



Clinical Policy: Sodium ~~thiosulfate~~Thiosulfate (Pedmark)

Reference Number: LA.PHAR.610

Effective Date: 09.29.23

Last Review Date: ~~03.10.25~~07.24.24

Line of Business: Medicaid

[Revision Log](#)

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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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

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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 m²;
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/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: 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~~ 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	<p>Member's weight: <u>Administered IV, following cisplatin infusions that are 1 to 6 hours in duration. Pedmark dose is based on surface area according to weight:</u></p> <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

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VI. Product Availability

~~Injection~~ Single-dose vial: 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.pedmarkhcp.com/?gclid=EA1aIQobChMI2fWSxsClggMVPzXUAR2uDA42EAYASAAEgL_4PD_BwE. Accessed November ~~14, 2023~~ 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.; ~~2023~~ 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed November ~~14, 2023~~ 21, 2024.

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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.

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

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	08.28.23
Added HCPCS code [J0208].	02.10.24	05.10.2024
References reviewed and updated; revised HCPCS code [J0208] description and added HCPCS code [J0209].	07.24.24	<u>09.26.24</u>
<u>Annual review; no significant changes; references reviewed and updated.</u>	<u>03.10.25</u>	

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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.

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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.

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