Reference number(s)
4472-A

STANDARD MEDICARE PART B MANAGEMENT

ONCASPAR (pegaspargase)

POLICY

I. 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.

A. FDA-Approved Indications

Acute lymphoblastic leukemia (ALL):

1. Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the first line treatment of pediatric and adult patients with ALL.
2. 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 native forms of L-asparaginase.

B. Compendial Uses

1. Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
2. Aggressive NK-cell leukemia (ANKL)
3. Lymphoblastic lymphoma (managed in the same manner as ALL)
4. Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen or central nervous system directed therapy as systemic therapy (IV/IM route)
5. Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen, or as monotherapy for recurrent disease
6. Hepatosplenic T-cell lymphoma
7. Non-Hodgkin's lymphoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LL)

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

1. The requested medication is used in conjunction with multi-agent chemotherapy
2. The requested medication is used as central nervous system directed therapy as systemic therapy
3. The requested medication is used as a single agent for recurrent disease

B. **Extranodal NK/T-cell Lymphoma (ENKL) / Aggressive NK-cell Leukemia (ANKL)**
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.

C. **Hepatosplenic T-cell Lymphoma**
Authorization of 12 months may be granted for the treatment of hepatosplenic T-cell lymphoma as subsequent therapy when the requested medication is used in conjunction with multi-agent chemotherapy.

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

III. 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:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen
   2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Oncaspar.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: T-cell lymphomas
4. NCCN Guideline: Pediatric acute lymphoblastic leukemia
5. 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:
1. Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
2. Aggressive NK-cell leukemia (ANKL)
3. Lymphoblastic lymphoma (managed in the same manner as ALL)
4. Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen or central nervous system directed therapy as systemic therapy (IV/IM route)
5. Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen, or as monotherapy for recurrent disease
6. Hepatosplenic T-cell lymphoma
7. Non-Hodgkin’s lymphoma

V. 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).

1. Extranodal natural killer(NK)/T-cell lymphoma (ENKL)
2. Aggressive NK-cell leukemia (ANKL)
3. Lymphoblastic lymphoma (managed in the same manner as ALL)
4. Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen or central nervous system directed therapy as systemic therapy (IV/IM route)
5. Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen, or as monotherapy for recurrent disease
6. Hepatosplenic T-cell lymphoma

Support for using Oncaspar to treat non-Hodgkin's lymphoma can be found in the Micromedex DrugDex database. Use 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.

VI. REFERENCES

1. Oncaspar [package insert]. Boston, MA: Servier Pharmaceuticals LLC; November 2021.
2. The NCCN Drugs & Biologics Compendium® ©2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 12, 2022.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com [available with subscription]. Accessed May 12, 2022.