Mass General Brigham
Health Plan

Poteligeo (mogamulizumab-kpkc)
Effective 08/01/2020

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Mogamulizumab is a first-in-class defucosylated, humanized IgG1 kappa monoclonal antibody which selectively binds to C-C chemokine receptor 4 (CCR4). CCR4 mediates cell trafficking of lymphocytes to skin and various organs and is consistently expressed on the surface of T-cell malignancies. Binding to CCR4 targets a cell for antibody-dependent cellular cytotoxicity (ADCC), resulting in target cell depletion. Mogamulizumab is indicated for treatment of relapsed or refractory mycosis fungoides (MF) and relapsed or refractory Sézary syndrome (SS) in adult patients.

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with Poteligeo, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
Or
Authorization may be granted when all the following criteria are met, and clinical documentation has been submitted:

1. Member is diagnosed with relapsed or refractory mycosis fungoides or Sézary syndrome
2. Prescriber is an oncologist or hematologist AND
3. Member has received at least one prior systemic therapy (see Appendix), which resulted in an inadequate response.
4. Dosing is appropriate based on member's current weight.

Limitations
Approvals will be granted for 12 months.

Appendix

First-line systemic therapies for mycosis fungoides or Sézary syndrome

1. Extracorporeal phototherapy
2. Oral retinoids (bexarotene, tretinoin capsules, isotretinoin capsules)
3. Interferons (Pegasys/Intron-A)
4. HDAC inhibitors (vorinostat, romiDEPsin)
5. Methotrexate or pralatrexate
6. Adcetris (brentuximab)
7. Cyclophosphamide

References

1. Poteligeo (mogamulizumab-kpkc) [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc; August 2018.
2. Kim YH, Bagot M, Pinter-Brown L, et al; MAVORIC Investigators. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomized, controlled phase 3 trial [published online August 9, 2018
3. Stephen S, Morrissey KA, Benoit BM, et al. Inhibition of cell-mediated immunity by the histone deacetylase inhibitor vorinostat: implications for therapy of cutaneous T-cell lymphoma. Am J Hematol 2012; 87:226
4. Avilés A, Nambo MJ, Neri N, et al. Interferon and low dose methotrexate improve outcome in refractory mycosis fungoides/Sézary syndrome. Cancer Biother Radiopharm 2007; 22:836Iclusig (ponatinib) [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals Inc; October 2018
5. Booken N, Weiss C, Utikal J, et al. Combination therapy with extracorporeal photopheresis, interferon-alpha, PUVA and topical corticosteroids in the management of Sézary syndrome. J Dtsch Dermatol Ges 2010; 8:428
6. Scarisbrick JJ, Child FJ, Clift A, et al. A trial of fludarabine and cyclophosphamide combination chemotherapy in the treatment of advanced refractory primary cutaneous T-cell lymphoma. Br J Dermatol 2001; 144:1010
7. Horwitz SM, Kim YH, Foss F, et al. Identification of an active, well-tolerated dose of pralatrexate in patients with relapsed or refractory cutaneous T-cell lymphoma. Blood 2012; 119:4115.
8. Burg G, Dummer R. Historical perspective on the use of retinoids in cutaneous T-cell lymphoma (CTCL). Clin Lymphoma 2000; 1 Suppl 1:S41
9. Kim YH, Demierre MF, Kim EJ, et al. Clinically meaningful reduction in pruritus in patients with cutaneous T-cell lymphoma treated with romidepsin. Leuk Lymphoma 2013; 54:284

Review History

04/17/2019 – Reviewed

05/20/2020 – Reviewed and Updated May P&T; updated overview; added started and stabilized statement. Effective 8/1/20.