Reference number(s)
5655-A

Specialty Guideline Management Pedmark

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pedmark	sodium thiosulfate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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 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.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Authorization of 12 months may be granted to reduce the risk of ototoxicity in pediatric members 1 month

of age and older when both of the following criteria are met:

- Member will be receiving cisplatin for treatment of localized, non-metastatic solid tumor
- Cisplatin infusion will not be longer than 6 hours in duration

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Pedmark [package insert]. Hoboken, NJ: Fennec Pharmaceuticals, Inc.; September 2022.