

# **Evolent Clinical Guideline 3003 for Asparlas™ (calaspargase pegol-mknl)**

<b>Guideline Number:</b> Evolent_CG_3003	<b><u>Applicable Codes</u></b>	
<b><i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. © 2019 - 2025 Evolent. All rights Reserved.</i></b>		
<b>Original Date:</b> February 2019	<b>Last Revised Date:</b> February 2025	<b>Implementation Date:</b> February 2025

## **TABLE OF CONTENTS**

<b>STATEMENT .....</b>	<b>2</b>
PURPOSE .....	2
<b>INDICATIONS .....</b>	<b>2</b>
ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) .....	2
<b>CONTRAINDICATIONS/WARNINGS .....</b>	<b>2</b>
<b>EXCLUSION CRITERIA .....</b>	<b>2</b>
<b>CODING AND STANDARDS .....</b>	<b>3</b>
CODES .....	3
APPLICABLE LINES OF BUSINESS .....	3
<b>POLICY HISTORY .....</b>	<b>4</b>
<b>LEGAL AND COMPLIANCE .....</b>	<b>4</b>
GUIDELINE APPROVAL .....	4
Committee .....	4
DISCLAIMER .....	4
<b>REFERENCES .....</b>	<b>5</b>

## STATEMENT

### Purpose

To define and describe the accepted indications for Asparlas (calaspargase pegol-mknl) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## INDICATIONS

**Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided**

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

### Acute Lymphoblastic Leukemia (ALL)

- Asparlas (calaspargase pegol-mknl) may be used in members age 1 month to 21 years with a diagnosis of ALL, as part of a multi-agent chemotherapy regimen, and as therapy for induction/consolidation/relapsed/refractory disease.

## CONTRAINDICATIONS/WARNINGS

- Contraindications
  - History of serious hypersensitivity reactions to pegylated L-asparaginase
  - History of serious thrombosis during L-asparaginase therapy
  - History of serious pancreatitis related to previous L-asparaginase treatment
  - History of serious hemorrhagic events during previous L-asparaginase therapy
  - Severe hepatic impairment

## EXCLUSION CRITERIA

- Asparlas (calaspargase pegol-mknl) is being used after disease progression with an Asparlas (calaspargase pegol-mknl) containing regimen or following hypersensitivity reactions to another pegylated L-asparaginase [i.e. Oncaspar (pegaspargase)].
- Dosing exceeds single dose limit of Asparlas (calaspargase pegol-mknl) 2,500 units/m<sup>2</sup> (maximum 3,750 units per dose).
- Investigational use of Asparlas (calaspargase pegol-mknl) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

## CODING AND STANDARDS

### Codes

- J9118 - Injection, calaspargase pegol-mknl, 10 units

### Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace

<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## POLICY HISTORY

Date	Summary
February 2025	<ul style="list-style-type: none"><li>• Converted to new Evolent guideline template</li><li>• This guideline replaces UM ONC_1352 Asparlas (calaspargase pegol-mknl)</li></ul>
February 2024	<ul style="list-style-type: none"><li>• Updated NCH verbiage to Evolent</li><li>• Updated “continuation request” verbiage</li></ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

### Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

## REFERENCES

1. Schore RJ, et al. Plasma asparaginase activity and asparagine depletion in acute lymphoblastic leukemia patients treated with pegaspargase on Children's Oncology Group AALL07P4. *Leuk Lymphoma*. 2019 Jul;60(7):1740-1748. doi: 10.1080/10428194.2018.1542146.
2. Asparlas prescribing information. Servier Pharmaceuticals LLC. Boston, MA 2023.
3. Clinical Pharmacology Elsevier Gold Standard 2025.
4. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2025.
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
7. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
8. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
9. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.