Clinical Policy Title:	sodium thiosulfate
Policy Number:	RxA.780
Drug(s) Applied:	Pedmark®
Original Policy Date:	01/17/2023
Last Review Date:	01/17/2023
Line of Business Policy Applies to:	All lines of business

Background

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.

Limitations of Use: The safety and efficacy 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sodium thiosulfate (Pedmark®)	Reduction of ototoxicity risk associated with cisplatin	Weight less than 5 kg: 10 gm/m^2/dose 6 hours after completion of each cisplatin infusion. Weight 5 to 10 kg: 15 gm/m^2/dose 6 hours after completion of each cisplatin infusion. Weight greater than 10 kg: 20 gm/m^2/dose 6 hours after completion of each cisplatin infusion.	Weight less than 5 kg: 10 gm/m^2 Weight 5 to 10 kg: 15 gm/m^2 Weight greater than 10 kg: 20 gm/m^2

Dosage Forms

- 12.5 gm/100 mL single-dose vial for injection.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cisplatin-induced ototoxicity; risk reduction (must meet all):
1. Diagnosis of localized, non-metastatic solid tumor;
2. Age ≥ 1 month and < 18 years;
3. Member must be receiving a cisplatin-based regimen;
4. Member has a baseline serum sodium level < 145mmol/L;
5. Dose does not exceed one of the following (a, b, or c):
   a. Weight less than 5 kg: 10 gm/m^2;
   b. Weight 5 to 10 kg: 15 gm/m^2;
   c. Weight greater than 10 kg: 20 gm/m^2.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Cisplatin-induced ototoxicity; risk reduction (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Member has a baseline serum sodium level < 145mmol/L;
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. Weight less than 5 kg: 10 gm/m^2;
   b. Weight 5 to 10 kg: 15 gm/m^2;
   c. Weight greater than 10 kg: 20 gm/m^2.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
Not Applicable.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):*
  - History of severe hypersensitivity to sodium thiosulfate or any components.

  *Contraindications listed reflect direct statements made in manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information
- Hypersensitivity: Immediately discontinue Pedmark® and institute appropriate care. Administer premedication before each subsequent dose. Pedmark® may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions.
- Hypernatremia and Hypokalemia: Pedmark® is not indicated for use in pediatric patients less than 1 month

of age. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold Pedmark® in patients with serum sodium greater than 145 mmol/L.
- Nausea and Vomiting: Administer antiemetics prior to each Pedmark® administration.
- Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m^2.

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 December 09, 2022.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2022. Available at: http://www.clinicalkey.com. Accessed December 09, 2022.
3. IPD Analytics Rx Insights_New Drug Review_Pedmark® _09.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Pedmark. Accessed December 09, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/9/2022	01/17/2023