

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

Reference Number: PA.CP.PHAR.353

Effective Date: 10/2018

Last Review Date: 10/2023

[Coding Implications](#)

[Revision Log](#)

### 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, 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 units/m<sup>2</sup> every 14 days (age ≤ 21 years) or 2,000 IU/m<sup>2</sup> every 14 days (age > 21 years);
  - b. Asparlas: dose does not exceed 2,500 units/m<sup>2</sup> 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 one of the following (a or b):
  - a. Extranodal NK/T-cell lymphoma;
  - b. Hepatosplenic T-cell lymphoma;
2. Request is for Oncaspar;

3. Prescribed by or in consultation with an oncologist or hematologist;
  4. Age  $\geq$  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*).
- 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.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for Asparlas, age 1 month to  $\leq$  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<sup>2</sup> every 14 days (age  $\leq$  21 years) or 2,000 IU/m<sup>2</sup> every 14 days (age  $>$  21 years);
  - b. Asparlas: new dose does not exceed 2,500 IU/m<sup>2</sup> 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.LTSS.PHAR.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 $\leq$ 21 years: 2,500 IU/m <sup>2</sup> IM or IV no more frequently than every 14 days  Age > 21 years: 2,000 IU/m <sup>2</sup> IM or IV no more frequently than every 14 days	Age $\leq$ 21 years: 2,500 IU/m <sup>2</sup> every 14 days  Age > 21 years: 2,000 IU/m <sup>2</sup> every 14 days
Asparlas (calaspargase pegol-mknl)	ALL	Age 1 month to 21 years: 2,500 IU/m <sup>2</sup> IV no more frequently than every 21 days	2,500 IU/m <sup>2</sup> 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. Available at: <http://www.oncaspar.com/>. Accessed July 7, 2023.

2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; October 2022. Available at: <http://asparlas.com/>. Accessed July 7, 2023.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed August 7, 2023.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.2023. Available at [www.nccn.org](http://www.nccn.org). Accessed August 7, 2023.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/ped\\_all.pdf](https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf). Accessed August 7, 2023.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2023. Available at [www.nccn.org](http://www.nccn.org). Accessed August 7, 2023.

### 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	Approval 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 $\leq 21$ 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 $\leq 21$ years for Asparlas per PI; references reviewed and updated.	10/2022	
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023	