Medical Policy:

Asparlas® (calaspargase pegol-mknl) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.198	February 18, 2025	August 22, 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Asparlas contains an Escherichia (E.) coli-derived asparagine specific enzyme as a conjugate of L-asparaginase (L-asparagine amidohydrolase) and monomethoxy polyethylene glycol (MPEG) with a succinimidyl carbonate (SC) linker. L-asparaginase is a tetrameric enzyme that deaminates asparagine and glutamine resulting in the cell death of lymphoblasts that are deficient in asparagine synthetase and depend on exogenous L-asparagine for survival. Calaspargase pegol uses the identical enzyme and polyethylene glycol moiety as pegaspargase, another pegylated form of E. Coli L-asparaginase. However, it differs from pegaspargase by replacing the succinimidyl succinate linker with a SC linker which creates a more stable drug.

Asparlas (calaspargase pegol-mknl) is an asparagine specific enzyme FDA approved as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adults.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

750 billable units (2 vials) per 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

Asparlas *may be considered medically necessary if all the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Acute lymphoblastic leukemia (ALL)**
    A. Asparlas is being used for a patient whose age falls between 1 month up to 21.5 years old; **AND**
    B. Must be a used as a component of multi-agent chemotherapy; **AND**
    C. Patient has been diagnosed with an acute lymphoblastic leukemia.

Limitations/Exclusions

Asparlas is not considered medically necessary for when any of the following selection criteria is met:

1. Patient must not have a history of serious hypersensitivity, pancreatitis, severe hepatic impairment, thrombosis, or hemorrhagic events with prior L-asparaginase* therapy.
2. Patient will receive premedication prior to administration of Asparlas to decrease the risk and severity of both infusion and hypersensitivity reactions§ (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]);
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include reactions (including anaphylaxis), thrombosis, coagulopathy, severe hepatotoxicity, pancreatitis, etc*.; **AND**
3. Disease stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.

Dosage/Administration

Indication	Dose
All indications	Administer 2,500 units/m^2 intravenously given no more frequently than every 21 days.

Applicable Procedure Codes

Code	Description
J9118	Injection, calaspargase pegol-mknl, 10 units

Applicable NDCs

Code	Description
72694-0515-01	Injection, calaspargase pegol-mknl, 750u/mL, 5mL vial

ICD-10 Diagnoses

Code	Description
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Revision History

<table>
<tr><th>Company(ies)</th><th>DATE</th><th>REVISION</th></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>2/18/2025</td><td>Annual Review: Updated 7,500 units to 750 billable units as per FDA guidelines.
Initial criteria update: 21 years to 21.5 years old
Removed from exclusions/limitations: Asparlas (calaspargase pegol-mknl) is being used after disease progression with the same regimen or Oncaspar (pegaspargase) AND Dosing exceeds single dose limit of Asparlas (calaspargase pegol-mknl) 2,500 units/m2. Added in Patient will receive premedication prior to administration of Asparlas to decrease the risk and severity of both infusion and hypersensitivity reactions§ (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]);</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>4/2/2024</td><td>Annual Review: No criteria changes</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>7/31/2023</td><td>Annual Review:
ICD-10 Codes: added
<table>
<tr><td>C83.50</td><td>Lymphoblastic (diffuse) lymphoma, unspecified site</td></tr>
<tr><td>C83.51</td><td>Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck</td></tr>
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<tr><td>C83.56</td><td>Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes</td></tr>
<tr><td>C83.57</td><td>Lymphoblastic (diffuse) lymphoma, spleen</td></tr>
<tr><td>C83.58</td><td>Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites</td></tr>
<tr><td>C83.59</td><td>Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites</td></tr>
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		Removed: C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
		C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
		C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
		C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
		C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
		C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
		C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
		C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
		C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
		C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
		C84.ZO	Other mature T/NK-cell lymphomas, unspecified site
		C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
		C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
		C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
		C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
		C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
		C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
		C84.Z7	Other mature T/NK-cell lymphomas, spleen
		C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
		C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
		C86.0	Extranodal NK/T-cell lymphoma, nasal type
EmblemHealth & ConnectiCare	3/24/2022	Transferred policy to new template	
EmblemHealth & ConnectiCare	12/30/2020	Annual Review: changed “Patient has B-cell lineage acute lymphoblastic leukemia.” to “Patient has ben diagnosed with an acute lymphoblastic leukemia.”	
EmblemHealth & ConnectiCare	8/22/2019	New Medical Policy	

References

1. Asparlas [package insert]. Boston, MA; Servier Pharmaceuticals Inc.; June 2020. Accessed December 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series; Thomson Micromedex, Greenwood Village, Co. 2019.
4. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs.

Bethesda, MD. 2019.