Mass General Brigham
Health Plan

# Lumoxiti (moxetumomab pasudotox-tdfk)
# Effective 4/1/2023

| | | | |
|---|---|---|---|
| **Plan** | ☒ MassHealth UPPL<br>☐Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☒ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☐ Pharmacy Benefit<br>☒ Medical Benefit (NLX) | | |
| **Specialty Limitations** | | | |
| **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** | | | |

**Overview**

Lumoxiti® (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

| No PA | Drugs that require PA |
|---|---|
| cladribine injection | Lumoxiti® (moxetumomab pasudotox-tdfk) |
| Intron A® (interferon alfa-2b) | Rituxan® (rituximab)* |
| Nipent (pentostatin) | |

*Please refer to the rituximab (Rituxan) guideline for guidance on handling these requests.

**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 will be granted when all the following criteria has been met and documentation has been submitted:

1. Diagnosis of relapsed or refractory hair cell leukemia (HCL)
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing

4. Documentation of prior therapy for the treatment of HCL with at least two systemic therapies (e.g., cladridine (Leustatin®), pentostatin (Nipent®), rituximab (Rituxan®), peginterferon alfa-2a and vemurafenib (Zelboraf®) including at least one purine nucleoside analog (PNA)

**Limitations**

1. Approvals will be granted for 6 months.
2. Reauthorizations for use beyond six treatment cycles will be evaluated on a case-by-case basis as Lumoxiti is FDA-approved for a maximum of six treatment cycles.
3. Stability on Lumoxiti for the treatment of HCL can be approved for the remaining treatment cycles (up to six treatment cycles maximum)

| Drug | Dosing |
|---|---|
| Lumoxiti® (moxetumomab pasudotox-tdfk)<br>**Vial:** 1 mg | HCL:<br>IV infusion over 30 minutes: 0.04 mg/kg on days one, three, and five of each 28-day treatment cycle; maximum of six treatment cycles or until disease progression or unacceptable toxicity |

HCL=hairy cell leukemia, IV=intravenous

**References**


1. Lumoxiti® (moxetumomab pasudotox-tdfk) [package insert]. Rockville (MD): Innate Pharma Inc.; 2021 Oct.
2. FDA approves new kind of treatment for hairy cell leukemia [press release on the internet]. Silver Spring (MD): FDA; 2018 Sep 13 [cited 2020 Dec 5] Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620448.htm.
3. Rare Diseases. Classic Hairy Cell Leukemia [webpage on the internet]. Orphanet; 2020 [cited 2020 Dec 5]. Available from: https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=58017.
4. Leukemia & Lymphoma Society. Hairy Cell Leukemia [webpage on the internet]. LLS; 2020 [cited 2020 Dec 5] Available from: https://www.lls.org/leukemia/hairy-cell-leukemia.
5. National Comprehensive Cancer Network. Hairy Cell Leukemia, Version 1.2022 [guideline on the internet]. NCCN; 2021 Sep 8 [cited 2021 Nov 17]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf.
6. Kreitman R, Dearden C, Zinzani P, Delgado J, Karlin L, Robak T, et al. Moxetumomab pasudotox in relapsed/refractory hairy cell leukemia. Leukemia. 2018 Jul 20; 32(8):1768-77.


**Review History**

01/11/23 - Reviewed and created for Jan P&T; matched MH UPPL. Created criteria to be in compliance with MassHealth unified formulary requirements. Effective 4/1/23.