

Sample Letter of Medical Necessity

[Date]

[Name of contact at health insurer]

[His/her title]

[Name of health insurance company]

[Address]

[City, state, ZIP]

Regarding: Letter of Medical Necessity for Axumin® (fluciclovine F 18)

Insured: [Name]

Patient: [Name]

Patient date of birth: [DOB]

Insurance ID #: [Policy #]

Dear [Name of contact]:

I am writing on behalf of my patient, [name of patient], to request that [name of insurance company] approve coverage for Axumin, which is used in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men who have elevated blood levels of prostate-specific antigen (PSA) following prior treatment.¹

Axumin is the first FDA-approved F 18 PET agent indicated for use in patients with suspected recurrent prostate cancer.¹ On September 10, 2021, the National Comprehensive Cancer Network® (NCCN®) updated the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Guideline for Prostate Cancer to Version 1.2022. The NCCN Guidelines® now state that F 18 fluciclovine PET/CT or PET/MRI should be considered in the clinical workup of patients with recurrence or progression of their prostate cancer.²

On behalf of the patient, I am requesting authorization to use Axumin in PET imaging to [describe intended clinical use].

Patient's medical history

[provide patient information regarding condition, symptoms, and history related to his prostate cancer]

Clinical rationale/supporting information

[provide clinical rationale for ordering Axumin scan and supporting documentation]

Based on the above information, I hope that you will agree that Axumin is indicated and medically necessary for the detection and localization of [name of patient]'s suspected recurrent prostate cancer. If you have any questions, please contact me at [physician's telephone number].

Thank you in advance for your immediate attention to this request. Please let me know if you have any questions.

Sincerely,

[Physician's name]

[Physician's practice name]

[Practice address]

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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 $\leq 1\%$ 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.

Please see accompanying full Axumin Prescribing Information, also available at www.axumin.com.

References: 1. Axumin [package insert]. Oxford, UK: Blue Earth Diagnostics Ltd; May 2021. 2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Guideline for Prostate Cancer (Version v1.2022). © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed September 17, 2021. To view the most recent and complete version of the guideline, go to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.