



# MASSACHUSETTS

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## Medical Policy

### AXUMIN® (fluciclovine F-18) for Recurrent Prostate Cancer

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#### Policy Number: 025

BCBSA Reference Number: N/A

NCD/LCD: N/A

#### Related Policies

- Positron Emission Tomography, Other PET Applications, Including Oncologic Tumor Imaging, #229
- Positron Emission Tomography (PET) Brain, #903

#### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

AXUMIN® (fluciclovine F-18) injection is considered **MEDICALLY NECESSARY** for positron emission tomography (PET) imaging in patients with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

AXUMIN® (fluciclovine F-18) injection is considered **INVESTIGATIONAL** for all other indications.

#### Prior Authorization Information

##### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

##### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

### CPT Codes

CPT codes:	Code Description
78811	Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
78812	Tumor imaging, positron emission tomography (PET); skull base to mid-thigh
78813	Tumor imaging, positron emission tomography (PET); whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)
78815	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh
78816	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body

### HCPCS Codes

HCPCS codes:	Code Description
A9588	Fluciclovine f-18, diagnostic, 1 millicurie

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

### ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
C61	Malignant neoplasm of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate

## Summary

Axumin® is a radioactive diagnostic agent. It is FDA approved for use in patients with suspected prostate cancer recurrence. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer give F-18 fluciclovine PET/CT a 2A rating based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate and state Axumin® should be considered as an option in the clinical workup of patients with recurrence or progression of their prostate cancer.

## Policy History

Date	Action
7/2018	New medical policy describing medically necessary and investigational indications. Effective 7/1/2018.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf)
2. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/208054s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208054s000lbl.pdf)
3. Evangelista L, Briganti A, Fanti S, et al. [New Clinical Indications for \(18\)F/\(11\)C-choline, New Tracers for Positron Emission Tomography and a Promising Hybrid Device for Prostate Cancer Staging: A Systematic Review of the Literature](#). Eur Urol. 2016 Jul;70(1):161-175.
4. Odewole OA, Tade FI, Nieh PT et al. Recurrent prostate cancer detection with anti-3-[(18)F]FACBC PET/CT: comparison with CT. Eur J Nucl Med Mol Imaging. 2016 Sep;43(10):1773-83. <https://www.ncbi.nlm.nih.gov/pubmed/27091135>
5. Nanni C, Schiavina R, Brunocilla E et al. 18F-Fluciclovine PET/CT for the Detection of Prostate Cancer Relapse: A Comparison to 11C-Choline PET/CT. Clin Nucl Med. 2015 Aug;40(8) <https://www.ncbi.nlm.nih.gov/pubmed/26053708>