RXADVANCE
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Clinical Policy Title:	pegaspargase
Policy Number:	RxA.428
Drug(s) Applied:	Oncaspar®
Original Policy Date:	01/2020
Last Review Date:	09/14/2020
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 IM or IV no more frequently than every 14 days Patients >21 years of age: 2,000 IU/m^2 IM or IV 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.

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
HIM: 6 months

B. Extranodal NK/T-Cell Lymphoma (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, or c):*
   a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, egaspargase, etoposide);
   b. P-GEMOX (gemcitabine, pegaspargase, oxaliplatin);
   c. AspaMetDex (pegaspargase, methotrexate, dexamethasone);

   *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
HIM: 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 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):
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*
   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
HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym 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 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

References

1. Oncaspar Prescribing Information. Lexington, MA: Baxalta US Inc.; August 2019. Available at: https://www.oncaspar.com/. Accessed July 23,2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org /professionals/drug_compendium. Accessed July 23, 2020.
3. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version1.2020. Available at www.nccn.org. Accessed July 23, 2020.
4. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 1.2020. Available at: ww.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 23, 2019.
5. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2020 -January 6, 2020. Available at www.nccn.org. Accessed July 23, 2020.

Review/Revision History	Review/Revised 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