CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Chemoprotective Agent – Pedmark Utilization Management Medical Policy
- Pedmark® (sodium thiosulfate intravenous infusion – Fennec)

REVIEW DATE: 09/18/2024

OVERVIEW

Pedmark, an inorganic salt, is indicated to **reduce the risk of ototoxicity associated with cisplatin** in patients ≥ 1 month to 18 years of age with localized, non-metastatic solid tumors.[1]

Limitation of use: The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours.[1] Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Dosing Information

The recommended dose of Pedmark is based on body surface area according to actual body weight and is administered as an intravenous infusion over 15 minutes.[1] The dose should be administered 6 hours after administration of cisplatin and if cisplatin is administered on multiple days, the dose should be given at least 10 hours before the subsequent dose of cisplatin. Do not administer Pedmark if the next dose of cisplatin is scheduled to begin in less than 10 hours. Pedmark should not be started if the serum sodium level is > 145 mmol/L. The recommended dosing of Pedmark is summarized in Table 1.

Table 1. Recommended Dosing of Pedmark.[1]

Actual Body Weight	Pedmark Dose
Less than 5 kg	10 g/m^2
5 to 10 kg	15 g/m^2
Greater than 10 kg	20 g/m^2

Premedicate with an antiemetic before each dose of Pedmark.[1] For patients who develop a hypersensitivity reaction to Pedmark, administer an antihistamine and a glucocorticoid before each subsequent dose of Pedmark.

Guidelines

Pedmark has not been addressed in National Comprehensive Cancer Network clinical practice guidelines.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Pedmark. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pedmark as well as the monitoring required for adverse events and long-term efficacy, approval requires Pedmark to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pedmark is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Ototoxicity Risk Reduction. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):

- **A)** Patient is ≥ 1 month and < 18 years of age; AND
- **B)** Patient is receiving cisplatin chemotherapy; AND
- **C)** Patient has a solid tumor; AND
  Note: Examples of solid tumors include medulloblastoma, osteosarcoma, germ cell tumor, neuroblastoma, hepatoblastoma, anaplastic astrocytoma.
- **D)** Patient has localized, non-metastatic disease; AND
- **E)** Patient has a baseline serum sodium level ≤ 145 mmol/L; AND
- **F)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 20 g/m^2 administered by intravenous infusion, given 6 hours after each dose of cisplatin.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pedmark is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pedmark intravenous infusion [prescribing information]. Hoboken, NJ: Fennec Pharmaceuticals; September 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/04/2023
Annual Revision	No criteria changes.	09/18/2024