Clinical Policy Title:	belinostat
Policy Number:	RxA.025
Drug(s) Applied:	Beleodaq®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Belinostat is a histone deacetylase inhibitor. It is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

This indication is 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
belinostat (Beleodaq®)	PTCL	1,000 mg/m^2 IV on days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity.	1,000 mg/m^2 IV per day

Dosage Forms

- Single-dose vial: 500 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Peripheral T-Cell Lymphoma (must meet all)**:**

1. Member has a diagnosis of relapsed or refractory PTCL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Member is 18 years of age or older;
4. Prescribed as monotherapy;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,000 mg/m^2 per day 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Compendial Indications (off-label) (must meet all)**:**
1. Member has one of the following diagnoses (a, b, c, d, or e):
   a. Mycosis fungoides or Sézary syndrome that is refractory to multiple previous therapies;
   b. Relapsed or refractory primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions or cutaneous ALCL with regional nodes;
   c. Peripheral T-cell lymphoma not otherwise specified;
   d. Angioimmunoblastic T-cell lymphoma;
   e. Monomorphic epitheliotropic intestinal T-cell lymphoma;
   f. Nodal peripheral T-cell lymphoma with TFH phenotype;
   g. Follicular T-cell lymphoma;
   h. Adult T-cell leukemia/lymphoma as second-line or subsequent therapy for nonresponders to first-line therapy for acute and lymphoma subtypes;
   i. Relapsed or refractory breast implant-associated ALCL as second-line or subsequent therapy;
   j. Relapsed or refractory extranodal NK/T-cell lymphoma (nasal type) following additional therapy with an alternate combination asparaginase-based chemotherapy regimen not previously used;
   k. Refractory hepatosplenic gamma-delta T-cell lymphoma after two (2) first-line therapy regimens;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Member is 18 years of age or older;
4. Prescribed as monotherapy;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (e.g., partial or complete response);
3. Dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use.
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ALCL: anaplastic Large Cell Lymphoma
FDA: Food and Drug Administration
IV: Intravenous/Intravenously

NCCN: National Comprehensive Cancer Network
PTCL: Peripheral T-Cell Lymphoma

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- NCCN Compendium lists belinostat as a category 2A recommendation for:
  - Mycosis fungoides or Sézary syndrome that is refractory to multiple previous therapies;
  - Relapsed or refractory primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions or cutaneous ALCL with regional nodes;
  - Peripheral T-cell lymphoma not otherwise specified;
  - Angioimmunoblastic T-cell lymphoma;
  - Monomorphic epitheliotropic intestinal T-cell lymphoma;
  - Nodal peripheral T-cell lymphoma with TFH phenotype;
  - Follicular T-cell lymphoma;
  - Adult T-cell leukemia/lymphoma as second-line or subsequent therapy for nonresponders to first-line therapy for acute and lymphoma subtypes;
  - Relapsed or refractory breast implant-associated ALCL as second-line or subsequent therapy;
  - Relapsed or refractory extranodal NK/T-cell lymphoma (nasal type) following additional therapy with an alternate combination asparaginase-based chemotherapy regimen not previously used;
  - Refractory hepatosplenic gamma-delta T-cell lymphoma after two (2) first-line therapy regimens;

References

1. Beleodaq® Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; January 2020. Available at: http://www.beleodaq.com/downloads/Beleodaq_PI.pdf. Accessed January 20, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 20, 2021.
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4. Beleodaq® Prescribing Information. East Windsor, NJ: Acrotech Biopharma, LLC; January 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206256s003lbl.pdf. Accessed January 20, 2021.
5. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed January 20, 2021.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed January 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy reviewed & updated.	04/29/2020	05/20/2020
Policy reviewed and updated 1. Clinical policy title and lines of business updated. 2. Compendial indications updated. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. References updated.	01/20/2021	03/09/2021