

Drug Policy:

Pepaxto™ (melphalan flufenamide)

POLICY NUMBER UM ONC_1426	SUBJECT Pepaxto™ (melphalan flufenamide)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 04/14/21, 08/11/21	APPROVAL DATE August 11, 2021	EFFECTIVE DATE August 27, 2021	COMMITTEE APPROVAL DATES 04/14/21, 08/11/21	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Pepaxto (melphalan flufenamide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines shall follow NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

B. Multiple Myeloma

In the light of the suspension of clinical trials due to an increased risk of death, New Century Health now recommends that Pepaxto (melphalan flufenamide) be removed from formularies. Likewise, per NCH Policy, Pepaxto (melphalan flufenamide) is NOT Recommended for use. Patient receiving clinical benefit from Pepaxto (melphalan flufenamide) may continue should they and their physician mutually agree it is in their best interest following a discussion of the risks. A Please refer to the NCH Pathway document for the recommended/preferred regimens in the treatment of relapsed/refractory Multiple Myeloma.

III. EXCLUSION CRITERIA

- A. Disease progression while taking Pepaxto (melphalan flufenamide).
- B. Dosing exceeds single dose limit of Pepaxto (melphalan flufenamide) 40 mg.
- C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. FDA drug safety communications accessed on July 28, 2021: https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-about-clinical-trial-results-showing-increased?utm_medium=email&utm_source=govdelivery.
- B. Pepaxto prescribing information. Oncopeptides Waltham, MA 2021.
- C. Clinical Pharmacology Elsevier Gold Standard 2021.
- D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

G. Richardson PG, et al. Melflufen and Dexamethasone in Heavily Pretreated Relapsed and Refractory Multiple Myeloma. J Clin Oncol. 2021 Mar 1;39(7):757-767.