

### <u>T-Cell Lymphoma Agents</u> Beleodaq (belinostat) Istodax (romidepsin lyophilized) Poteligeo (mogamulizumab-kpkc) romidepsin (non- lyophilized) Effective 06/01/2025

Plan	<ul> <li>☑ MassHealth UPPL</li> <li>□Commercial/Exchange</li> </ul>		☑ Prior Authorization
Benefit	<ul> <li>Pharmacy Benefit</li> <li>Medical Benefit</li> </ul>	Program Type	<ul> <li>Quantity Limit</li> <li>Step Therapy</li> </ul>
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-190	8 Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-455	5 Fax: 844-403-1029
Notes	Additional agents from this class are available through the pharmacy benefit. Please see		
	the MassHealth Drug List for coverage and criteria.		

#### Overview

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

Istodax (romidepsin) is a histone deacetylase (HDAC) inhibitor indicated for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy.

Poteligeo is a humanized monoclonal antibody that is directed against CC chemokine receptor type 4 (CCR4), which is frequently expressed on leukemic cells of certain hematologic malignancies. It is indicated for the treatment of two types of CTCL, mycosis fungoides and Sézary syndrome.

#### **Coverage Guidelines**

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

#### Istodax (romidepsin lyophilized)

Romidepsin (non-lyophilized)

- 1. Diagnosis of cutaneous T-cell lymphoma
- 2. Prescriber is an oncologist, hematologist, or dermatologist
- 3. Appropriate dosing (current weight and height required)

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

### Poteligeo (mogamulizumab)

- 1. Diagnosis of **ONE** of the following:
  - a. Sézary syndrome
  - b. Mycosis fungoides and **ONE** of the following:
    - i. Stage IA disease with documentation that member is refractory to skin-directed therapy (e.g., topical corticosteroids, topical chemotherapy, topical retinoids, phototherapy, local radiation, and total skin electron beam therapy)
    - ii. Stage IB to III disease
- 2. Prescriber is an oncologist or hematologist
- 3. Appropriate dosing

# Beleodaq (belinostat)

- 1. Diagnosis of peripheral T-cell lymphoma
- 2. Prescriber is an oncologist or hematologist
- 3. Inadequate response or adverse reaction to **ONE** or contraindication to ALL second line treatment options (see appendix)
- 4. Appropriate dosing

# **Off-Label Indications**

# Istodax (romidepsin lyophilized)

Romidepsin (non-lyophilized)

- 1. Diagnosis of peripheral T-cell lymphoma
- 2. Prescriber is an oncologist or hematologist
- 3. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** second line treatment options (see appendix)
- 4. Appropriate dosing

# **Continuation of Therapy**

Reauthorization by physician will infer a positive response to therapy.

# Limitations

- 1. Initial approvals will be granted for 2 months.
- 2. Reauthorizations will be granted for 6 months.

# Appendix

Second-line treatment options may include:

- Clinical trial enrollment (preferred)
- Single agents (alphabetical order)
  - o brentuximab vedotin
  - o pralatrexate
  - o romidepsin
- Combination regimens (alphabetical order)
  - o DHAP (dexamethasone, cisplatin, cytarabine)
  - o DHAX (dexamethasone, cytarabine, oxaliplatin)
  - o ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin)
  - o GDP (gemcitabine, dexamethasone, cisplatin)
  - GemOx (gemcitabine, oxaliplatin)



- o ICE (ifosfamide, carboplatin, etoposide)
- Alternative regimens (alphabetical order) o alemtuzumab
  - o bendamustine
  - bortezomib (category 2B)
  - o cyclophosphamide and/or etoposide
  - o duvelisib
  - o gemcitabine
  - o GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
  - $\circ$  lenalidomide
  - radiation therapy

### References

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# **Review History**

02/08/2023 - Reviewed and created for Feb P&T; Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

05/15/2025 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Removed required trial of generic equivalent per Brand Name guideline as it is not applicable to medical benefit. Effective 6/1/25