

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.

[Date]

FOR IMMEDIATE RELEASE

[Facility Name] Now Provides New Type of Prostate Cancer Detection Imaging

[CITY, State, Date] – [Facility Name] now offers a diagnostic imaging agent called Axumin® (fluciclovine F 18) for use in positron emission tomography (PET) imaging for men with suspected recurrent prostate cancer based on elevated blood prostate specific antigen (PSA) levels following prior treatment.¹ An Axumin scan can help determine if prostate cancer has spread within the prostate or prostate bed or to other parts of the body.²

Prostate cancer is the second leading cause of cancer death in men in the United States. After the initial diagnosis of prostate cancer, many patients undergo treatment such as surgery, cryotherapy, or radiation. Most primary prostate cancer can be successfully treated. However, for some patients, the cancer may come back — this is called a recurrence. Prostate cancer recurrence occurs in up to 40% of patients, which is the reason why these patients are monitored with periodic Prostate Specific Antigen (PSA) blood tests. Recurrent disease is typically detected by a rise in PSA level, but often the location and extent of the disease cannot be detected by standard imaging.

“Many treatment options exist for these men, and knowing where the disease has recurred when PSA levels rise after primary treatment is essential to making appropriate patient management decisions. PET/CT imaging with Axumin can provide reliable information for these patients,” said [Name, Title, Affiliation].

An Axumin study is done using a PET/CT scanner in a hospital or imaging facility and typically takes 20 to 30 minutes. PET imaging is usually combined at the same time with computerized tomography (CT) scanning to improve the quality of the images and to help localize abnormalities. Like many diagnostic imaging agents, Axumin includes a radioactive element (fluorine 18) which is used in producing images of the body and its internal organs and tissues.

Indication and Important Safety Information About 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 $\leq 1\%$ 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.

About [Facility Name]

[Information about Facility here]

Contact:

[Imaging site representative name]

[Imaging site telephone]

[Imaging site email]

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 (18F) positron emission tomography/computerized tomography imaging in the staging of biochemically recurrent prostate cancer. *J Urol*. 2017;197:676-683.