Evolent Clinical Guideline 3017 for Oncaspar™ (pegaspargase)

Guideline Number:	Applicable Codes	
Evolent_CG_3017		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
February 2011	February 2025	February 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Oncaspar (pegaspargase) 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 Lymphocytic Leukemia (ALL) including T-Cell Lymphoma/Leukemia

- Oncaspar (pegaspargase) may be used in adults and pediatric members as part of a multi-agent chemotherapy regimen for all sub-types of Acute Lymphocytic Leukemia (ALL), for induction/consolidation therapy, and for therapy of relapsed/refractory disease.

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - History of serious hypersensitivity reactions to Oncaspar (pegaspargase).
  - History of serious thrombosis with prior L-asparaginase therapy.
  - History of pancreatitis with prior L-asparaginase therapy.
  - History of serious hemorrhagic events with prior L-asparaginase therapy.
  - Severe hepatic impairment
- Warnings
  - Anaphylaxis or serious hypersensitivity reactions: Observe patients for 1 hour

after administration. Discontinue Oncaspar (pegaspargase) in patients with serious hypersensitivity reactions.

- Thrombosis: Discontinue Oncaspar (pegaspargase) in patients with serious thrombotic events.
- Pancreatitis: Evaluate patients with abdominal pain for pancreatitis. Discontinue Oncaspar (pegaspargase) in patients with pancreatitis.
- Glucose intolerance: Monitor serum glucose.
- Hemorrhage: Discontinue Oncaspar (pegaspargase) for severe or life-threatening hemorrhage. Evaluate for etiology and treat.
- Hepatotoxicity: Monitor for toxicity through recovery from cycle. Discontinue Oncaspar (pegaspargase) for severe liver toxicity

EXCLUSION CRITERIA

- Disease progression on or after an Oncaspar (pegaspargase) containing regimen or following hypersensitivity reactions to another pegylated L-asparaginase [i.e., Asparlas (calaspargase pegol-mknl)].
- Oncaspar (pegaspargase) is being used as a single agent and not part of a multi-agent chemotherapy.
- Dosing exceeds single dose limit of Oncaspar (pegaspargase) 2,500 IU/m^2 (maximum 3,750 units per dose).
- Investigational use of Oncaspar (pegaspargase) 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

- J9266 - Injection, pegaspargase, per single dose vial

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1063 Oncaspar (pegaspargase)
February 2024	• Updated NCH verbiage to Evolent • Updated "continuation request" verbiage

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.

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