Metastron™ (Strontium-89 Chloride) (Intravenous)

Document Number: OHSU HEALTHSERVICES-0434

Last Review Date: 07/01/2021 Date of Origin: 03/04/2019

Dates Reviewed: 03/2019, 07/2020, 07/2021

I. Length of Authorization

Coverage will be provided for 1 treatment course and may be renewed, one-time only, after 90 days.

II. Dosing Limits

- A. Quantity Limit (max daily dose) [NDC Unit]:
- N/A
- B. Max Units (per dose and over time) [HCPCS Unit]:
- 6 billable units (6 mCi) per each treatment course

III. Initial Approval Criteria 1-4

Coverage is provided in the following conditions:

- Patient is at least 18 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 at least 6 weeks prior to administration; AND

Universal Criteria

- Patient has not had a treatment course of strontium-89 chloride within the previous 90 days;
 AND
- Patient will not use in combination with or 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 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); Φ Orphan Drug

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and/or other indication specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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	• The recommended dose of Metastron is 148 MBq, 4 mCi, administered by slow
Bone Pain	intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 -2.2 MBq/kg, 40-60 mCi/kg, body weight may be used.

[—] Metastron is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling. Metastron 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.

VI. Billing Code/Availability Information

HCPCS Code:

• A9600 – Strontium sr-89 chloride, therapeutic, per millicurie: 1 billable unit = 1 mCi

OHSU HealthServices applies pre-payment claims edits to diagnosis criteria and criteria for maximum units. Prior authorization criteria do not apply for this policy.

NDC:

• Metastron 148 MBq (4 mCi) 10 mL single-dose vial: 17156-0524-XX

VII. References

- 1. Metastron [package insert]. Arlington Heights, IL; GE Healthcare, Medi-Physics, Inc.; December 2013. Accessed May 2021.
- 2. 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.
- 3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Prostate Cancer. Version 2.2021. National Comprehensive Cancer Network, 2021. 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 May 2021.
- 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). 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)

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/new-search/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/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
		Noridian Healthcare Solutions, LLC		

OHSUHealthServices

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
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, 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)		
15	KY, OH	CGS Administrators, LLC		