Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PHAR.353	**Effective Date: 01/2020** **Revision Date: 10/2021**
Policy Name: Pegaspargase (Oncaspar), Calaspargase Pegol-mknl (Asparlas)	

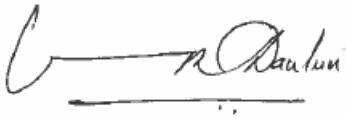
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

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.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

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

Reference Number: PA.CP.PHAR.353
Effective Date: 10.17.18
Last Review Date: 10/2021

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 health plans affiliated with 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 ≤ 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*).

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*).

   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 Pennsylvania Health and 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 ≤ 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 Pennsylvania Health and 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 ≤ 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; 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.

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
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96411	Intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)

Reviews, Revisions, and Approvals	Date	Approval Date
New policy created.	10/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
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.	08/20	11/20
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	