Reference number(s)
5655-A

SPECIALTY GUIDELINE MANAGEMENT

PEDMARK (sodium thiosulfate)

POLICY

I. 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 Indication
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.

II. CRITERIA FOR INITIAL APPROVAL

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

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

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