

## Drug Policy:

# Pepaxto™ (melphalan flufenamide)

<b>POLICY NUMBER</b> UM ONC_1426	<b>SUBJECT</b> Pepaxto™ (melphalan flufenamide)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 2</b>
<b>DATES COMMITTEE REVIEWED</b> 04/14/21	<b>APPROVAL DATE</b> April 14, 2021	<b>EFFECTIVE DATE</b> April 30, 2021	<b>COMMITTEE APPROVAL DATES</b> (latest version listed last) 04/14/21	
<b>PRIMARY BUSINESS OWNER: UM</b>		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM 1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> 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**

1. Pepaxto is recommended for members with relapsed/refractory multiple myeloma for 5th line (fifth-line) therapy. Members must have received prior therapy and experienced disease progression on 4 or more lines of therapy including: one or more proteasome inhibitors, one or more immunomodulatory agents, and one anti CD-38 antibody.
2. **NOTE: Based on the HORIZON trial, febrile neutropenia was 5% and primary prophylaxis with a G-CSF is not required.**

### **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. Pepaxto prescribing information. Oncopeptides Waltham, MA 2021.
- B. Clinical Pharmacology Elsevier Gold Standard 2021.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.
- F. 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.