Asparlas

Description

Asparlas (calaspargase pegol-mknl)

Background
Asparlas (calaspargase pegol-mknl) 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 Asparlas 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).

The toxicity and efficacy of asparaginase is being studied in adult patients with acute lymphoblastic leukemia (ALL) (2).

Regulatory Status
FDA-approved indication: Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years (1).

Asparlas is contraindicated in patients with a history of pancreatitis, thrombosis, hemorrhagic events or anaphylaxis reaction with prior L-asparaginase therapy. Discontinue Asparlas 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), Asparlas 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 Asparlas in patients 1 month to 21 years of age have been established (1).

**Related policies**
*Erwinaze, Oncaspar*

**Policy**

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

Asparlas may be considered **medically necessary** in patients age 1 month to 21 years for the treatment of patients with acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Asparlas is considered **investigational** in patients not between the ages of 1 month and 21 years and for all other indications.

**Prior-Approval Requirements**

**Age**

1 month to 21 years of age

**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
Duration 12 months

Rationale

Summary
Asparlas (calaspargase pegol-mknl) 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 Asparlas is thought to be based on selective killing of
leukemic cells due to depletion of plasma L-asparagine. Leukemic cells with low expression of
asparaginase 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 Asparlas
in patients 1 month to 21 years of age have been established (1).

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

References
2. Koprivnikar J, McCloskey J, Faderl S. Safety, efficacy, and clinical utility of asparaginase

Policy History

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.