Reference number(s)
4472-A

Standard Medicare Part B Management Oncaspar

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Oncaspar	pegaspargase

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy

FDA-approved Indications[1]

Acute lymphoblastic leukemia (ALL):

- Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the first line treatment of pediatric and adult patients with ALL.
- Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with ALL and hypersensitivity to asparaginase.

Compendial Uses [2,3]

- Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
- Aggressive NK-cell leukemia (ANKL)
- Lymphoblastic lymphoma (managed in the same manner as ALL)
- Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen

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- Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen, or as monotherapy for recurrent disease
- Non-Hodgkin's lymphoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LL)[1-3]

Authorization of 12 months may be granted for the treatment of ALL or LL when any of the following criteria are met:

- The requested medication is used in conjunction with multi-agent chemotherapy
- The requested medication is used as a single agent for recurrent disease

Extranodal NK/T-cell Lymphoma (ENKL) / Aggressive NK-cell Leukemia (ANKL)[2,4]

Authorization of 12 months may be granted for the treatment of ENKL or ANKL when the requested medication is used in conjunction with multi-agent chemotherapy.

Non-Hodgkin's Lymphoma[3]

Authorization of 12 months may be granted for the treatment of refractory Non-Hodgkin's lymphoma.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Oncaspar.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: T-cell lymphomas
- NCCN Guideline: Pediatric acute lymphoblastic leukemia
- NCCN Guideline: Acute lymphoblastic leukemia

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Oncaspar are covered in addition to the following:

- Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
- Aggressive NK-cell leukemia (ANKL)
- Lymphoblastic lymphoma (managed in the same manner as ALL)
- Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen
- Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen, or as monotherapy for recurrent disease
- Non-Hodgkin's lymphoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Oncaspar to treat the below listed indications can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

- Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
- Aggressive NK-cell leukemia (ANKL)
- Lymphoblastic lymphoma (managed in the same manner as ALL)
- Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen
- Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen

Support for using Oncaspar to treat pediatric acute lymphoblastic leukemia (ALL) as monotherapy for recurrent disease and non-Hodgkin's lymphoma can be found in the Micromedex DrugDex database. Use

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of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen). Oncaspar has demonstrated some activity in patients with refractory non-Hodgkin's lymphoma.

References

1. Oncaspar [package insert]. Boston, MA: Servier Pharmaceuticals LLC; March 2024.
2. The NCCN Drugs & Biologics Compendium® ©2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 13, 2025.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com [available with subscription]. Accessed June 13, 2025.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. Version 2.2025. https:// www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed June 13, 2025.

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