



LOCAMETZ[®] (kit for the preparation of gallium Ga 68 gozetotide injection)

INDICATION

LOCAMETZ, after radiolabeling with gallium-68, 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
- for selection of patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated

LOCAMETZ PRODUCT SPECIFICATION GUIDE*

NDC¹	69488-017-61		
List price (WAC)⁺	3-5 mCi dose \$4000	6 mCi dose \$4800	7 mCi dose \$5600
Nomenclature¹	A radioactive diagnostic agent		
Dosage and administration¹	The recommended amount of radioactivity to be administered for PET is 111 MBq to 259 MBq (3 mCi to 7 mCi) by slow intravenous injection. [‡]		

IMPORTANT SAFETY INFORMATION

Risk for Misinterpretation

Image interpretation errors can occur with LOCAMETZ PET. Negative imaging does not rule out the presence of prostate cancer and a positive imaging does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as nonmalignant processes. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Imaging prior to initial definitive or suspected recurrence therapy

The performance of LOCAMETZ seems to be affected by serum PSA levels and by site of disease for imaging of biochemically recurrent prostate cancer, and by Gleason score for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy.

Imaging to select patients for lutetium Lu 177 vipivotide tetraxetan therapy

The interpretation of LOCAMETZ PET may differ depending on imaging readers. LOCAMETZ PET interpretations to select patients for lutetium Lu 177 vipivotide tetraxetan therapy may be more consistent when judging gallium Ga 68 gozetotide uptake in any 1 tumor lesion compared with judging uptake for all lesions larger than size criteria. Multidisciplinary consultation is recommended, particularly for LOCAMETZ imaging that a single reader finds borderline or difficult to interpret, or when patient eligibility hinges only on judgment of gallium Ga 68 gozetotide uptake for all lesions larger than size criteria.

NDC, National Drug Code; WAC, wholesale acquisition cost.

*Product invoice may be required for proper billing along with product Prescribing Information. Individual payers may require you to enter total dosage in the remarks or comment box when submitting the claim.

⁺List price may differ from contracted radiopharmacy sale price.

[‡]Please see full Prescribing Information for complete information on dosing and administration, including safe handling of radiopharmaceuticals.

**Please see additional Important Safety Information on the next page.
 Please see the full [Prescribing Information](#).**

LOCAMETZ PRODUCT SPECIFICATION GUIDE (continued)

HCPCS code²

A4641	Radiopharmaceutical, diagnostic, not otherwise classified*
-------	--

CPT codes³

78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

CPT, *Current Procedural Terminology*; HCPCS, Healthcare Common Procedure Coding System.

*In the absence of a product-specific code, a not otherwise classified (NOC) HCPCS is required. A9597 and A9598 may also be accepted. Payers may also require the NDC. Health care professionals should contact third-party payers for specific information on their coding, coverage, and payment policies.



It is the health care professional's responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules. These codes are provided for informational purposes only. AAA does not guarantee success in obtaining reimbursement or financial assistance. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved.

IMPORTANT SAFETY INFORMATION (continued)

Radiation Risk

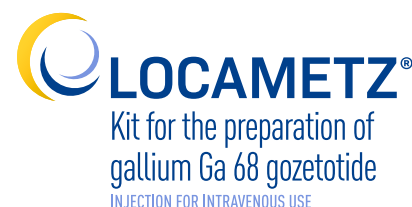
Gallium Ga 68 gozetotide contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to be well hydrated prior to gallium Ga 68 gozetotide administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure.

Adverse Reactions

Adverse reactions $\geq 0.5\%$ in the VISION study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%). Adverse reactions occurring at a rate of $<0.5\%$ were diarrhea, dry mouth, injection site reactions, and chills.

Please see the full [Prescribing Information](#).

References: **1.** Locametz [prescribing information]. Millburn, NJ: Advanced Accelerator Applications; 2022. **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update: January 2022. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed March 9, 2022. **3.** American Medical Association. *CPT Professional Edition*. Chicago, IL; 2021.



Advanced Accelerator Applications USA, Inc., 57 East Willow Street, Millburn, NJ 07041
© 2022 Advanced Accelerator Applications. All Rights Reserved. 157556 3/22