

Permanent J-Code Assigned for Pepaxto® (melphalan flufenamide)



**Effective, October 1, 2021
J9247**

Injection, melphalan flufenamide, 1 mg¹



Billing and Coding Summary¹⁻⁵

National Drug Code (NDC)	10-digit: 73657-020-01	11-digit: 73657-0020-01
Revenue Center (Hospital use only)	0260: IV therapy	
	0335: Chemotherapy administration, IV	
	0636: Drugs requiring detailed coding	
International Classification of Diseases (ICD)-10-CM	C90.00: Multiple myeloma not having achieved remission	
	C90.02: Multiple myeloma in relapse	
Healthcare Common Procedure Coding System (HCPCS)*	J9247: Injection, melphalan flufenamide, 1mg	
	C9080: Injection, melphalan flufenamide, 1mg†	
Current Procedural Terminology (CPT)	96413: Injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration; up to 1 hour, single or initial substance/drug (for 30-minute IV infusion)	

*Medicare only hospital outpatient department.

Note: The information provided herein is suggestive only. Oncopeptides does not make any warranties as to its accuracy and has no obligation to update the information. Oncopeptides has not verified the accuracy of this information with any authority responsible for coverage, coding or payment. Individual payors may differ as to their coverage, coding, and payment rules. The healthcare provider is responsible for verifying the applicable coverage, coding, and payment rules with each applicable payor. This includes choosing the correct diagnostic and procedure codes based on the diagnosis and treatment of each individual patient. Even if a claim is properly completed, Oncopeptides makes no warranty regarding whether there will be payment on such claim.

Wholesale acquisition cost of PEPAXTO[®] is \$9,500.00 per 20 mg vial.⁶

INDICATION

PEPAXTO is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Limitation of Use

PEPAXTO is not indicated and is not recommended for use as a conditioning regimen for transplant outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

PEPAXTO is contraindicated in patients with a history of serious allergic reaction to melphalan flufenamide or melphalan.

PEPAXTO may cause thrombocytopenia, which may lead to hemorrhage. Monitor platelets at baseline, during treatment, and as clinically indicated. Monitor more frequently during the first 2 months of treatment with PEPAXTO. Do not administer PEPAXTO if the platelet count is less than $50 \times 10^9/L$. Withhold PEPAXTO until platelet count is $50 \times 10^9/L$ or greater and resume at same or reduced dose based on duration of interruption. Adjust dose and/or dose schedule based on signs and symptoms of bleeding.

PEPAXTO may cause neutropenia, which may lead to infection. Monitor neutrophil counts at baseline,

during treatment, and as clinically indicated. Monitor more frequently during the first 2 months of treatment with PEPAXTO. Do not administer PEPAXTO if absolute neutrophil count is less than $1 \times 10^9/L$. Withhold PEPAXTO until absolute neutrophil count is $1 \times 10^9/L$ or greater and resume at same or reduced dose based on duration of interruption. Consider leukocyte growth factor as clinically appropriate. PEPAXTO may cause anemia. Monitor red blood cell counts at baseline, during treatment, and as clinically indicated. Monitor more frequently during the first 2 months of treatment with PEPAXTO. Treat anemia as clinically indicated. Dosage modification and dose delay of PEPAXTO may be required to allow for recovery of red blood cells.

Patients taking PEPAXTO experienced infections, including fatal infections. Consider antimicrobials as clinically appropriate.

Nonclinical safety studies with melphalan flufenamide at dosages exceeding the recommended dose for PEPAXTO were associated with mortality. The safety and efficacy of PEPAXTO has not been established for use as a conditioning regimen in patients receiving transplant.

Secondary malignancies such as myelodysplastic syndromes or acute leukemia have been reported in patients with multiple myeloma who were treated with PEPAXTO. Monitor patients long term for the development of secondary malignancies.

Based on its mechanism of action, PEPAXTO can cause fetal harm when administered to a pregnant woman because it is genotoxic and targets actively dividing cells. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with PEPAXTO and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEPAXTO and for 3 months after the last dose.

The most common adverse reactions ($\geq 20\%$; Grade 1-4) were fatigue (55%), nausea (32%), diarrhea (27%), pyrexia (24%), and respiratory tract infection (24%).

Special Considerations

Use in Pregnancy

Based on the mechanism of action, PEPAXTO can cause fetal harm when administered to a pregnant woman. There are no available data on PEPAXTO use in pregnant women to evaluate for a drug-associated risk. PEPAXTO is a genotoxic drug. Advise a woman of childbearing potential of the potential risks to the fetus.

Lactation

There is no information regarding the presence of melphalan flufenamide or its metabolites in human breast milk, or the effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with PEPAXTO and for 1 week after the last dose.

Females and Males of Reproductive Potential

PEPAXTO can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with PEPAXTO and for 6 months after the last dose.

PEPAXTO may damage the developing male germ cells, resulting in possible genetic fetal abnormalities.

Advise males with a female partner of reproductive potential to use effective contraception during treatment with PEPAXTO and for 3 months after the last dose.

PEPAXTO can cause amenorrhea in premenopausal women and result in infertility. Based on findings of melphalan flufenamide in animals, PEPAXTO may impair male fertility. Alkylating drugs, such as PEPAXTO, can also cause irreversible testicular suppression in patients.

[Please click here for full Prescribing Information.](#)

Please do not reply to this email, if you require additional information or have any questions, contact us [here](#).

For more information, visit www.PEPAXTOHCP.com.

References: 1. 2021 HCPCS Codes Level II. HCPCS.codes website. <https://hcpcs.codes/search>. Accessed July 8, 2021. 2. PEPAXTO [prescribing information]. Waltham, MA: Oncopeptides, Inc., 2021. 3. Centers for Medicare & Medicaid Services. Medicare Intermediary Manual. Transmittal 1875. February 7, 2003. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1875A3.pdf>. Accessed February 20, 2021. 4. Multiple myeloma and malignant plasma cell neoplasms. ICD10Data.com website. <https://www.icd10data.com/ICD10CM/Codes/C00-D49/C81-C96/C90>. Accessed February 20, 2021. 5. Chemotherapy administration and other highly complex drug or highly complex biologic agent administration. Codify by American Association of PC website. <https://www.aapc.com/codes/cpt-codes-range/2855>. Accessed February 20, 2021. 6. Wolters Kluwer Clinical Drug Information. Medi-Span PriceRx Pro. Available at <https://pricerx.medispans.com/>. Accessed June 2021.

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