Clinical Policy: Rasburicase (Elitek)

Reference Number: IL.ERX.SPA.J33
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Rasburicase (Elitek®) is a recombinant urate-oxidase.

FDA Approved Indication(s)
Elitek is indicated for initial management of plasma uric acid levels in pediatric and adult patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anticancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Elitek is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hyperuricemia Associated with Malignancy (must meet all)**:**

1. Diagnosis of hyperureciemia associated with malignancy;
2. Failure of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated: hydration therapy and febuxostat;
3. Member meets one of the following (a or b):
   a. Failure of allopurinol, unless contraindicated or clinically significant adverse effects are experienced;
   b. Documentation of serum uric acid level ≥ 7.5 mg/dL (446 micromol/L);
4. Dose does not exceed 0.2 mg/kg/day for 5 days.

Approval duration: 5 days

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Hyperuricemia Associated with Malignancy:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications:

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
febuxostat (Uloric®)	60-120 mg/day PO for 6-14 days	120 mg/day
allopurinol	Adults: 600 mg to 800 mg/day PO in 2-3 divided doses. Pediatric: 150 mg/day or 300-600 mg/day PO in 2-3 divided doses, depending on age	800 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 the following reactions to rasburicase: anaphylaxis, severe hypersensitivity, hemolysis, methemoglobinemia
  - Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Boxed warning(s): hypersensitivity, hemolysis, methemoglobinemia, and interference with uric acid measurement

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hyperuricemia associated with malignancy	0.2 mg/kg IV daily for up to 5 days	0.2 mg/kg/day

VI. Product Availability

Single-dose vials: 1.5 mg and 7.5 mg lyophilized powder

VII. References

1. Elitek Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/103946s5103lbl.pdf. Accessed April 16, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 16, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 16, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from MRX J.33)	04.16.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of

medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.