Sample Prior Authorization Appeals Letter for PEDMARK

Contact Fennec HEARS for additional support
855-615-7946

An appeal letter can be submitted when a prior authorization (PA) request has been denied. You can submit more than one appeal. Plans generally publish their appeal guidelines on their website. An appeal should be submitted along with a Letter of Medical Necessity.

Use of the information in this letter does not guarantee that the health plan will provide reimbursement for PEDMARK and is not intended to be a substitute for or to influence the independent medical judgment of the physician. The information on pages 1 and 3 does not need to be included in your letter. Any and all information submitted to any payer is solely the responsibility of the submitting healthcare provider.

Suggested Documentation

- Include the patient's name, member ID, group number, policy number, and date of birth
- Restate why the PA was denied and why, in your clinical judgment, PEDMARK is appropriate for this patient
- Include the PA denial # and the date of the denial
- Include a copy of the denial letter
- Confirm that the patient's tumor is localized and non-metastatic
- Confirm that the patient is at risk for ototoxicity due to platinum-based therapy
- Document that all PA requirements specified by the plan have been met
- PEDMARK Prescribing Information
- Include National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines for Adolescent and Young Adult (AYA) Oncology - 2A Recommendation

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Reprints available from your Fennec representative:

- Brock PR, Maibach R, Childs M, et al. Sodium thiosulfate for protection from cisplatin-induced hearing loss. N Engl J Med. 2018;378(25):2376-2385. doi:10.1056/NEJMoa1801109

- Freyer DR, Chen L, Krailo MD, et al. Effects of sodium thiosulfate versus observation on development of cisplatin-induced hearing loss in children with cancer (ACCL0431): a multicentre, randomised, controlled, open-label, phase 3 trial. Lancet. 2017;18(1):63-74. doi:10.1016/S1470-2045(16)30625-8

Additional Resources

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Adolescent and Young Adult (AYA) Oncology V1.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed July 12, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org

INDICATIONS AND USAGE
PEDMARK (sodium thiosulfate injection) is indicated 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.
SELECT IMPORTANT SAFETY INFORMATION
• PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate.

Please see additional Important Safety Information on the last page. Click here for full Prescribing Information.

Sample Prior Authorization Appeals Letter for PEDMARK

[Print letter on office letterhead]

[Date]
[Plan name]
[Plan street address]
[Plan city, state zip code]

Re: [Patient full name]
Date of Birth: [Patient date of birth]
Member ID: [Patient ID number]
Group Number: [Patient group number]
Policy Number: [Patient policy number]
[Optional: PA denial reference # and date]

To whom it may concern:

I am writing to appeal your denial of coverage of PEDMARK® (sodium thiosulfate injection) for my patient, [patient name], diagnosed with [diagnosis] (ICD-10 code: [insert code]).

[Consider including this paragraph when submitting a 2nd- or 3rd-level appeal.] This is my [insert level] appeal. I have included a copy of the most recent denial letter, and I have included my medical notes addressing this denial.

Patient's diagnosis and treatment regimen:

Consider including the following information.

[Patient's history]

[Medical notes that specifically address the stated reason for the denial & summary reccomendation]

[Why patient is at risk for ototoxicity due to treatment with platinum based chemotherapy]

[Treating in accordance with NCCN 2A Guidelines]

Enter the dose:
Enter the vials per cycle:
# of treatment cycles:
Refills:

Site of administration:
PEDMARK is the first FDA-approved treatment to reduce the risk of cisplatin-induced hearing loss in children being treated for certain cancers. It is indicated for intravenous use in patients 1 month of age and older with localized, non-metastatic solid tumors, and is supported by two randomized clinical trials (RCTs) conducted at US oncology centers of excellence.

PEDMARK is administered as an intravenous infusion over 15 minutes starting 6 hours after completion of cisplatin infusion. For multiday cisplatin regimens, PEDMARK is administered 6 hours after each cisplatin infusion but at least 10 hours before the next cisplatin infusion.

The use of PEDMARK is supported by two RCTs [reprints are available from your representative].

Please expedite this request, as the patient's first treatment is scheduled for [insert date].

Please call me at [insert phone number] if I can be of further assistance or if you require additional information. Thank you in advance for your immediate attention to and prompt review of this request.

Sincerely,

[Physician's signature]
[Physician's name, Phone number, NPI#]
Enclosures: [See checklist on previous page]

Click here for full Prescribing Information.

Sample Prior Authorization Appeals Letter for PEDMARK

PEDMARK, for intravenous use

INDICATIONS AND USAGE

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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.

IMPORTANT SAFETY INFORMATION

PEDMARK is contraindicated in patients with a history of severe hypersensitivity to sodium thiosulfate or any of its components.

Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers

Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.

Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m2.

Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.

The most common adverse reactions (≥25% with a difference between arms of >5% compared to cisplatin alone) in SIOPEL6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with a difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Click here for full Prescribing Information.