Access and Reimbursement Information for POSLUMA® (flotufolastat F 18) Injection

The purpose of this resource is to offer information to providers and payers regarding reimbursement for POSLUMA® (flotufolastat F 18) injection. Reimbursement information and processes will evolve over time, as they do with any prescription drug.

Please visit https://www.posluma.com periodically for the most up-to-date information.

REIMBURSEMENT SUPPORT HELPLINE

Telephone
1-855-495-9200

Hours of Operation: Telephone support is available Monday through Friday, from 9 AM to 8 PM EST.

Fax
1-877-309-7514

Email
reimbursement@blueearthdx.com

NEW REIMBURSEMENT SUPPORT TO HELP PATIENTS ACCESS POSLUMA

- **Benefit investigation:** Investigation of patient insurance benefits, including deductible and copayments, and coverage status for POSLUMA and PET/CT, including insurance requirements and possible coverage restrictions
- **Prior authorization (PA) assistance:** Information on PA requirements*
- **Appeal assistance:** Information on appeals requirements for denied prior authorizations or denied claims†

ADDITIONAL SUPPORT OFFERED

- **Billing, coding, and claims information:** Assistance with questions specific to billing, coding, and claims submission for POSLUMA and PET
- **Patient support:** Support with issues related to reimbursement coverage, claim submission, and payment denials

Patient enrollment	Benefit investigation	Prior authorization assistance	Appeal assistance
Practice submits patient enrollment form to helpline and is contacted within 24 hours	Helpline conducts benefit investigation and notifies practice within 24 to 48 hours	Helpline assists practice in understanding PA requirements, submits and follows up within 48 to 72 hours*	Helpline assists practice in understanding appeal requirements for a denied PA or claim

*Prior Authorization response time varies by payer.

†Helpline provides information about PA/appeals requirements, and at the provider's option, submits PA forms completed by the provider to the payer.

This document contains factual information and is not intended to be legal or coding advice. Blue Earth Diagnostics does not guarantee coverage or reimbursement for POSLUMA® (flotufolastat F 18) injection. The information provided in this document is based upon current, general coding practices. The existence of billing codes does not guarantee coverage and payment. Payer policies vary and may change without notice. It is the provider's responsibility to determine and submit accurate information on claims. This includes submitting proper codes, modifiers, charges, and invoices for the services that were rendered. The coding on claims should reflect medical necessity and be consistent with the documentation in the patient's medical record.

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flotufolastat F 18 injection

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Important Safety Information

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

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