PAA

Sample Prior Authorization Appeals Letter for PEDMARK

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.

Checklist to consider

- ◯ Include the patient's name, member ID, group 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 cisplatin therapy
- ◯ Document that all PA requirements specified by the plan have been met
- ◯ PEDMARK Prescribing Information

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

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 or any of its components.

Please see additional Important Safety Information on the last page.

Click here for full Prescribing Information.

pedmark®
(sodium thiosulfate injection)

PAA

Example Prior Authorization Appeal Letter
for PEDMARK® (sodium thiosulfate injection)

[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]
[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
- Why patient is at risk for ototoxicity due to treatment with cisplatin chemotherapy
- Summary recommendation

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 with cisplatin is scheduled for [insert date].

Please call me at [insert phone number] if I can be of further assistance or 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]

PEDMARK, for intravenous use

INDICATIONS AND USAGE

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Limitations of Use

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IMPORTANT SAFETY INFORMATION

- PEDMARK is contraindicated in patients with history of a 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/1.73m^2.
- Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.
- The most common adverse reactions (≥25% with 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 difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Click here for full Prescribing Information.

FENNEC PHARMA

pedmark® (sodium thiosulfate injection)