

## Clinical Policy: Sodium thiosulfate (Pedmark)

Reference Number: PA.CP.PHAR.610

Effective Date: 01/2023

Last Review Date: 01/2026

### Description

Sodium thiosulfate (Pedmark<sup>®</sup>) 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 PA Health & Wellness<sup>®</sup> 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<sup>2</sup>;
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<sup>2</sup>;
  - b. For body weight ≥ 5 kg to 10 kg: 15 g/m<sup>2</sup>;
  - c. For body weight >10 kg: 20 g/m<sup>2</sup> per cisplatin dose.

**Approval duration: 12 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

#### II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Documentation of member's body surface area in m<sup>2</sup>;
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<sup>2</sup>;
  - b. For body weight ≥ 5 kg to 10 kg: 15 g/ m<sup>2</sup>;
  - c. For body weight >10 kg: 20 g/m<sup>2</sup> per cisplatin dose.

**Approval duration: 12 months**

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**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 – PA.CP.PMN.53.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

STS: sodium thiosulfatem

*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: <ul style="list-style-type: none"> <li>• Less than 5 kg: 10g/m<sup>2</sup>/dose</li> <li>• 5 to 10 kg: 15g/m<sup>2</sup>/dose</li> <li>• Greater than 10 kg: 20g/m<sup>2</sup>/dose</li> </ul>	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. October 2023. Available at:  
[https://www.pedmarkhcp.com/?gclid=EAIaIQobChMI2fWSxsClggMVPzXUAR2uDA42EAAYASAAEgL\\_4PD\\_BwE](https://www.pedmarkhcp.com/?gclid=EAIaIQobChMI2fWSxsClggMVPzXUAR2uDA42EAAYASAAEgL_4PD_BwE) Accessed November 6, 2025.
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/NEJMoal801109.
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 19, 2025.

**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
Policy created	01/2023
1Q 2024 annual review: added HCPCS code [J0208]; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025
1Q 2026 annual review: no significant changes; added HCPCS codes; extended initial approval duration from 6 to 12 months; references reviewed and updated.	