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| **Section** | Prescription Drugs | **Effective Date:** | October 1, 2024 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | September 27, 2019 |
| **Subject:** | Oncaspar | **Page:** | 1 of 3 |

***Last Review Date:*** September 6, 2024

# Oncaspar

## Description

## Oncaspar (pegaspargase)

**Background**
Oncaspar (pegaspargase) is an asparagine specific enzyme. L-asparaginase is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacological effect of Oncaspar is thought to be based on selective killing of leukemic cells due to depletion of plasma L-asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize L-asparagine, and therefore depend on an exogenous source of L-asparagine for survival (1).

**Regulatory Status**
FDA-approved indication: Oncaspar is an aspargine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for treatment of pediatric and adult patients with: (1)

- First-line acute lymphoblastic leukemia
- Acute lymphoblastic leukemia and hypersensitivity to asparginase

Oncaspar is contraindicated in patients with a history of pancreatitis, thrombosis, hemorrhagic events, or anaphylaxis reaction with prior L-asparaginase therapy. Discontinue Oncaspar in the event of serious hypersensitivity reactions, including anaphylaxis, and severe or hemorrhagic pancreatitis. Glucose intolerance can occur. Bilirubin, transaminases, and glucose should be monitored at least weekly until recovery from the cycle of therapy (1).

Due to the risk of serious allergic reactions (such as life-threatening anaphylaxis), Oncaspar should be administered in a clinical setting with resuscitation equipment and other agents

necessary to treat anaphylaxis and patients should be observed for 1 hour after administration (1).

The safety and effectiveness of Oncaspar in pediatric patients have been established (1).

**Related policies**
Asparlas, Erwinaze, Rylaze

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Oncaspar may be considered **medically necessary** if the conditions indicated below are met.

Oncaspar may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Diagnosis**

Patient must have the following:

1. Acute lymphoblastic leukemia (ALL)
    a. Prescriber agrees to monitor bilirubin, liver function tests (LFTs), and glucose

## Prior – Approval *Renewal* Requirements

Same as above

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Oncaspar (pegaspargase) is an asparagine specific enzyme. L-asparaginase is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacological effect of Oncaspar is thought to be based on selective killing of leukemic cells due to depletion of plasma L-asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize L-asparagine, and therefore depend on an exogenous source of L-asparagine for survival. The safety and effectiveness of Oncaspar in pediatric patients have been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Oncaspar while maintaining optimal therapeutic outcomes.

**References**

1. Oncaspar [package insert]. Boston, MA: Servier Pharmaceuticals LLC; February 2024.
2. NCCN Drugs & Biologics Compendium® Pegaspargase 2023. National Comprehensive Cancer Network, Inc. Accessed on July 15, 2024.

## Policy History

| Date | Action |
|---|---|
| September 2019 | Addition to PA |
| December 2019 | Annual review |
| June 2020 | Annual review and reference update |
| September 2021 | Annual review and reference update |
| September 2022 | Annual review and reference update |
| September 2023 | Annual review and reference update |
| September 2024 | Annual review and reference update |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective October 1, 2024.**