CVS Caremark®

|  |
| --- |
| 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 Indications1

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.