

## Quadramet® (Samarium Sm 153 Lexidronam) (Intravenous)

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### I. Length of Authorization

Coverage will be provided for 1 treatment course and may be renewed, one-time only, after 60 days.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- N/A

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 1 billable unit (up to 150 mCi) one time only

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 16 years old; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient will not use in combination with or has not had a treatment course of strontium-89 chloride within the previous 90 days; **AND**
- Patient has not had a treatment course of Samarium-Sm-153 Lexidronam within the previous 60 days; **AND**
- Patients of reproductive potential will use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient will not receive chemotherapy or external beam radiation therapy concurrently; **AND**
- Patient does not have significant bone marrow suppression (i.e., neutropenia, leukopenia, thrombocytopenia, etc.); **AND**
- Patient does not have disseminated intravascular coagulation; **AND**

#### Pain related to metastatic bone lesions †

- Used for palliative treatment of metastatic skeletal bone pain; **AND**

- Patient has had a positive (enhancement) radionuclide bone scan confirming osteoblastic metastatic bone lesions; **AND**
- Therapy will not be used for spinal cord compression pain; **AND**
- Patient has failed other conventional treatments for bone pain due to skeletal metastases (e.g., chemotherapy, hormonal therapy, external beam radiation, opioid analgesics, etc.); **AND**
- Patient has a life-expectancy of at least 6 months  
† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Patient had an inadequate response or recurrence of bone pain after the initial dose; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe leukopenia, severe thrombocytopenia, severe neutropenia, etc.; **AND**
- Patient has experienced hematological recovery since administration of the initial dose

#### V. Dosage/Administration

Indication	Dose
Metastatic Bone Pain	<ul style="list-style-type: none"> <li>• The recommended dose is 1.0 mCi/kg, administered intravenously over a period of one minute through a secure in-dwelling catheter and followed with a saline flush.               <ul style="list-style-type: none"> <li>– The patient should ingest (or receive by i.v. administration) a minimum of 500 mL (2 cups) of fluids prior to injection and should void as often as possible after injection to minimize radiation exposure to the bladder.</li> </ul> </li> </ul>
<p>– <i>Quadramet is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling. Quadramet should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.</i></p>	
<p>– <i>Thaw at room temperature before administration and use within 8 hours of thawing.</i></p>	

#### VI. Billing Code/Availability Information

HCPCS code:

- A9604 – Samarium sm-153 lexidronam, therapeutic, per treatment dose, up to 150 millicuries

NDC:

- Quadramet 5550 MBq (150 mCi) 3 mL frozen single-dose vial: 11994-0016-XX

#### VII. References

1. Quadramet [package insert]. N. Billerica, MA; Lantheus Medical Imaging; March 2018. Accessed January 2019.

2. Anderson PM, Wiseman GA, Dispenzieri A, et al. High-dose samarium-153 ethylene diamine tetramethylene phosphonate: low toxicity of skeletal irradiation in patients with osteosarcoma and bone metastases. J Clin Oncol. 2002 Jan 1;20(1):189-96.
3. American College of Radiology (ACR), American Society for Radiation Oncology (ASTRO). ACR-ASTRO practice guideline for the performance of therapy with unsealed radiopharmaceutical sources. [online publication]. Reston, VA: American College of Radiology (ACR); 2010.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Prostate Cancer. Version 4.2018. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2019

### Appendix 1 – Covered Diagnosis Codes

ICD10	ICD-10 Description
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
15	KY, OH	CGS Administrators, LLC