LOCAMETZ®
Kit for the preparation of gallium Ga 68 gozetotide
INJECTION FOR INTRAVENOUS USE

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

Indication

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

PRODUCT SPECIFICATION GUIDE*

NDC[1]	69488-017-61		
List price (WAC)†	3-5 mCi dose $4000	6 mCi dose $4800	7 mCi dose $5600
Nomenclature[1]	A radioactive diagnostic agent		
Dosage and administration[1]	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; PET, positron emission tomography; 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 full Prescribing Information.

PRODUCT SPECIFICATION GUIDE (continued)

HCPCS code[2]	
A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 mCi

CPT codes[3]	
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

Additionally, **CMS has granted LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) transitional pass-through status effective October 1, 2022**. Transitional pass-through status is a temporary payment policy granted by CMS under the Hospital Outpatient Prospective Payment System as indicated by status indicator "G". This only applies when LOCAMETZ is administered to Medicare patients in the hospital outpatient setting.

CMS, Centers for Medicare & Medicaid Services; CPT, *Current Procedural Terminology*; HCPCS, Healthcare Common Procedure Coding System.

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. Advanced Accelerator Applications 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 ≥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 full Prescribing Information.

References: 1. Locametz [prescribing information]. Millburn, NJ: Advanced Accelerator Applications, Inc. **2.** Centers for Medicare & Medicaid Services. Second quarter, [2022] HCPCS coding cycle. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-2-2022-drugs-and-biologicals.pdf. [Accessed August 25, 2022]. **3.** AAPC. *CPT 2022 Professional Edition.* 2021. https://aapc.vitalsource.com/#/. Accessed August 25, 2022.

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