



Drug Coverage Policy

Effective Date 10/1/2025
Coverage Policy NumberIP0512
Policy Title.....Pedmark

Chemoprotective Agent – Pedmark

- Pedmark® (sodium thiosulfate intravenous infusion – Fennec)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Pedmark, an inorganic salt, is indicated to **reduce the risk of ototoxicity associated with cisplatin** in patients ≥ 1 month 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 is addressed in National Comprehensive Cancer Network (NCCN) guidelines: **Adolescent and Young Adult Oncology:** Guidelines (version 2.2025 – September 24, 2024) recommend Pedmark to reduce the risk of ototoxicity associated with cisplatin in patients with localized, non-metastatic solid tumors.²

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POLICY STATEMENT

Prior Authorization is required for 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.

Pedmark is considered medically necessary when the following are met:

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 \geq 1 month 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. Up to 20g/m² administered by intravenous infusion, given 6 hours after each dose of cisplatin

Conditions Not Covered

Pedmark for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding

- Note:** 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPSC Codes	Description
J0208	Injection, sodium thiosulfate (Pedmark), 100 mg

References

- Pedmark intravenous infusion [prescribing information]. Hoboken, NJ: Fennec Pharmaceuticals; October 2023.
- The NCCN Adolescent and Young Adult Clinical Practice Guidelines in Oncology (version 2.2025 – September 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 17, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes Updated coding description: <ul style="list-style-type: none"> • from: Injection, sodium thiosulfate, 100 mg (Code effective 04/01/2023) • to: Injection, sodium thiosulfate (Pedmark), 100 mg 	12/15/2024
Annual Revision	Policy Title: Updated from "Sodium thiosulfate" to "Chemoprotective Agent – Pedmark" Ototoxicity Risk Reduction.	10/1/2025

	<p>Removed the requirement that patient must be <18 years of age.</p> <p>Updated from "Has localized, non-metastatic solid tumor" to "Patient has a solid tumor; <u>Note</u>: Examples of solid tumors include medulloblastoma, osteosarcoma, germ cell tumor, neuroblastoma, hepatoblastoma, anaplastic astrocytoma; Patient has localized, non-metastatic disease"</p>	
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The policy effective date is in force until updated or retired

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