Reference number(s)
4727-A

Standard Medicare Part B Management Beleodaq

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Beleodaq	belinostat

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.

FDA-approved Indications[1]

Treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

Compendial Uses[2]

T-Cell Lymphomas

- Hepatosplenic T-cell lymphoma
- Extranodal NK/T-cell lymphoma
- Adult T-cell leukemia/lymphoma (ATLL)
- Breast implant associated anaplastic large cell lymphoma (ALCL).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

T-Cell Lymphomas[1,2]

Authorization of 12 months may be granted for treatment T-cell lymphomas with any of the following subtypes:

- 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 both of the following criteria are met:
  - The requested drug will be used as a single agent.
  - The requested drug is used for relapsed or refractory disease or for palliative intent.
- Hepatosplenic T-cell lymphoma when both of the following are met:
  - The member has had two or more previous lines of chemotherapy.
  - The requested drug will be used a single agent.
- Extranodal NK/T-cell lymphoma when all of the following criteria are met:
  - The requested drug will be used as a single agent.
  - The member has relapsed or refractory disease.
  - The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).
- Adult T-cell leukemia/lymphoma (ATLL) when both of the following criteria are met:
  - The requested drug is used as a single agent.
  - The requested drug is used for subsequent therapy.
- Breast implant-associated anaplastic large cell lymphoma (ALCL) when both of the following criteria are met:
  - The requested drug is used as a single agent.
  - The requested drug is used for subsequent therapy.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested drug is being used to treat an indication in the coverage criteria section.

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- The member is receiving benefit from therapy. Benefit is defined as:
    - No unacceptable toxicity while on the current regimen AND
    - No disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Beleodaq.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guidelines: T-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Beleodaq are covered in addition to the following:

- Hepatosplenic T-cell lymphoma
- Extranodal NK/T-cell lymphoma
- Adult T-cell leukemia/lymphoma (ATLL)
- Breast implant associated anaplastic large cell lymphoma (ALCL)

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Beleodaq to treat hepatosplenic T-cell lymphoma, extranodal NK/T-cell lymphoma, adult T-cell leukemia/lymphoma, and breast implant-associated anaplastic large cell lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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References

1. Beleodaq [package insert]. East Windsor, NJ: Acrotech Biopharma Inc; April 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed April 11, 2025.

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