Clinical Policy: Sodium Thiosulfate (Pedmark)

Reference Number: CP.PHAR.610
Effective Date: 03.01.23
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sodium thiosulfate (Pedmark®) is an antidote.

FDA Approved Indication(s)

Pedmark is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Limitation(s) of use: The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Pedmark is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ototoxicity Prophylaxis (must meet all):

1. Diagnosis of localized, non-metastatic solid tumor(s);
2. Member will be treated with cisplatin chemotherapy;
3. Prescribed by or in consultation with an oncologist;
4. Age > 1 month and ≤ 18 years;
5. Documentation of member's body surface area in m^2;
6. Documentation of member's actual weight in kg;
7. Dose does not exceed one of the following (a, b, or c):
   a. For body weight < 5 kg: 10 g/m^2;
   b. For body weight ≥ 5 kg to 10 kg: 15 g/m^2;
   c. For body weight >10 kg: 20 g/m^2 per cisplatin dose.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Ototoxicity Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Pedmark for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Documentation of member's body surface area in m^2;
4. Documentation of member's actual weight in kg;
5. Dose does not exceed one of the following (a, b, or c):
   a. For body weight < 5 kg: 10 g/m^2;
   b. For body weight ≥ 5 kg to 10 kg: 15 g/ m^2;
   c. For body weight > 10 kg: 20 g/m^2 per cisplatin dose.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
STS: sodium thiosulfate

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication: Pedmark is contraindicated in patients with a history of a severe hypersensitivity to sodium thiosulfate or any of its components.
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ototoxicity Prophylaxis	Administered IV, following cisplatin infusions that are 1 to 6 hours in duration. Pedmark dose is based on surface area according to weight: • Less than 5 kg: 10g/m^2/dose • 5 to 10 kg: 15g/m^2/dose • Greater than 10 kg: 20g/m^2/dose	See dosing regimen

VI. Product Availability

Single-dose vial: 12.5 grams/100 mL

VII. References

1. Pedmark Prescribing Information. Hoboken, NJ: Fennec Pharmaceuticals Inc. September 2022. Available at: https://www.pedmarkhcp.com/?gclid=EAIaIQobChMI2fWSxsClggMVPzXUAR2uDA42EAAYASAAEgL_4PD_BwE. Accessed November 1, 2024.
2. Brock PR, Maibach R, Childs M, et al. Sodium Thiosulfate for Protection from Cisplatin-Induced Hearing Loss. The New England journal of medicine. 2018;378(25):2376-2385. doi:10.1056/NEJMoa1801109.

3. Freyer DR, Chen L, Krailo MD, et al. Effects of sodium thiosulfate versus observation on development of cisplatin-induced hearing loss in children with cancer (ACCL0431): a multicentre, randomised, controlled, open-label, phase 3 trial [published correction appears in Lancet Oncol. 2017 Jun;18(6):e301]. Lancet Oncol. 2017;18(1):63-74. doi:10.1016/S1470-2045(16)30625-8.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed November 21, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0208	Injection, sodium thiosulfate (pedmark), 100 mg
J0209	Injection, sodium thiosulfate (hope), 100 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.14.22	02.23
Added HCPCS code [J0208].	04.17.23	
1Q 2024 annual review: no significant changes; references reviewed and updated.	11.14.23	02.24
Revised HCPCS code [J0208] description and added HCPCS code [J0209].	02.22.24	
1Q 2025 annual review: for continued therapy, added commercial duration language of "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated.	11.01.24	02.25

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members, and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.