POSLUMA® (flotufolastat F 18) injection Coding Information Sheet

Information current as of January 1, 2024.

HCPCS code for POSLUMA®

HCPCS code	HCPCS descriptor	For dates of service
A9608	Flotufolastat f18, diagnostic, 1 millicurie*	Effective January 1, 2024*

*units of billing 1 unit per millicurie (mCi) administered; label-recommended patient dose is 8mCi

Most commonly used CPT Codes for POSLUMA PET Scans

The Current Procedural Terminology (CPT®) codes for PET imaging are 78811- 78816. Providers should choose the code that accurately describes the procedure performed and is supported by documentation in the medical record. Based on POSLUMA's Prescribing Information, it is expected that the following 2 CPT codes will be commonly used for POSLUMA PET or PET/CT imaging of patients with prostate cancer prior to initial therapy or suspected recurrent prostate cancer based on elevated PSA levels:

CPT® code	CPT descriptor
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78815	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh

Medicare Required Oncologic PET Billing Modifier

Medicare requires oncologic PET imaging be billed using either the PI or PS modifier.

Modifier	Modifier descriptor
PI	Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing. Short descriptor: PET tumor init tx strat
PS	Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent antitumor strategy. Short descriptor: PET tumor subsq tx strategy

Note: effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separatly payable under Medicare Part B when there are no discard amounts. For more information go to:. https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf

Effective January 1, 2017, providers and suppliers are required to report the JW modifier on all claims that bill for drugs and biologicals (hereafter, drugs) separately payable under Medicare Part B with unused and discarded amounts (hereafter, discarded amounts) from single-dose containers or single- use packages (hereafter, single-dose containers). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf

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National Drug Code (NDC) Codes for POSLUMA

NDC Code for POSLUMA® (flotufolastat F 18) injection	NDC Code Descriptor
69932-002-01	10-digit NDC Codes for a single dose of POSLUMA
69932-0002-01	11-digit NDC Codes for a single dose of POSLUMA

This is the published code associated with the Wholesale Acquisition Cost (WAC) submitted by Blue Earth Diagnostics.

Providers should follow payer coding and billing guidelines regarding which NDC number is appropriate.

ICD-10-CM Codes most commonly used for POSLUMA PET Scans

ICD-10-CM Codes	Descriptor
C61	Malignant neoplasm of the prostate
R97.20	Elevated prostate specific antigen (PSA)
R97.21	Rising PSA following treatment for malignant neoplasm of the prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z19.1	Hormone Sensitive malignancy status
Z19.2	Hormone resistant malignancy status

The above codes are representative. Providers should choose the code(s) that most accurately describes the patient's diagnoses.

NOTE: Whenever a personal history diagnosis code (Z85.XXX) is on a claim, the claim must also contain a diagnosis code from the list of covered "C","D" or "R" codes.

https://www.cms.gov/medicare/coverage/determinationprocess/downloads/petforsolidtumorsoncologicdxcodesattachment_NCD220_6_17.pdf

Your Blue Earth Diagnostics Field Reimbursement Manager is available to review information about local and national payer coverage requirements and to answer other reimbursement-related questions.

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INDICATION

POSLUMA® (flotufolastat F 18) injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

IMPORTANT SAFETY INFORMATION

- Image interpretation errors can occur with POSLUMA PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of POSLUMA for imaging metastatic pelvic lymph nodes in patients prior to initial definitive therapy seems to be affected by serum PSA levels and risk grouping. The performance of POSLUMA for imaging patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. Flotufolastat F 18 uptake is not specific for prostate cancer and may occur in other types of cancer, in non-malignant processes, and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.
- Risk of Image Misinterpretation in Patients with Suspected Prostate Cancer Recurrence: The interpretation of POSLUMA PET may differ depending on imaging readers, particularly in the prostate/prostate bed region. Because of the associated risk of false positive interpretation, consider multidisciplinary consultation and histopathological confirmation when clinical decision-making hinges on flotufolastat F 18 uptake only in the prostate/prostate bed region or only on uptake interpreted as borderline.
- POSLUMA use contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Advise patients to hydrate before and after administration and to void frequently after administration. Ensure safe handling to minimize radiation exposure to the patient and health care providers.
- The adverse reactions reported in ≥0.4% of patients in clinical studies were diarrhea, blood pressure increase and injection site pain.
- Drug Interactions: androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of flotufolastat F 18 in prostate cancer. The effect of these therapies on performance of POSLUMA PET has not been established.

To report suspected adverse reactions to POSLUMA, call 1-844-POSLUMA (1-844-767-5862) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full POSLUMA prescribing information is available at www.posluma.com/prescribing-information.pdf