Effective Date **4/1/2024**
Next Review Date… **4/1/2025**
Coverage Policy Number **IP0512**

Sodium thiosulfate

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Related Coverage Resources

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. 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

This policy supports medical necessity review for sodium thiosulfate intravenous infusion (**Pedmark®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Sodium thiosulfate (Pedmark) is considered medically necessary when the following are met:

1. **Ototoxicity Risk Reduction.** Individual meets **ALL** of the following criteria:
   A. 1 month of age or older and less than 18 years of age
   B. Has localized, non-metastatic solid tumor
   C. Has a baseline serum sodium level less than or equal to 145 mmol/L
   D. Will be used with Cisplatin chemotherapy
   E. Medication is prescribed by or in consultation with an oncologist

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

Reauthorization Criteria

Continuation of sodium thiosulfate (Pedmark) is considered medically necessary for continued use when the above medical necessity criteria are met AND there is documentation of beneficial response

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding

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:

HCPCS Codes	Description
J0208	Injection, sodium thiosulfate, 100 mg (Code effective 04/01/2023)

Background

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 glucocorticoids before each subsequent dose of Pedmark.

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

References

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