FENNEC PHARMA

Coding for PEDMARK

pedmark® (sodium thiosulfate injection)

Important instructions for PEDMARK including J code and temporary C code until assigned (anticipated 2023)

Drug: HCPCS	J0208	PEDMARK-Injection, Sodium Thiosulfate, 100 ml.
	C9399	For unclassified drugs and biologics provided in hospital outpatient facilities that bill under the Outpatient Prospective Payment System (OPPS) for Medicare patients. May also be used by some Medicaid and private payers.

Category	ICD-10-CM Code	Description
CNS Tumors	C72.21; C72.22; C74.9	Neuroblastoma
	C72.9	CNS glioma
	C71.9; C71.0; C71.1; C71.2; C71.3; C71.4; C71.5; C71.7	Astrocytoma
	C69.20; C69.21; C69.22	Retinoblastoma
Germ Cell Tumors	C62.9; C62.91; C62.92; C62.01; C62.02; C62.11; C62.12	Malignant testicular germ cell tumors
	Z85.43; C56.9; C56.1; C56.2	Malignant ovarian germ cell tumors
	Z85.848; G07	Malignant intracranial/intraspinal germ cell tumors
	C80.1	Malignant extracranial/extragonadal germ cell tumors
Other	C40.01; C40.02; C40.11; C40.12; C40.31; C40.32; C40.21; C40.22; C40.20; C41.1; Z85.830; C41.2; C40.00; C41.4	Osteosarcoma
	C69.31; C69.32; H31.9; C69.3	Ependymomas and choroid plexus tumors
	Z85.831; C49.4; C49.6; C49.9; C49.3; C49.11; C49.12; C49.21; C49.22; C49.8; C49.0	Rhabdomyosarcoma
	C11.9; C11.3; C11.0; C11.8; C11.2; C11.1; D00.02; D00.04; D00.05; D02.1	Nasopharyngeal carcinoma
	C22.2	Hepatoblastoma
	C71.6	Medulloblastoma
Drug: NDC	10-digit	11-digit
	73077-010-01	73077-0010-01

Note: Payer requirements regarding use of a 10-digit or an 11-digit NDC may vary. Both formats are listed here for your reference.

CNS=central nervous system, HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

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.

The information herein is provided for educational purposes only. Fennec cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient. Coding is the sole responsibility of the treating health care provider.

Please see additional Important Safety Information on the following page.

Click here for full Prescribing Information.

PEDMARK, for intravenous use

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.

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)