Reference number(s)
1701-A

SPECIALTY GUIDELINE MANAGEMENT

BELEODAQ (belinostat)

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.

A. FDA-Approved Indication
Treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)

B. Compendial Uses
1. T-Cell Lymphomas
   i. Hepatosplenic T-cell lymphoma
   ii. Extranodal NK/T-cell lymphoma, nasal type
   iii. Adult T-cell leukemia/lymphoma (ATLL)
   iv. Breast implant associated anaplastic large cell lymphoma (ALCL)
2. Primary Cutaneous Lymphomas
   i. Mycosis fungoides (MF)/Sezary syndrome (SS)
   ii. Primary cutaneous anaplastic large cell lymphoma (ALCL)

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

II. CRITERIA FOR INITIAL APPROVAL

A. T-Cell Lymphomas
Authorization of 12 months may be granted for treatment T-cell lymphomas with any of the following subtypes:
1. Peripheral T-cell lymphoma [including the following subtypes: anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma] when used for relapsed or refractory disease or for palliative intent.
2. Hepatosplenic T-cell lymphoma when both of the following are met:
   i. The requested drug will be used a single agent for subsequent therapy, and
   ii. The member has had two or more previous lines of chemotherapy.
3. Extranodal NK/T-cell lymphoma, nasal type when all of the following criteria are met:
   i. The requested drug will be used as a single agent, and
   ii. The member has relapsed or refractory disease, and
   iii. The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).
4. Adult T-cell leukemia/lymphoma (ATLL) when both of the following criteria are met:
   i. The requested drug is used as a single agent, and

ii. The requested drug is used for subsequent therapy.

5. Breast implant-associated anaplastic large cell lymphoma (ALCL) when both of the following criteria are met:
   i. The requested drug is used as a single agent, and
   ii. The requested drug is used for subsequent therapy.

B. Primary Cutaneous Lymphomas

Authorization of 12 months may be granted for treatment of primary cutaneous lymphomas with any of the following subtypes:

1. Mycosis fungoides (MF)/Sezary syndrome (SS)
2. Primary cutaneous anaplastic large cell lymphoma when both of the following criteria are met:
   i. The requested drug is used as a single agent, and
   ii. The disease is relapsed or refractory.

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. Beleodaq [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc. January 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org Accessed April 14, 2021.