MODA applies pre-payment claims edits to diagnosis criteria and criteria for maximum units. Prior Authorization criteria *do not apply* for this policy.

OHSUHealthServices

Quadramet® (Samarium Sm 153 Lexidronam) (Intravenous)

Document Number: IC-0435

Last Review Date: 10/03/2024
Date of Origin: 03/04/2019
Dates Reviewed: 03/2019, 07/2020, 07/2021, 07/2022, 12/2023, 10/2024

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) [NDC Unit]:

- N/A

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit for 1 treatment course, may repeat one-time only after 60 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 16 years of age; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to treatment; **AND**
- Lactating women should discontinue breast feeding and substitute with formula feedings prior to administration; **AND**

Universal Criteria [1,3]

- 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 6 months after the last dose; **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 † [1,2]

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

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- 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); Φ Orphan Drug

IV. Renewal Criteria [1,3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe leukopenia, severe thrombocytopenia, severe neutropenia, etc.; **AND**
- Patient has experienced hematological recovery since administration of the initial dose; **AND**
- Patient had an inadequate response or recurrence of bone pain after the initial dose

V. Dosage/Administration [1]

Indication	Dose
Metastatic Bone Pain	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. – **Note:** The patient should ingest (or receive by IV 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.
– *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.* – *Thaw at room temperature before administration and use within 8 hours of thawing.*	

VI. Billing Code/Availability Information

HCPCS Code:

- A9604 – Samarium sm-153 lexidronam, therapeutic, per treatment dose, up to 150 millicuries; 1 billable unit = 150 mCi

NDC:

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

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VII. References

1. Quadramet [package insert]. N. Billerica, MA; Lantheus Medical Imaging, Inc.; September 2017. Accessed September 2024.
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); 2011.
4. American College of Radiology (ACR), American College of Nuclear Medicine (ACNM), American Society for Radiation Oncology (ASTRO), and Society of Nuclear Medicine and Molecular Imaging (SNMMI). ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources. [online publication]. Reston, VA: American College of Radiology (ACR); Revised 2019 (Resolution 41).
5. American College of Radiology (ACR), American College of Nuclear Medicine (ACNM), American Radium Society (ARS), American Society for Radiation Oncology (ASTRO), and Society of Nuclear Medicine and Molecular Imaging (SNMMI). ACR–ACNM–ARS–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Radiopharmaceuticals. [online publication]. Reston, VA: American College of Radiology (ACR); Revised 2023 (Resolution 27). https://www.acr.org/-/media/ACR/Files/Practice-Parameters/UnsealedSources.pdf

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

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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 GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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)
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