Clinical Policy: Pegaspargase (Oncaspar), Calaspargase Pegol-mknl (Asparlas)

Reference Number: LA.PHAR.353
Effective Date: 11.04.23
Last Review Date: ~~04.28.24~~12.10.24 Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Pegaspargase (Oncaspar®) and calaspargase pegol-mknl (Asparlas™) are asparagine specific enzymes.

FDA Approved Indication(s)
Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with:

- Acute lymphoblastic leukemia (ALL), as first-line treatment
- ALL and hypersensitivity to native forms of L-asparaginase

Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL in pediatric and young adult patients age 1 month to 21 years.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Oncaspar and Asparlas are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. If request is for Asparlas, age 1 month to ≤ 21 years;
4. Prescribed as part of a multi-agent chemotherapeutic regimen;
5. Request meets one of the following (a, b, or c):*
   a. Oncaspar: Dose does not exceed 2,500 IU/m^2 every 14 days (age ≤ 21 years) or 2,000 IU/m^2 every 14 days (age > 21 years);
   b. Asparlas: Dose does not exceed 2,500 units/m^2 every 21 days;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. T-Cell Lymphoma (off-label) (must meet all)**:**
~~1.~~ Diagnosis of ~~one of the following (a or b):~~
~~2.~~1. ~~Extranodal~~extranodal NK/T-cell lymphoma;
~~a. Hepatosplenic T-cell lymphoma;~~
~~3.~~2. Request is for Oncaspar;
~~4.~~3. Prescribed by or in consultation with an oncologist or hematologist;
~~5.~~4. Age ≥ 18 years;
~~6.~~5. Prescribed as a component of any of the following regimens (a, b, c, d, or ~~d~~e):*
a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, etoposide);
b. P-GEMOX (gemcitabine, pegaspargase, oxaliplatin);
c. DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase);
d. AspaMetDex (pegaspargase, methotrexate, dexamethasone);
e. GELAD (gemcitabine, etoposide, pegaspargase, dexamethasone);
**Prior authorization may be required*
~~7.~~6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
**Prescribed regimen must be FDA-approved or recommended by NCCN*
Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Oncaspar or Asparlas for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for Asparlas, age 1 month to ≤ 21 years;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
a. Oncaspar: New dose does not exceed 2,500 IU/m^2 every 14 days (age ≤ 21 years) or 2,000 IU/m^2 every 14 days (age > 21 years);
b. Asparlas: New dose does not exceed 2,500 units/m^2 every 21 days;
c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
**Prescribed regimen must be FDA-approved or recommended by NCCN*
Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key
ALL: acute lymphoblastic leukemia
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious allergic reactions to Oncaspar or to pegylated L-asparaginase therapy
  - History of serious thrombosis with prior L-asparaginase therapy
  - History of pancreatitis with prior L-asparaginase therapy
  - History of serious hemorrhagic events with prior L-asparaginase therapy
  - Severe hepatic impairment
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Oncaspar (pegaspargase)	ALL	Age ≤ 21 years: 2,500 IU/m^2 IM or IV no more frequently than every 14 days Age > 21 years: 2,000 IU/m^2 IM or IV no more frequently than every 14 days	Age ≤ 21 years: 2,500 IU/m^2 every 14 days Age > 21 years: 2,000 IU/m^2 every 14 days
Asparlas (calaspargase pegol-mknl)	ALL	Age 1 month to 21 years: 2,500 units/m^2 IV no more frequently than every 21 days	2,500 units/m^2 every 21 days

VI. Product Availability

Drug Name	Availability
Oncaspar (pegaspargase)	Single-dose vial: 3,750 IU/5 mL solution
Asparlas (calaspargase pegol-mknl)	Single-dose vial: 3,750 units/5 mL solution

VII. References

1. Oncaspar Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; ~~December 2022.~~March 2024. Available at: ~~http~~ https://www.~~oncaspar.com/.~~accessdata.fda.gov/drugsatfda_docs/label/2024/103411s5207lbl.pdf. Accessed July ~~7, 2023~~11, 2024.
2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; ~~October 2022.~~December 2023. Available at: http://asparlas.com/. Accessed July ~~7, 2023~~11, 2024.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~7, 2023~~22, 2024.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.~~2023~~2024. Available at www.nccn.org. Accessed August ~~7, 2023~~22, 2024.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version ~~2.2023~~6.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed August ~~7, 2023~~22, 2024.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version ~~1.2023~~4.2024. Available at www.nccn.org. Accessed August ~~7, 2023~~22, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9118	Injection, calaspargase pegol-mknl (Asparlas), 10 units
J9266	Injection, pegaspargase (Oncaspar), per single dose vial

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.20.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	04.28.24	07.10.24
For T-cell lymphoma, removed hepatosplenic T-cell lymphoma indication and added GELAD regimen option per NCCN; references reviewed and updated.	12.10.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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