09-J2000-21

Original Effective Date: 11/15/14

Reviewed: 01/09/19

Revised: 10/01/21

Subject: Belinostat (Beleodaq™) Injection

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Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Belinostat (Belodaq®) was approved by the U.S. Food and Drug Administration (FDA) in July 2014 for treatment of relapsed or refractory peripheral T-cell lymphoma. This indication was approved under accelerated approval based on tumor response rate and duration of response; an improvement in survival or disease-related symptoms has not been established. Prior to FDA approval, belinostat received orphan drug status for treatment of relapsed or refractory peripheral T-cell lymphoma. Belinostat inhibits the histone deacetylase family of enzymes to stimulate the immune system and block angiogenesis.

National Comprehensive Cancer Network (NCCN) Guidelines for T-cell Lymphomas (Version 2.2019) and Primary Cutaneous Lymphomas (Version 2.2019) include recommendations for use of belinostat.

POSITION STATEMENT:

Initiation of belinostat (Beleodaq) meets the definition of **medical necessity** when **ALL** of the following criteria are met:

1. Use is for treatment of an indication listed in Table 1 and ALL of the indication-specific criteria are met
2. The dose does not exceed 1000 mg/m2 on days 1-5 of a 21-day cycle.

Table 1

Indication for Use	Criteria
Adult T-Cell leukemia/lymphoma (ATLL)	Use is a medical necessity when **EITHER** of the following is met: 1. Member did not respond to first-line therapy for acute disease or

	lymphoma (NOT to be used for chronic/smoldering ATLL) 2. Belinostat is used as subsequent therapy after high dose therapy/autologous stem cell rescue (HDT/ASCR)
Extranodal NK/T-Cell Lymphoma, nasal type	Use is a medical necessity when ALL criteria are met: 1. Member's disease is relapsed or refactory 2. Belinostat is used as a single-agent therapy
Hepatosplenic Gamma-Delta T-Cell Lymphoma	Use is a medical necessity when ALL criteria are met: 1. Member's disease is refactory 2. Belinostat is used as a single-agent therapy
Mycosis Fungoides (MF)/Sezary Syndrome (SS)	Use is a medical necessity when **ALL** criteria are met: 1. Member's disease meets **ANY** of the following: a. Relapsed or persistent stage IA with B1 blood involvement, with or without skin-directed therapy b. Relapsed or persistent stage IB to IIA with B1 blood involvement, with or without skin-directed therapy c. Stage IIB disease with limited or generalized tumor lesions, with or without skin-directed therapy d. Stage III disease, with or without skin-directed therapy e. Stage IV disease f. Large cell transformation with limited or generalized cutaneous or extracutaneous lesions, with or without skin-directed therapy 2. Belinostat is used as single-agent therapy
Peripheral T-cell Lymphoma	Use is a medical necessity when **ALL** criteria are met: 1. Member's disease is relapsed or refactory 2. Belinostat is used as second-line or subsequent therapy for ANY of the following disease types: a. Angioimmunoblastic T-cell lymphoma b. Peripheral T-cell lymphoma not otherwise specified (NOS) c. Anaplastic large cell lymphoma (ALCL) d. Enteropathy-associated T-cell lymphoma e. Monomorphic epitheliotropic intestinal T-cell lymphoma f. Nodal peripheral T-cell lymphoma with TFH phenotype g. Follicular T-cell lymphoma 3. Belinostat is used as single-agent therapy
Primary cutaneous CD30+ T-Cell lymphoproliferative disorders	Use is a medical necessity when **ALL** criteria are met: 1. Member's disease is relapsed or refactory 2. Member's disease meets **EITHER** of the following: a. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions b. Cutaneous ALCL with regional nodes (excludes systemic ALCL)

	3. Belinostat is used as a single-agent therapy
Other FDA-approved or NCCN supported diagnosis (not previously listed above)	Use is a medical necessity when **EITHER** of the following is met: 1. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert) 2. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

Approval duration: 6 months

Continuation of belinostat (Beleodaq) meets the definition of **medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization for belinostat (Beleodaq) has been previously approved by Florida Blue or another health plan in the past two years for the treatment of an indication in Table 1 **OR** the member currently meets all indication-specific initiation criteria
2. Member has not experienced disease progression while receiving treatment with belinostat
3. The dose does not exceed 1000 mg/m^2 on days 1-5 of a 21-day cycle

Duration of approval: 6 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 1,000 mg/m^2 administered over 30 minutes by intravenous infusion once daily on days 1-5 of a 21-day cycle
- Cycles can be repeated until disease progression or unacceptable toxicity

Dose Adjustments

- Adjust dose due to treatment-related toxicity

Drug Availability

- 500 mg, lyophilized powder in single-use vial for reconstitution

PRECAUTIONS:

Boxed Warning

None

Contraindications

None

Precautions/Warnings

- Thrombocytopenia, leukopenia (neutropenia and lymphopenia), and anemia
- Infection: Serious and fatal infections (e.g., pneumonia and sepsis)
- Hepatotoxicity
- Tumor lysis syndrome
- Embryo-fetal toxicity

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J9032	Injection, belinostat, 10 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

C84.00 – C84.09	Mycosis fungoides
C84.40	Peripheral T-cell lymphoma, not classified unspecified site
C84.41	Peripheral T-cell lymphoma, not classified lymph nodes of head, face, and neck
C84.42	Peripheral T-cell lymphoma, not classified intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified lymph nodes of inguinal region and lower limb
C84.46	Peripheral T-cell lymphoma, not classified intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified spleen
C84.48	Peripheral T-cell lymphoma, not classified lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified extranodal and solid organ sites
C84.60-C84.69	Anaplastic large cell lymphoma, ALK-positive
C84.70-C84.79A	Anaplastic large cell lymphoma, ALK-negative
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/09/19.

GUIDELINE UPDATE INFORMATION:

11/15/14	New Medical Coverage Guideline.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/15	Review and revision to guideline; consisting of updating position statement and references
01/01/16	Annual HCPCS coding update: added code J9032 and deleted codes C9442 and J9999.
11/15/16	Review and revision to guideline; consisting of updating position statement, coding, references.
12/15/17	Review and revision to guideline; consisting of updating position statement, coding, references.
2/15/19	Review and revision to guideline; consisting of updating position statement, coding, references.
10/01/21	ICD10 code update