



#### 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 who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products.

### **PRODUCT SPECIFICATION GUIDE\***

NDC <sup>1</sup>	69488-017-61
Price (WAC)	\$4120 per dose
Nomenclature <sup>1</sup>	A radioactive diagnostic agent
Dosage and administration <sup>1</sup>	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. <sup>‡</sup>

### 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.

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.

### **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.

NDC, National Drug Code; PET, positron emission tomography; WAC, wholesale acquisition cost.

Please see additional Important Safety Information on the back. Please see full Prescribing Information.

<sup>\*</sup>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.

<sup>†</sup>List price may differ from contracted radiopharmacy sale price.

<sup>†</sup>Please see full Prescribing Information for complete information on dosing and administration, including safe handling of radiopharmaceuticals.

# **PRODUCT SPECIFICATION GUIDE (continued)**

HCPCS code <sup>2</sup>	
A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 mCi
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

Additionally, CMS has granted LOCAMETZ transitional pass-through status effective October 1, 2022 that will expire September 30, 2025.

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. Novartis Pharmaceuticals Corporation 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)

#### **Adverse Reactions**

Adverse reactions  $\ge$ 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 <u>Prescribing Information</u>.

**References: 1.** Locametz. Prescribing information. Millburn, NJ: Advanced Accelerator Applications, Inc. **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated May 24, 2023. Accessed June 16, 2023. https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update **3.** American Medical Association. CPT® (Current Procedural Terminology). Accessed June 16, 2023. https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology



