Mass General Brigham
Health Plan

Asparaginase Agents
Asparlas (calaspargase pegol-mknl)
Erwinase (asparaginase erwinia chrysanthemi)
Rylaze (asparaginase erwinia chrystanthemi [recombinant]-rywn)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) in pediatric and young adult patients ages 1 month to 21 years.

Erwinase is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to E. coli-derived asparaginase.

Rylaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Approval of requested medication will be granted if the member meets all following criteria and documentation has been submitted:

Asparlas (calaspargase pegol-mknl)
1. Diagnosis of acute lymphoblastic leukemia (ALL)
2. Member is ≥ 1 month and < 22 years of age
3. Prescriber is a hematologist or oncologist
4. **ONE** of the following:
    a. Physician attestation of inadequate response, adverse reaction, or contraindication to Oncaspar (pegaspargase)

b. Appropriate rationale for use instead of Oncaspar (pegaspargase) (e.g., Documentation that Asparlas (calaspargase pegol-mknl) is preferred due to every three-week dosing in order to align administration with other agents in the chemotherapy regimen)

5. Appropriate dosing

Erwinase (asparaginase erwinia chrysanthemi)
Rylaze (asparaginase erwinia chrysanthemi-rywn)

1. Diagnosis of acute lymphoblastic leukemia (ALL)
2. Prescriber is a hematologist or oncologist
3. Hypersensitivity to *E. coli*-derived asparaginase (i.e., Oncaspar, Asparlas)
4. Appropriate dosing

Continuation of Therapy

Reauthorizations by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 8 weeks
2. Reauthorizations will be granted for up to an additional 28 weeks for a total treatment duration of 36 weeks.
    a. Requests that exceed a total treatment duration of 36 weeks, documentation of clinical evidence supporting such an extended duration is required.

References

1. Erwinase [package insert on the internet]. Porton Biopharma Limited; 2021 Jun.
2. Asparlas [package insert on the internet]. Boston (MA): Servier Pharmaceuticals LLC.; 2024 Oct.
3. Rylaze [prescribing information]. Palo Alto,CA: Jazz Pharmaceuticals, Inc.; 2024 Apr.
4. Fierce Pharma. Lundbeck to Stop Making Cancer Drug [press release on the Internet]. 2012 Sep 19 [cited 2022 Aug 9]. Available from: https://www.fiercepharma.com/m-a/lundbeck-to-stop-making-cancer-drug.
5. Horton TM, Steuber CP. Overview of the treatment of acute lymphoblastic leukemia in children and adolescents. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 [cited 2022 Aug 8]. Available from: http://www.utdol.com/utd/index.do.
6. Pieters R, Hunger SP, Boos J, Rizzari C, Silverman L, Baruchel A, et al. L-asparaginase treatment in acute lymphoblastic leukemia: a focus on Erwinia asparaginase. Cancer. 2011 Jan 15;117(2):238-49.
7. Jabbour EJ, Faderl S, Kantarjian HM. Adult Acute Lymphoblastic Leukemia. Mayo Clin Proc. 2005 Nov;80(11):1517-27.
8. National Comprehensive Cancer Network (NCCN). NCCN Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia V1.2022 [guideline on the Internet]. 2022 Apr 4 [cited 2022 Aug 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf.
9. National Comprehensive Cancer Network (NCCN). NCCN Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia V1.2022 [guideline on the Internet]. 2021 Oct 1 [cited 2022 Aug 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf.
10. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2022 Aug 9]. Available from: https://clinicaltrials.gov/ct2/results?term=asparaginase.
11. Jaccard A, Gachard N, Marin B, Rogez S, Audrain M, Suarez F, et al. Efficacy of L-asparaginase with methotrexate and dexamethasone (AspaMetDex regimen) in patients with refractory or relapsing extranodal NK/T-cell lymphoma: A phase 2 study. Blood. 2011 Feb 10;117(6):1834-9.

12. Yamaguchi M, Kwong YL, Kim WS, Maeda Y, Hashimoto C, Suh C, et al. Phase II study of SMILE chemotherapy for newly diagnosed stage IV, relapsed, or refractory extranodal natural killer (NK)/T-cell lymphoma, nasal type: the NK-Cell Tumor Study Group study. J Clin Oncol. 2011 Nov 20;29(33):4410-6.
13. Jiang M, Zhang H, Jiang Y, Yang Q, Xie L, Liu W, et al. Phase 2 trial of "sandwich" L-asparaginase, vincristine, and prednisone chemotherapy with radiotherapy in newly diagnosed, stage IE to IIE, nasal type, extranodal natural killer/T-cell lymphoma. Cancer. 2012 Jul 1;118(13):3294-301.
14. Ito Y, Kimura H, Maeda Y, Hashimoto C, Ishida F, Izutsu K, et al. Pretreatment EBV-DNA copy number is predictive of response and toxicities to SMILE chemotherapy for extranodal NK/T-cell lymphoma, nasal type. Clin Cancer Res. 2012 Aug 1;18(15):4183-90.
15. Kim SJ, Yang DH, Kim JS, Kwak JY, Eom HS, Hong DS, et al. Concurrent chemoradiotherapy followed by L-asparaginase-containing chemotherapy, VIDL, for localized nasal extranodal NK/T cell lymphoma: CISL08-01 phase II study. Ann Hematol. 2014 Nov;93(11):1895-901.
16. Kim TM, Kim DW, Kang YK, Chung J, Song HS, Kim HJ, et al. A phase II study of ifosfamide, methotrexate, etoposide, and prednisolone for previously untreated stage I/II extranodal natural killer/T-cell lymphoma, nasal type: a multicenter trial of the Korean Cancer Study Group. Oncologist. 2014 Nov;19(11):1129-30.
17. Kwong YL, Kim WS, Lim ST, Kim SJ, Tang T, Tse E, et al. SMILE for natural killer/T-cell lymphoma: Analysis of safety and efficacy from the Asia Lymphoma Study Group. Blood. 2012 Oct 11;120(15):2973-80.

Review History

01/19/2022 - Reviewed and Created at Jan P&T. Effective 03/01/2022
02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. Added criteria for drugs: Asparlas and Erwinase. Criteria updated for Rylaze. Clarified approval durations and continuation criteria. Updated references. Effective 4/1/23.
05/15/2025 – Reviewed and updated for P&T. Updated formatting and references. Effective 6/1/25