Clinical Policy Title:	pegaspargase
Policy Number:	RxA.428
Drug(s) Applied:	Oncaspar®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Pegaspargase (Oncaspar®) is an asparagine specific enzyme.
Oncaspar® is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with:

- First-line acute lymphoblastic leukemia (ALL).
- ALL and hypersensitivity to asparaginase.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pegaspargase (Oncaspar®)	Acute lymphoblastic leukemia	Patients ≤ 21 years of age: 2,500 IU/m^2 intramuscularly or intravenously no more frequently than every 14 days Patients >21 years of age: 2,000 IU/m^2 intramuscularly or intravenously no more frequently than every 14 days	Patients ≤ 21 years of age: 2,500 IU/m^2 every 14 days Patients >21 years of age: 2,000 IU/m^2 every 14 days

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Request meets one of the following (a or b):*
   a. 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. 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
Commercial: 6 months
Medicaid: 6 months

B. Extranodal NK/T-Cell Lymphoma, nasal type (off-label) (must meet all)**:**
1. Diagnosis of NK/T-cell lymphoma, nasal type;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed as a component of any of the following regimens (a, b, c, or d):*
   a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, egaspargase, etoposide);
   b. P-GEMOX (gemcitabine, pegaspargase, oxaliplatin);
   c. AspaMetDex (pegaspargase, methotrexate, dexamethasone);
   d. DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase);
   *Prior authorization may be required.
5. 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy, or documentation supports that member is currently receiving Oncaspar® 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 a dose increase, request meets one of the following* (a or b):
   a. 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. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ALL: Acute lymphoblastic leukemia
FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network
IU: International Unit
IM: intramuscular
IV: Intravenous

APPENDIX B: Therapeutic Alternatives

- Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious hypersensitivity 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;
  - Severe hepatic impairment.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Anaphylaxis or serious hypersensitivity reactions: Observe patients for 1 hour after administration. Discontinue Oncaspar® in patients with serious hypersensitivity reactions.
- Thrombosis: Discontinue Oncaspar® in patients with serious thrombotic events.
- Pancreatitis: Evaluate patients with abdominal pain for pancreatitis. Discontinue Oncaspar® in patients with pancreatitis.
- Glucose intolerance: Monitor serum glucose.
- Hemorrhage: Discontinue Oncaspar® for severe or life-threatening hemorrhage. Evaluate for etiology and treat.
- Hepatotoxicity: Monitor for toxicity through recovery from cycle. Discontinue Oncaspar® for severe liver toxicity.

References

1. Oncaspar® Prescribing Information. Lexington, MA: Baxalta US Inc.; June 2020. Available at: https://www.oncaspar.com/. Accessed June 28, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed June 28, 2021.
3. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed June 28, 2021.
4. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2021. Available at: ww.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed June 28, 2021.
5. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed June 28, 2021.
6. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology-ip.com/. Accessed June 28, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.		

	01/2020	03/06/2020
Policy was reviewed: 1. Policy description table updated 2. Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance" 3. Initial therapy and continued therapy approval duration added for commercial, Medicaid and HIM separately. 4. References were updated.	07/23/2020	09/14/2020
Policy was reviewed: 1. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 2. Initial Approval Criteral I.B was updated to include "nasal type…". 3. Initial Approval criteria I.B.4.d was updated to include "DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase)…". 4. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 5. Appendix A was updated to include abbreviations IU, IM, and IV.. 6. Appendix B was updated to remove all prior therapeutic alternatives and to include "Not applicable." 7. Appendix D was updated to include various warnings and precautions, "Anaphylaxis or serious hypersensitivity reactions…". 8. References were reviewed and updated.	06/28/2021	09/14/2021