

Clinical Policy: Pegaspargase (Oncaspar)

Reference Number: PA.CP.PHAR.353

Effective Date: 10.17.18

Last Review Date: 10.17.18

[Coding Implications](#)
[Revision Log](#)

Description

Pegaspargase (Oncaspar®) is an asparagine specific enzyme.

FDA Approved Indication(s)

Oncaspar is indicated as:

- A component of a multi-agent chemotherapeutic regimen as a first line treatment for acute lymphoblastic leukemia (ALL)
- A component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL and hypersensitivity to native forms of L-asparaginase

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 is **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. Age ≥ 1 years;
4. For members with Philadelphia chromosome-positive (Ph+) ALL, disease has relapsed or is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, Sprycel®, Tassigna®, Bosulif®, Iclusig®) [off-label];
**Prior authorization is (or may be) required for tyrosine kinase inhibitor therapy*
5. Request meets one of the following (a or b):
 - a. Dose does not exceed 2,500 IU/m² every 14 days;
 - b. 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. Extranodal NK/T-Cell Lymphoma (off-label) (must meet all):

1. Diagnosis of NK/T-cell lymphoma of the nasal type;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 1 years;
4. Prescribed as a component of any of the following regimens (a, b, or c):
 - a. Modified-SMILE (regimen containing dexamethasone, methotrexate, ifosfamide, pegaspargase, and etoposide);
 - b. P-GEMOX (regimen containing gemcitabine, pegaspargase, and oxaliplatin);

- c. AspaMetDex (regimen containing pegaspargase, methotrexate, and dexamethasone);
- 5. Request meets one of the following (a or b):
 - a. Dose does not exceed 2,500 IU/m² every 14 days;
 - b. 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

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 a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 2,500 IU/m² every 14 days;
 - b. 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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec®)	600 mg PO QD	600 mg/day
Sprycel (dasatinib)	140 mg PO QD	180 mg/day
Tasigna (nilotinib)	400 mg PO BID	800 mg/day
Bosulif (bosutinib)	400-500 mg PO QD	600 mg/day
Iclusig (ponatinib)	45 mg PO QD	45 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - History of serious allergic reactions to Oncaspar
 - 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
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ALL	2,500 IU/m ² IM or IV no more frequently than every 14 days	2,500 IU/m ² every 14 days

VI. Product Availability

Single-use vial: 3,750 International Units of L-asparaginase per 5 mL solution

VII. References

1. Oncaspar Prescribing Information. Lexington, MA: Baxalta US Inc.; October 2017. Available at: <http://www.oncaspar.com/>. Accessed June 12, 2018.
2. Acute lymphoblastic leukemia (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed July 12, 2018.
3. T-Cell Lymphomas (Version 4.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed July 12, 2018.

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.

HCPSC Codes	Description
J9299	Injection, pegaspargase (Oncaspar)

HCPCS Codes	Description
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	