PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Beleodaq® (belinostat injection for intravenous use – Spectrum Pharmaceuticals)

APPROVAL DATE: 09/04/2019

OVERVIEW

Beleodaq is a histone deacetylase (HDAC) inhibitor which catalyzes the removal of acetyl groups from the lysine residues of histones and some non-histone proteins.[1] *In vitro*, this results in the accumulation of acetylated histones and other proteins leading to cell cycle arrest and/or apoptosis in some transformed cells. Beleodaq exhibits preferential cytotoxicity towards tumor cells vs. normal cells.

Beleodaq, a HDAC inhibitor, is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on T-Cell Lymphomas (version 2.2019 – December 17, 2018) recommends Beleodaq as a single-agent for second-line and subsequent therapy of peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, extranodal NK/T-cell lymphoma – nasal type, and hepatosplenic gamma – delta T-cell lymphoma.[2,3]

NCCN guidelines on Primary Cutaneous Lymphomas (version 2.2019 – December 17, 2018) recommend Beleodaq for systemic therapy of mycosis fungoides/Sezary syndrome and for primary cutaneous CD30+ T-cell lymphoproliferative disorders.[3,4]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Beleodaq. All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Beleodaq as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Beleodaq to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Beleodaq is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **T-Cell Lymphoma** (NOTE: Examples include Peripheral T-Cell Lymphoma, Mycosis Fungoides/Sezary Syndrome, Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders, Adult T-Cell Leukemia/Lymphoma, Hepatosplenic Gamma-Delta T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma – Nasal Type).[2-4] Approve for 1 year if Beleodaq is prescribed by or in consultation with an oncologist or a dermatologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Beleodaq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Beleodaq® injection for intravenous use [prescribing information]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; April 2017.
2. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019 – December 17, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 16, 2019.
3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 16, 2019. Search term: belinostat.
4. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019 – December 17, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 16, 2019.