Evolent Clinical Guideline 3095 for Elitek™ (rasburicase)

Guideline Number:	Applicable Codes	
Evolent_CG_3095		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
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STATEMENT

Purpose

To define and describe the accepted indications for Elitek (rasburicase) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Tumor Lysis Syndrome (TLS)

- Elitek (rasburicase) may be used either as a single agent or in combination with allopurinol, for prevention and/or treatment of TLS in adult or pediatric members with hematologic malignancies/solid tumors who are receiving anti-cancer therapy, and are expected to be at a significant risk of developing TLS or have clinical/laboratory evidence of TLS with an increase in plasma uric acid level above the upper limit of normal.

CONTRAINDICATIONS/WARNINGS

- Contraindications
    - History of anaphylaxis or severe hypersensitivity to rasburicase or any component of the formulation
    - History of hemolytic reaction or methemoglobinemia associated with rasburicase
    - Glucose-6-phosphatase dehydrogenase (G6PD) deficiency

- US Boxed Warning
  - Hypersensitivity
    - Rasburicase may cause serious and fatal hypersensitivity reactions, including anaphylaxis. Immediately and permanently discontinue rasburicase in patients who experience a serious hypersensitivity reaction.
  - Hemolysis
    - Do not administer rasburicase to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Immediately and permanently discontinue rasburicase in patients developing hemolysis. Screen patients at higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting rasburicase.
  - Methemoglobinemia
    - Rasburicase can result in methemoglobinemia in some patients. Immediately and permanently discontinue rasburicase in patients developing methemoglobinemia.
  - Interference with uric acid measurements
    - Rasburicase enzymatically degrades uric acid in blood samples left at room temperature. Collect blood samples in prechilled tubes containing heparin and immediately immerse and maintain sample in an ice water bath. Assay plasma samples within 4 hours of collection.

EXCLUSION CRITERIA

- Dosing exceeds the single dose limit of Elitek (rasburicase) 0.2 mg/kg (up to maximum 6 mg fixed single dose).
- Treatment exceeds the maximum duration limit of 5 days which is equivalent to one course of treatment.
- Investigational use of Elitek (rasburicase) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under

investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).

- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J2783 - Injection, rasburicase, 0.5 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
May 2026	• Updated references
May 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1403 Elitek (rasburicase) • Updated references
May 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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2. Elitek prescribing information. Sanofi-Aventis U.S. LLC. Morristown, NJ 2025.
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4. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
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9. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.