Clinical Policy: Sodium thiosulfate (Pedmark)

Reference Number: PA.CP.PHAR.610
Effective Date: 01/2023
Last Review Date: 01/2023

Revision Log

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 PA Health & Wellness® 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

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.LTSS.PHAR.01) applies;
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. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.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	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	P&T Approval Date
Policy created	01/2023	