Mass General Brigham
Health Plan

T-Cell Lymphoma Agents:
Beleodaq (belinostat)
Istodax (romidepsin)
Poteligeo (mogamulizumab-kpkc)
romidepsin
Effective 04/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

No PA	Drugs that require PA
Multi-drug chemotherapy regimens (The therapeutic alternatives recommended by the NCCN guidelines used in the treatment of peripheral T-cell lymphoma are defined in the coverage guidelines below)	Istodax® (romidepsin)* Beleodaq®(belinostat) Poteligeo®(mogamulizumab-kpkc)
Actimmune®(interferonγ-1b) Folotyn®(pralatrexate)† Intron A®(interferonα-2b) Targretin®#(bexarotene) Zolinza®(vorinostat)	romidepsin

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*Available as an A-rated generic; both brand and A-rated generic require PA.
†Authorized generic available.

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)
Romidepsin

1. Diagnosis of cutaneous T-cell lymphoma
2. Prescriber is an oncologist, hematologist, or dermatologist
3. Appropriate dosing (current weight and height required)
4. If the request is for BRAND NAME Istodax®, member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic romidepsin (Istodax®) (as per the Brand Name and Non-Preferred Generic Drugs guideline)

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. Physician attestation of 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)
Romidepsin

1. Diagnosis of peripheral T-cell lymphoma
2. Prescriber is an oncologist or hematologist
3. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** second line treatment options (see appendix)
4. Appropriate dosing
5. If the request is for BRAND NAME Istodax®, member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic romidepsin (Istodax®) (as per the Brand Name and Non-Preferred Generic Drugs guideline)

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)
    - brentuximab vedotin
    - pralatrexate
    - romidepsin
- Combination regimens (alphabetical order)
    - DHAP (dexamethasone, cisplatin, cytarabine)
    - DHAX (dexamethasone, cytarabine, oxaliplatin)
    - ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin)
    - GDP (gemcitabine, dexamethasone, cisplatin)
    - GemOx (gemcitabine, oxaliplatin)
    - ICE (ifosfamide, carboplatin, etoposide)
- Alternative regimens (alphabetical order) o alemtuzumab
    - bendamustine
    - bortezomib (category 2B)
    - cyclophosphamide and/or etoposide
    - duvelisib
    - gemcitabine
    - GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
    - 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.