Pedmark® (sodium thiosulfate injection)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2025
Revision Date: January 01, 2025
Review Date: September 18, 2024
Line of Business: Medicare, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Pedmark intravenous solution

Listed Indications

Cisplatin-Induced Ototoxicity - Pediatric

Cisplatin-Induced Ototoxicity - Pediatric

Does the member meet all of the following criteria?	
Criteria #1	The member must be 1 month of age or older but less than 18 years old
Criteria #2	The member must have a localized, non-metastatic solid tumor
Criteria #3	The member must be receiving cisplatin-based therapy
Approval Duration	
Initial	plan year duration or as determined through clinical review.

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Background

This is a prior authorization policy about Pedmark (sodium thiosulfate).

Pedmark (sodium thiosulfate) 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 of sodium thiosulfate have not been established when administered following cisplatin infusions longer than 6 hours.
- Sodium thiosulfate may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Cisplatin-induced ototoxicity is caused by irreversible damage to hair cells in the cochlea and is thought to be due to a combination of reactive oxygen species production and direct alkylation of DNA leading to cell death. Sodium thiosulfate interacts directly with cisplatin to produce an inactive platinum species. Sodium thiosulfate can enter cells through sodium sulfate cotransporter 2 and cause intracellular effects such as the increase in antioxidant glutathione levels and inhibition of intracellular oxidative stress to reduce the risk of ototoxicity. In clinical trials, the incidence of hearing loss was lower in the sodium thiosulfate + cisplatin arm compared with the cisplatin alone arm.

Sodium thiosulfate is available as:

- Pedmark SDV solution: 12.5 grams/100 mL (125mg/mL)

Recommended dosing and administration:

- Administer antiemetics before each Pedmark infusion.
- Pedmark (sodium thiosulfate) is not substitutable with other sodium thiosulfate products.
- The recommended dose of Pedmark (sodium thiosulfate) is based on surface area according to actual body weight.
- Pedmark (sodium thiosulfate) should be administered as an intravenous infusion over 15 minutes starting 6 hours after completion of cisplatin infusion.
- For multiday cisplatin regimens, administer Pedmark (sodium thiosulfate) 6 hours after each cisplatin infusion but at least 10 hours before the next cisplatin infusion.

Please see product package insert(s) for full prescribing information.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Pedmark; sodium thiosulfate; cisplatin; ototoxicity; pediatric; supportive care; intravenous; IV

References

1. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; URL: https://www.clinicalkey.com/pharmacology/. Updated periodically.
2. Freyer DR, Brock PR, Chang KW, et al. Prevention of cisplatin-induced ototoxicity in children and adolescents with cancer: a clinical practice guideline. Lancet Child Adolesc Health. 2020;4(2):141-150.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Merative Micromedex® DRUGDEX [database online]. Ann Arbor, MI: Merative L.P.; URL: https://www.micromedexsolutions.com/. Updated periodically.
5. NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically. Pedmark [package insert]. Hoboken, NJ; Fennec Pharmaceuticals Inc. September 2022.