Clinical Policy: Sodium thiosulfate (Pedmark)

Reference Number: LA.PHAR.610
Effective Date:
Last Review Date: 05.01.23 Revision Log
Line of Business: Medicaid

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

Please note: This policy is for medical benefit

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 Louisiana Healthcare Connections® 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 LA.PMN.255
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: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections 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: 12 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 LA.PMN.255
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: LA.PMN.53 for Medicaid.

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

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 – LA.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	Member's 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

Injection: 12.5 grams/100 mL in a single-dose vial

VII. References

1. Pedmark Prescribing Information. Hoboken, NJ: Fennec Pharmaceuticals Inc. September 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212937s000lbl.pdf. Accessed October 6, 2022.
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. Pedmark Drug Monograph. Clinical Pharmacology. Accessed October 2022. https://www.clinicalkey.com/pharmacology/monograph/2485?sec=monindi&n=Pedmark

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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