

Federal Employee Program.
Blue Cross Blue Shield Association 750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060

Fax 1-877-378-4727

5.21.135

Section Prescription Drugs Effective Date: October 1, 2025

Subsection: Antineoplastic Agents Original Policy Date: September 27, 2019

Subject: Oncaspar Page: 1 of 4

Last Review Date: September 19, 2025

### 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

# 5.21.135

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Antineoplastic Agents Original Policy Date: September 27, 2019

Subject: Oncaspar Page: 2 of 4

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

## 5.21.135

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Antineoplastic Agents Original Policy Date: September 27, 2019

Subject: Oncaspar Page: 3 of 4

### 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 2025. National Comprehensive Cancer Network, Inc. Accessed on July 29, 2025.

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
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Keywords	

# 5.21.135

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Antineoplastic Agents Original Policy Date: September 27, 2019

Subject: Oncaspar Page: 4 of 4

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.