RXADVANCE
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Clinical Policy Title:	pegaspargase, calaspargase pegol-mknl
Policy Number:	RxA.347
Drug(s) Applied:	Oncaspar®, Asparlas™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Pegaspargase (Oncaspar®) and calaspargase pegol-mknl (Asparlas™) are 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 treatment of acute lymphoblastic leukemia (ALL)
- 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pegaspargase (Oncaspar®)	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
Calaspargase pegol-mknl (Asparlas™)	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

Dosage Forms

- Pegaspargase (Oncaspar®): Single-dose vial: 3,750 IU/5 mL solution.
- Calaspargase pegol-mknl (Asparlas™): Single-dose vial: 3,750 units/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, b, or c):*
   a. Request is for 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. Request is for 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*).

   **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 of age or older;
4. Prescribed as a component of any of the following regimens (a, b, or c):*
   a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, 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. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Oncaspar or Asparlas 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, b, or c):*
   a. Request is for 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. Request is for 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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration

Commercial: 12 months
Medicaid: 12 months
HIM: 12 months

III. 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

APPENDIX D: General Information

- Not applicable

References

1. Oncaspar Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; August 2019. Available at: https://www.oncaspar.com/ONCASPAR%20PI_September%202019.pdf. Accessed July 19, 2020.
2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; September 2019. Available at: http://asparlas.com/. Accessed July 19, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 19, 2020.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed July 19, 2020.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 19, 2020.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed July 19, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy	07/19/2020	09/14/2020

Review/Revision History	Review/Revised Date	P&T Approval Date
Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. References were reviewed and updated.		