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

Reference Number: PA.CP.PHAR.353
Effective Date: 10/2018
Last Review Date: 10/2024

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 PA Health & Wellness® 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, age1 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 units/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 (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*).

Approval duration: 6 months

B. T-Cell Lymphoma (off-label) (must meet all)**:**

1. Diagnosis of extranodal NK/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);
   e. GELAD (gemcitabine, etoposide, pegaspargase, 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*).
   Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies;
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 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*).

   Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices

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 IU/m^2 IV no more frequently than every 21 days	2,500 IU/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; March 2024. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103411s5207lbl.pdf.. Accessed July 11, 2024.
2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; December 2023. Available at: http://asparlas.com/. Accessed July 11, 2024.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed Accessed August 22, 2024.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.2024. Available at www.nccn.org. Accessed August 22, 2024.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 6.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed August 22, 2024.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 4.2024. Available at www.nccn.org. Accessed August 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
New policy created.	10/2018
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019
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.	08/2020
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.	10/2021
4Q 2022 annual review: no significant changes; clarified age 1 month to ≤ 21 years for Asparlas per PI; references reviewed and updated.	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023
4Q 2024 annual review: for T-cell lymphoma removed hepatosplenic T-cell lymphoma indication and added GELAD regimen option per NCCN; references reviewed and updated.	10/2024