Clinical Policy Title:	pegaspargase, calaspargase pegol-mknl
Policy Number:	RxA.347
Drug(s) Applied:	Oncaspar®
Original Policy Date:	03/06/2020
Last Review Date:	09/04/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (ALL) (must meet all)**:**

1. Diagnosis of ALL;
2. Prescribed as part of a multi-agent chemotherapeutic regimen.

Approval duration

All lines of business (except Medicare): 6 months

B. Extranodal NK/T-Cell Lymphoma (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Extranodal NK/T-cell lymphoma;
   b. Hepatosplenic T-cell lymphoma
2. Request is for Oncaspar®;
3. Prescribed as a component of any of the following regimens (a, b, c, or d):
   a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, etoposide);
   b. P-GEMOX (gemcitabine, pegaspargase, oxaliplatin);
   c. DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase);
   d. AspaMetDex (pegaspargase, methotrexate, dexamethasone);

   *Prior authorization may be required.

Approval duration

All lines of business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All lines of business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia. Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed September 4, 2024.
2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed September 4, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	07/19/2020	09/14/2020
Policy was reviewed 1. Initial Approval Criteria I.B.1 was updated from “Diagnosis of NK/T-cell lymphoma, nasal type” to “Diagnosis of one of the following NK/T-cell lymphoma subtypes (a, b, or c)…”. 2. Initial Approval Criteria I.B.1.a was updated to include “Nasal type;”. 3. Initial Approval Criteria I.B.1.b was updated to include “Extranasal type;”. 4. Initial Approval Criteria I.B.1.c was updated to include “Aggressive NK-cell leukemia;”. 5. Initial Approval Criteria I.B.2 was updated to include “Request is for Oncaspar®;”. 6. Initial Approval Criteria I.B.5.c was updated to include “DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase);”. 7. Initial Approval Criteria I.C was updated to include off-label indication, “Hepatosplenic T-Cell Lymphoma (off-label) (must meet all):”. 8. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 9. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 10. References were reviewed and updated.	05/31/2021	09/14/2021

Policy was reviewed: 1. References were reviewed and updated.	02/17/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated to include new age criteria If request is for Asparlas®, age 1 month to ≤ 21 years. 2. Initial Approval Criteria, I.A.4: Updated to include new prescribing criteria Prescribed as part of a multi-agent chemotherapeutic regimen. 3. Initial Approval Criteria, I.B.1: Updated diagnosis criteria from Diagnosis of one of the following NK/T-cell lymphoma subtypes (a, b, or c): a. Nasal type; b. Extranasal type; c. Aggressive NK-cell leukemia to Diagnosis of one of the following (a or b): a. Extranodal NK/T-cell lymphoma; b. Hepatosplenic T-cell lymphoma 4. Initial Approval Criteria, I.C: Updated approval criteria to merge into one as Extranodal NK/T-Cell Lymphoma (off-label) (I.B). 5. References were reviewed and updated.	03/30/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed Asparlas from policy.	03/15/2024	02/28/2024
Policy was reviewed: 1. Removed prescriber, dosing, and age requirements. 2. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 3. References were reviewed and updated.	08/28/2024	09/13/2024