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Sample Letter of Medical Necessity for PEDMARK

The letter on the following page is an example of the type of information that may be provided to a patient's insurance company when a letter of medical necessity is appropriate. 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 with your letter. Any and all information submitted to any payer is solely the responsibility of the submitting healthcare provider.

Suggestions

- Consider including a letter of medical necessity with your prior authorization requests, along with any appeals that are submitted
- Letters of medical necessity should be signed by the physician

Checklist to consider

- ◯ Include the patient's name, member ID, group number, and date of birth
- ◯ Indicate the type of childhood cancer, with the appropriate ICD-10 code
- ◯ Confirm that the patient's tumor is localized and non-metastatic
- ◯ Confirm that the patient is at risk for ototoxicity due to cisplatin therapy
- ◯ 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)

MN

Example Letter of Medical Necessity
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]
[Optional: PA denial reference # and date]

To whom it may concern:

I am writing on behalf of my patient, [patient name], to document the medical necessity of PEDMARK® (sodium thiosulfate injection) to reduce the risk of ototoxicity following cisplatin therapy for the treatment of [diagnosis] (ICD-10 code: [insert code]).

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.

I have included information about the patient's medical history, my rationale for the use of PEDMARK, and a statement explaining why, in my clinical judgment, it is required for the appropriate management of this patient.

[Consider including the following information.]

- Patient's history
- Why patient is at risk for ototoxicity due to treatment with cisplatin chemotherapy
- Summary recommendation

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].

Based on the available clinical information and evidence, I am requesting that you approve [X doses of PEDMARK] for this patient. In order for me to provide appropriate care for my patient, it is important that [plan name] provide adequate coverage for this treatment.

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

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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)