Reference number(s)
3119-A

Specialty Guideline Management

XPOVIO (selinexor)

POLICY

I. INDICATIONS

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

FDA-Approved Indications

1. Xpovio is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

2. Xpovio 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 therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

3. Xpovio is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

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

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma

Authorization of 12 months may be granted for the treatment of multiple myeloma in either of the following settings:

1. The requested medication will be used in combination with dexamethasone and all of the following are met:
    a. The member has received at least four prior therapy regimens
    b. The member is refractory to at least two proteasome inhibitors
    c. The member is refractory to at least two immunomodulatory agents
    d. The member is refractory to an anti-CD38 monoclonal antibody

2. The requested medication will be used in combination with bortezomib and dexamethasone and the member has received at least one prior therapy.

B. Diffuse Large B-Cell Lymphoma

Authorization of 12 months may be granted for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, as a single agent when the member has received at least 2 prior lines of systemic therapy.

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 who have not experienced an unacceptable toxicity or disease progression.

IV. REFERENCES

1. Xpovio [package insert]. Newton, MA: Karyopharm Therapeutics; June 2020.