

Clinical Policy: Belinostat (Beleodaq)

Reference Number: CP.PHAR.311

Effective Date: 02.01.17

Last Review Date: 11.17

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Belinostat (Beleodaq[®]) is a histone deacetylase inhibitor.

FDA Approved Indication(s)

Beleodaq is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Beleodaq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Hodgkin T-Cell Lymphomas (must meet all):

1. Age \geq 18 years;
2. Diagnosis of one of the following:
 - a. A peripheral T-cell lymphoma (PTCL):
 - i. Meets (a or b):
 - a) FDA approved use:
 - 1) Relapsed or refractory PTCL;
 - b) NCCN recommended use:
 - 1) Second-line or subsequent therapy for relapsed or refractory angioimmunoblastic T-cell lymphoma, PTCL not otherwise specified, anaplastic large cell lymphoma (ALCL), enteropathy-associated T-cell lymphoma, or monomorphic epitheliotropic intestinal T-cell lymphoma;
 - b. Mycosis fungoides (MF) or Sezary syndrome (SS):
 - i. NCCN recommended use (a or b):
 - a) First-line therapy in low doses for (1, 2 or 3):
 - 1) Stage IB-IIA MF with histologic evidence of folliculotropic or large cell transformation or stage IIB with generalized tumor lesions, with or without skin-directed therapy;
 - 2) Stage IV non-Sezary or visceral disease;

- 3) Stage III MF or SS which has progressed or is refractory to multiple previous therapies;
- b) Single-agent therapy for tumors with histologic evidence of large cell transformation and aggressive growth rate for (1 or 2):
 - 1) Stage IB-IIA MF with histologic evidence of folliculotropic or large cell transformation or stage IIB with generalized tumor lesions, with or without skin-directed therapy;
 - 2) Stage IV non-Sezary or visceral disease;
- c. Primary cutaneous CD30+T-cell lymphoproliferative disorder;
 - i. NCCN recommended use:
 - a) Single-agent therapy for primary cutaneous ALCL with multifocal lesions or cutaneous ALCL with regional nodes (excludes systemic ALCL) as (1 or 2):
 - 1) Primary treatment;
 - 2) Therapy for relapsed or refractory disease;
 - d. Adult T-cell leukemia/lymphoma;
 - i. NCCN recommended use:
 - a) Second-line therapy as a single agent for nonresponders to first-line therapy for acute disease or lymphoma or as subsequent therapy after high dose therapy/autologous stem cell rescue (HDT/ASCR);
3. Request meets one of the following (a or b):
 - a. PTCL: Dose does not exceed 1,000/mg/m² once daily on days 1-5 of a 21-day cycle;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 for specialty if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 1,000/mg/m² once daily on days 1-5 of a 21-day cycle;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

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1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALCL: anaplastic large cell lymphoma	NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration	PTCL: peripheral T-cell lymphoma
HDT/ASCR: high dose therapy/autologous stem cell rescue	SS: Sezary syndrome
MF: mycosis fungoides	

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PTCL	1,000 mg/m ² over 30 minutes by intravenous infusion once daily on Days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity.	See regimen

VI. Product Availability

Single 30 mL vial: 500 mg

VII. References

1. Beleodaq Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; April 2017. Available at: http://www.beleodaq.com/downloads/Beleodaq_PI.pdf. Accessed August 2017.
2. Belinostat. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed August 2017.
3. Peripheral T-cell lymphoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed August 2017.
4. T-cell lymphomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed August 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

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date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9032	Injection, belinostat, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182.Excellus Oncology.	01.01.17	02.17
Age and dosing added NCCN recommended uses added separately.	09.05.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

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for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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