

## **Clinical Policy: Sodium thiosulfate (Pedmark)**

Reference Number: PA.CP.PHAR.610

Effective Date: 01/2023

Last Review Date: 01/2025

### **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: 6 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. September 2022. Available at: [https://www.pedmarkhcp.com/?gclid=EAIaIQobChMI2fWSxsClggMVPzXUAR2uDA42EAAYASAAEgL\\_4PD\\_BwE](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/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 21, 2024.

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