Clinical Policy Title:	moxetumomab pasudotox-tdfk
Policy Number:	RxA.400
Drug(s) Applied:	Lumoxiti®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hairy Cell Leukemia (must meet all)**:**

1. Diagnosis of HCL;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Disease is relapsed or refractory;
5. Trial and failure of at least two (2) prior systemic therapies , one of which must be a purine nucleoside analog (e.g., cladribine, Nipent®), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced*;
   *Prior authorization may be required.
6. Lumoxiti is prescribed for no more than 6 cycles total;
7. Request meets one of the following (a or b)*:
   a. Dose does not exceed 0.04 mg/kg/dose (actual body weight) for three days of each 28-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Hairy Cell Leukemia (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Lumoxiti® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member has not received ≥ 6 treatment cycles;
4. If request is for a dose increase, request meets one of the following (a or b)*:
   a. New dose does not exceed 0.04 mg/kg/dose (actual body weight) for three days of each 28-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Hairy Cell Leukemia. Version 1. 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed April 19, 2023.
2. Jones J, Andritsos L, Kreitman RJ, et al. (2016). Efficacy and Safety of the Bruton Tyrosine Kinase Inhibitor Ibrutinib in Patients with Hairy Cell Leukemia: Stage 1 Results of a Phase 2 Study. Blood, 128(22), 1215. Available at: https://www.researchgate.net/publication/337318739_Efficacy_and_Safety_of_the_Bruton_Tyrosine_Kinase_Inhibitor_Ibrutinib_in_Patients_with_Hairy_Cell_Leukemia_Stage_1_Results_of_a_Phase_2_Study. Accessed April 19, 2023.
3. Tiacci E, Park JH, De Carolis L, et al. Targeting Mutant BRAF in Relapsed or Refractory Hairy-Cell Leukemia. N Engl J Med. 2015 Oct 29;373(18):1733-47. doi: 10.1056/NEJMoa1506583. Epub 2015 Sep 9. Available at: https://pubmed.ncbi.nlm.nih.gov/26352686/. Accessed April 19, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy description table was updated 2. Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance” 3. References were updated	07/21/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria and Continued Therapy Approval Criteriawere updated to remove HIM approval duration. 2. References were reviewed and updated.	6/1/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.6: Updated to add that Lumoxiti® is prescribed for no more than 6 cycles total. 2. Continued Therapy Criteria II.A.3: Updated to add that member has not received ≥ 6 treatment cycles. 3. References were reviewed and updated.	04/19/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023