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 asparagine 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 asparaginase

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

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 for the treatment of patients with acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Oncaspar is 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


Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.