

Clinical Policy: Sodium thiosulfate (Pedmark)

Reference Number: LA.PHAR.610

Effective Date:

Last Review Date: 05.01.23

Line of Business: Medicaid

[Revision Log](#)

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 m²;
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/m²;
 - b. For body weight ≥ 5 kg to 10 kg: 15 g/m²;
 - c. For body weight > 10 kg: 20 g/m² per cisplatin dose.

Approval duration: 6 months

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

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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: $10 \text{ g}/m^2$;
 - b. For body weight ≥ 5 kg to 10 kg: $15 \text{ g}/m^2$;
 - c. For body weight > 10 kg: $20 \text{ g}/m^2$ 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

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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: <ul style="list-style-type: none"> • Less than 5 kg: 10g/m²/dose • 5 to 10 kg: 15g/m²/dose • Greater than 10 kg: 20g/m²/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/2022/212937s0001bl.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

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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.

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