RXADVANCE
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Clinical Policy Title:	asparaginase erwinia chrysanthemi
Policy Number:	RxA.377
Drug(s) Applied:	Erwinaze ®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Asparaginase *Erwinia chrysanthemi* (Erwinaze ®) is an asparagine specific enzyme. It is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E. coli*-derived asparaginase.

Dosing Information

Drug Name		Dosing Regimen	Maximum Dose
asparaginase *Erwinia chrysanthemi* (Erwinaze®)	Acute lymphoblastic leukemia	To substitute for pegaspargase: The recommended dose for each planned dose of pegaspargase is 25,000 International Units/m^2 administered IM or IV three times weekly (Monday/Wednesday/Friday) for six doses.	25,000 IU/m^2/dose

Dosage Forms

- 10,000 International Units lyophilized powder per vial.

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. Prescribed as a component of a multi-agent chemotherapeutic regimen;
4. Member has developed hypersensitivity to an *E. coli* derived asparaginase product (Elspar® - off-market) or pegaspargase (Oncaspar®);
5. Request meets one of the following (a, b, or c):
   a. Dose should not exceed 25,000 International Units per m^2 administered three times per week;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration
Commercial: 3 months
Medicaid: 3 months
HIM: 3 months

II. Continued Therapy Approval

A. Acute lymphoblastic leukemia (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Erwinaze for a covered indication and has received this medication for at least 30 days;
2.
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. New dose should not exceed 25,000 International Units per m^2 administered three times per week;
   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: 6 months
Medicaid: 6 months
HIM: 6 months

III. Appendices

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

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
Oncaspar (pegaspargase)	2,500 International Units/m^2 IM or IV, administered no more frequently than every 14 days, as part of a multi-agent chemotherapeutic regimen.	Varies

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):
  <u>In patients with a history of:</u>
  - Serious hypersensitivity reactions to Erwinaze, including anaphylaxis,
  - Serious pancreatitis with prior L-asparaginase therapy,

  - Serious thrombosis with prior L-asparaginase therapy,
  - Serious hemorrhagic events with prior L-asparaginase therapy.
- Boxed warning(s):
  - None

References

1. Erwinaze Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; December 2019. Available at http://www.erwinaze.com. Accessed July 22, 2020 .
2. Oncaspar Prescribing Information. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.; August 2019 . Available at https://www.shirecontent.com/PI/PDFs/ONCASPAR_USA_ENG.pdf. Accessed July 22, 2020.
3. Asparaginase Erwinia chrysanthemi. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at ww.nccn.org. Accessed July 23, 2020 .
4. Acute lymphoblastic leukemia (Version 1.2020). National Comprehensive Cancer Network Guidelines. 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