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Section	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 11, 2019
Subject:	Asparlas	**Page:**	1 of 4

Last Review Date: March 8, 2024

Asparlas

Description

Asparlas (calaspargase pegol-mknl)

Background
Asparlas (calaspargase pegol-mknl) 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 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, 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.

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

Asparlas may be considered **investigational** 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

Same as above

Rationale

Summary

Asparlas (calaspargase pegol-mknl) 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 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. 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

1. Asparlas [package insert]. Boston, MA: Servier Pharmaceuticals LLC.; December 2023.
2. Koprivnikar J, McCloskey J, Faderl S. Safety, efficacy, and clinical utility of asparaginase in the treatment of adult patients with acute lymphoblastic leukemia. Onco Targets Ther. 2017; 10:1413-1422.
3. NCCN Drugs & Biologics Compendium® Calaspargase pegol-mknl 2024. National Comprehensive Cancer Network, Inc. Accessed on January 18, 2024.

Policy History

Date	Action
January 2019	Addition to PA
March 2019	Annual review

September 2019	Annual review. Added Onco Targets and Therapy reference per SME
June 2020	Annual review and reference update
March 2021	Annual editorial review and reference update
September 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.