Template Letter for Appeal of Denial

[Date]
[Medical director]
[Insurance company name]
[Address]
[City, State, ZIP]

Re: [Patient name]
Patient Date of Birth: [DOB]
Policy #: [Policy #]
Claim #: [Claim #]

Dear [Medical director]:

I am writing this letter to formally request a reconsideration of the adverse determination for an Axumin® (fluciclovine F 18) PET scan in the above-referenced claim. It is my understanding based on your letter of denial dated [insert date] that this procedure has been denied because: [quote the specific reason for the denial stated in denial letter].

[If the denial criteria is unclear, you may consider requesting additional information such as:]

Therefore, I am requesting the following information, which will allow me to assess the appropriate application of the clinical guideline and determine if the referenced guideline is specific to this patient's needs:

1. Name and specialty of the board-certified physician who reviewed this claim
2. Board-certified physician's recommendation regarding alternative diagnostic assessment or work-up
3. A copy of applicable internal clinical guideline, source, and the date of development
4. An outline of the specific records reviewed and a description of any records that would be necessary to justify coverage
5. Copies of any peer-reviewed literature, technical assessments, or expert medical opinions used to determine coverage

As documented below, on May 27, 2016, the Food and Drug Administration approved the use of Axumin injection. Axumin is indicated for 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. It is my opinion that the use of Axumin PET imaging is appropriate and medically necessary for [patient name] and should be covered by [plan].

[This is where you should summarize your rationale as to why an Axumin PET scan is appropriate and medically necessary for the patient. Consider including the following information:]

- Description of patient's condition, date of original diagnosis, and history related to his prostate cancer
- Circumstances surrounding care, including current symptoms and need for diagnostic imaging with Axumin
- Previous diagnostic tests, therapies, and any complications
- Standard of care (may also include Centers for Medicare and Medicaid Services [CMS] National Coverage Determination, NCCN Clinical Practice Guidelines in Oncology [NCCN Guidelines®], American College of Radiology [ACR] Appropriate Use Criteria)
- Any other relevant information

Based on [patient name]'s condition, medical history, and the attached information, I believe this treatment is medically appropriate and necessary.

I respectfully request that you review the information provided and reevaluate your coverage of Axumin PET imaging for [patient name]. If you have any further questions about this request, please contact me at [insert practice phone number]. I look forward to your reconsideration.

Regards,

[Provider Name]

Please see back for enclosure requirements.

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Enclosure

[Prescribing Information is a mandatory enclosure]

- FDA-approved Prescribing Information for Axumin® (fluciclovine F 18)

[Enclose additional documents as specifically required by payer in appeal procedures or supportive of use.]

May also include:

- Copy of the original claim
- Designated payer-specific appeal form
- Copy of the denial notification from the payer
- Patient's complete medical history
- CMS National Coverage Policy regarding Axumin PET and PET/CT imaging for suspicion of recurrent prostate cancer
- ACR Appropriate Use Criteria
- Relevant peer-reviewed articles supporting the use of Axumin PET and PET/CT imaging for suspicion of recurrent prostate cancer

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

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