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

Reference Number: ERX.SPA.257
Effective Date: 12.01.18
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

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

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≤ 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 IU/m^2 every 21 days (age 1 month to 21 years);
   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):
   a. Extranodal NK/T-cell lymphoma, nasal type;
   b. Hepatosplenic T-cell lymphoma;
2. Request is for Oncaspar;
3. Prescribed by or in consultation with an oncologist or hematologist;
4. Age ≥ 18 years;
5. Prescribed as a component of any of the following regimens (a, b, c, or d):*

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);

**Prior authorization may be required.*

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

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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 ≤ 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 IU/m^2 every 21 days (age 1 month to 21 years);
   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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym 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; June 2020. Available at: http://www.oncaspar.com/. Accessed July 26, 2021.
2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; June 2020. Available at: http://asparlas.com/. Accessed July 26, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 28, 2021.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.2021. Available at www.nccn.org. Accessed July 26, 2021.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 15, 2021.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at www.nccn.org. Accessed July 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.07.18	11.18
4Q 2019 annual review: ALL age limit/drug trial removed per PI; off-label T-cell age limit added in absence of NCCN pediatric guidance; FDA/NCCN dosing limitation added; references reviewed and updated.	08.27.19	11.19
RT4: added Asparlas to policy.	02.04.20	
4Q 2020 annual review: extranasal and aggressive NK/T-cell subtypes and DDGP regimen added to NK/T-cell off-label criteria set - limited to Oncaspar per NCCN; references reviewed and updated.	08.11.20	11.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: for ALL, clarified that age ≤ 21 years for Asparlas and added requirement that the requested agent is prescribed as part of a multi-agent chemotherapeutic regimen per FDA label and NCCN; for T-cell lymphoma, revised to include only nasal type extranodal NK/T-cell lymphoma (removed extranasal type and aggressive NK cell leukemia) and added hepatosplenic T-cell lymphoma per NCCN; references reviewed and updated.	06.28.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.