Reference number(s)
4576-A

SPECIALTY GUIDELINE MANAGEMENT

PEPAXTO (melphalan flufenamide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Multiple myeloma
Authorization of 12 months may be granted for treatment of multiple myeloma in combination with dexamethasone when all of the following are met:
1. The member has received at least four prior lines of therapy.
2. The disease is refractory to at least one proteasome inhibitor.
3. The disease is refractory to at least one immunomodulatory agent.
4. The disease is refractory to at least one anti-CD38 monoclonal antibody.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Pepaxto [package insert]. Waltham, MA: Oncopeptides Inc.; February 2021.