

Pepaxto (melphalan flufenamide)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Pepaxto (melphalan flufenamide)

APPROVAL CRITERIA

Requests for Pepaxto (melphalan flufenamide) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of relapsed or refractory multiple myeloma; **AND**
- III. Individual is using in combination with dexamethasone (IV or oral); **AND**
- IV. Individual has received at least four prior lines of therapy; **AND**
- V. Individual's disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody; **AND**
- VI. Individual has an ECOG status of 0-2.

Requests for Pepaxto may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 1, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 1, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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