter retrospective study, Axumin detected prostate cancer in 68% of men with elevated PSA (overall detection rate).² Metastases smaller than 5 mm were detected, and overall detection rates were ~40% at PSA levels ≤0.79 ng/mL, ~60% at PSA 0.8 to 2.03 ng/mL, ~75% at PSA 2.04 to 6.00 ng/mL, and ~85% at PSA ≥6.00 ng/mL.²

A PET/CT scan using Axumin typically takes 20 to 30 minutes.¹ Axumin PET/CT is usually covered by Medicare and private insurance plans for its approved use. As commercial payer policies and contracts vary widely, you should check with the appropriate payer to ascertain their coverage policies for Axumin.

Consider Axumin for your patients with suspected prostate cancer recurrence. To schedule a scan, please contact me, [Imaging facility representative name], at [Imaging facility Telephone] or [Imaging facility email].

Please visit www.Axumin.com to review real-world cases and learn how Axumin PET/CT scans may be able to help inform your treatment decisions.

Yours sincerely,

[Imaging facility representative name]

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 $\leq 1\%$ 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.

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

References: **1.** Axumin [package insert]. Oxford, UK: Blue Earth Diagnostics Ltd; 2016. **2.** 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;197:676-683.