

T-Cell Lymphoma Agents

Beleodaq (belinostat)

Istodax (romidepsin lyophilized)

Poteligeo (mogamulizumab-kpkc)

romidepsin (non- lyophilized)

Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	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)

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)
 - 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)
 - alemtuzumab



- bendamustine
- bortezomib (category 2B)
- cyclophosphamide and/or etoposide
- duvelisib
- gemcitabine
- GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
- lenalidomide
- radiation therapy

References

1. Istodax [package insert]. Summit (NJ): Celgene Corporation; 2023 Jan.
2. Beleodaq [package insert]. East Windsor (NJ): Acrotech Biopharma LLC; 2024 Nov.
3. Updated: FDA gives an early OK to lymphoma drug Beleodaq [press release on the internet]. Spectrum Pharmaceuticals; 2014 July 3 [cited 2022 Jul 11]. Available from: <http://www.fiercebiotech.com/story/fda-gives-early-ok-lymphoma-drug-beleodaq/2014-07-03>.
4. Poteligeo [package insert on the internet]. Bedminster (NJ): Kyowa Kirin, Inc.; 2025 Mar.
5. Poteligeo Approved for 2 Rare Types of Non-Hodgkin Lymphoma [press release on the internet]. Tokyo, Japan: Kyowa Kirin; 2018 Aug 09 [cited 2022 Jul 11]. Available from: http://www.kyowa-kirin.com/news_releases/2018/e20180809_01.html.
6. Girardi M, Heald PW, Wilson LD. The Pathogenesis of Mycosis Fungoides. *N Engl J Med.* 2004; 350: 1978-88.
7. Hwang ST, Janik JE, Jaffe ES, Wilson WH. Mycosis fungoides and Sézary syndrome. *Lancet.* 2008; 371: 945-57.
8. Lansigan F, Foss FM. Current and Emerging Treatment Strategies for Cutaneous T-cell Lymphoma. *Drugs.* 2010; 70(3): 273-286.
9. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Primary Cutaneous Lymphomas Version 2.2022 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2021 Jun 08 [cited 2022 Jul 11]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf.
10. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): T-Cell Lymphomas Version 1.2022 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2022 Mar 7 [cited 2022 Jul 11]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf.
11. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2022 Jul 12]. Available from: <https://clinicaltrials.gov/ct2/results?term=romidepsin>.
12. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2022 Jul 12]. Available from: <https://clinicaltrials.gov/ct2/results?term= belinostat>.
13. Whitehead RP, Rankin C, Hoff PMG, Gold PJ, Billingsley KG, Chapman RA, et al. Phase II trial of romidepsin (NSC-630176) in previously treated colorectal cancer patients with advanced disease: a Southwest Oncology Group study (S0336). *Invest New Drugs.* 2009;27:469-75.
14. Iwamoto FM, Lamborn KR, Kuhn JG, Wen PY, Yung WK, Gilbert MR, et al. A phase I/II trial of the histone deacetylase inhibitor romidepsin for adults with recurrent malignant glioma: North American Brain Tumor Consortium Study 03-03. *Neuro Oncol.* 2011 May;13(5):509-16.
15. Stadler WM, Margolin K, Ferber S, McCulloch W, Thompson JA. A phase II study of depsipeptide in refractory metastatic renal cell cancer. *Clin Genitourin Cancer.* 2006 Jun; 5(1):57-60.
16. Sherman EJ, Su YB, Lyall A, Schöder H, Fury MG, Ghossein RA, et al. Evaluation of romidepsin for clinical activity and radioactive iodine reuptake in radioactive iodine-refractory thyroid carcinoma. *Thyroid.* 2013 May;23(5):593-9.



17. Otterson GA1, Hodgson L, Pang H, Vokes EE. Phase II study of the histone deacetylase inhibitor Romidepsin in relapsed small cell lung cancer (Cancer and Leukemia Group B 30304). *J Thorac Oncol.* 2010 Oct;5(10):1644-8.
18. Harrison SJ, Quach H, Link E, Seymour JF, Ritchie DS, Ruell S, et al. A high rate of durable responses with romidepsin, bortezomib, and dexamethasone in relapsed or refractory multiple myeloma. *Blood.* 2011 Dec 8;118(24):6274-83.
19. Niesvizky R, Ely S, Mark T, Aggarwal S, Gabrilove JL, Wright JJ, et al. Phase 2 trial of the histone deacetylase inhibitor romidepsin for the treatment of refractory multiple myeloma. *Cancer.* 2011 Jan 15;117(2):336-42.
20. Odenike OM, Alkan S, Sher D, Godwin JE, Huo D, Brandt SJ, et al. Histone deacetylase inhibitor romidepsin has differential activity in core binding factor acute myeloid leukemia. *Clin Cancer Res.* 2008 Nov 1;14(21):7095-101.
21. Schrump DS, Fischette MR, Nguyen DM, Zhao M, Li X, Kunst TF, et al. Clinical and Molecular Responses in Lung Cancer Patients Receiving Romidepsin. *Clin Cancer Res.* 2008; 14(1):188-98.
22. Molife LR, Attard G, Fong PC, Karavasilis V, Reid AHM, Patterson S, et al. Phase II, two-stage, single-arm trial of the histone deacetylase inhibitor (HADCi) romidepsin in metastatic castration-resistant prostate cancer (CRPC). *Annals of Oncology.* 2010;21:109-13.
23. Haigentz M Jr, Kim M, Sarta C, Lin J, Keresztes RS, Culliney B, et al. Phase II trial of the histone deacetylase inhibitor romidepsin in patients with recurrent/metastatic head and neck cancer. *Oral Oncol.* 2012 Dec;48(12):1281-8.
24. Ramalingam SS, Belani CP, Ruel C, Frankel P, Gitlitz B, Koczywas M, et al. Phase II study of belinostat (PXD101), a histone deacetylase inhibitor, for second line therapy of advanced malignant pleural mesothelioma. *J Thorac Oncol.* 2009 Jan;4(1):97-101.
25. Kirschbaum MH, Foon KA, Frankel P, Ruel C, Pulone B, Tuscano JM, et al. A phase 2 study of belinostat (PXD101) in patients with relapsed or refractory acute myeloid leukemia or patients over the age of 60 with newly diagnosed acute myeloid leukemia: a California Cancer Consortium Study. *Leuk Lymphoma.* 2014 Oct;55(10):2301-4.
26. Hainsworth JD, Daugaard G, Lesimple T, Hübner G, Greco FA, Stahl MJ, et al. Paclitaxel/carboplatin with or without belinostat as empiric first-line treatment for patients with carcinoma of unknown primary site: A randomized, phase 2 trial. *Cancer.* 2015 May 15;121(10):1654-61.
27. Dizon DS, Damstrup L, Finkler NJ, Lassen U, Celano P, Glasspool R, et al. Phase II activity of belinostat (PXD-101), carboplatin, and paclitaxel in women with previously treated ovarian cancer. *Int J Gynecol Cancer.* 2012 Jul;22(6):979-86.
28. Dizon DS, Blessing JA, Penson RT, Drake RD, Walker JL, Johnston CM, et al. A phase II evaluation of belinostat and carboplatin in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube, or primary peritoneal carcinoma: a Gynecologic Oncology Group study. *Gynecol Oncol.* 2012 May;125(2):367-71.
29. Thomas A, Rajan A, Szabo E, Tomita Y, Carter CA, Scepura B, et al. A phase I/II trial of belinostat in combination with cisplatin, doxorubicin, and cyclophosphamide in thymic epithelial tumors: a clinical and translational study. *Clin Cancer Res.* 2014 Nov 1;20(21):5392-402.
30. Giaccone G1, Rajan A, Berman A, Kelly RJ, Szabo E, Lopez-Chavez A, et al. Phase II study of belinostat in patients with recurrent or refractory advanced thymic epithelial tumors. *J Clin Oncol.* 2011 May 20;29(15):2052-9.
31. Mackay HJ, Hirte H, Colgan T, Covens A, MacAlpine K, Grenci P, et al. Phase II trial of the histone deacetylase inhibitor belinostat in women with platinum resistant epithelial ovarian cancer and micropapillary (LMP) ovarian tumours. *Eur J Cancer.* 2010 Jun;46(9):1573-9.



32. Cashen A, Juckett M, Jumonville A, Litzow M, Flynn PJ, Eckardt J, et al. Phase II study of the histone deacetylase inhibitor belinostat (PXD101) for the treatment of myelodysplastic syndrome (MDS). *Ann Hematol.* 2012 Jan;91(1):33-8.
33. Force J, Rajan A, Dombi E, Steinberg SM, Giaccone G. Assessment of objective responses using volumetric evaluation in advanced thymic malignancies and metastatic non-small cell lung cancer. *J Thorac Oncol.* 2011 Jul;6(7):1267-73.
34. Yeo W, Chung HC, Chan SL, Wang LZ, Lim R, Picus J, et al. Epigenetic therapy using belinostat for patients with unresectable hepatocellular carcinoma: a multicenter phase I/II study with biomarker and pharmacokinetic analysis of tumors from patients in the Mayo Phase II Consortium and the Cancer Therapeutics Research Group. *J Clin Oncol.* 2012 Sep 20;30(27):3361-7.

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

