Elitek® (rasburicase)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for a single course of treatment, consisting of 5 days of therapy, and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Elitek 1.5 mg single-dose vial: 4 vials per day
- Elitek 7.5 mg single-dose vial: 3 vials per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 45 billable units daily for 5 days; one 5-day therapy course only

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Hyperuricemia due to Tumor Lysis † Φ [1,6]

- Patient is at least 1 month of age; **AND**
- Patient must not have a deficiency in glucose-6-phosphate dehydrogenase (G6PD); **AND**
- Patient must be receiving chemotherapy for leukemia, lymphoma, or solid tumors; **AND**
    - Used as prophylactic therapy in patients whose chemotherapy is expected to result in tumor lysis and subsequent elevation of plasma uric acid; **AND**
        - Patient must be at high-risk* for developing hyperuricemia; **OR**
    - Used for treatment in patients who develop hyperuricemia despite standard prophylactic therapies (i.e., hydration, allopurinol, febuxostat, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

*Risk factors for development of tumor lysis syndrome and subsequent hyperuricemia [4,6,16]
– High Risk Tumor Type (i.e., Burkitt lymphoma/leukemia; lymphoblastic lymphomas; ALL; DLBCL; other tumor types with high proliferative rate or high sensitivity to cytotoxic therapy) or patients

receiving treatment with high-risk medications (e.g., venetoclax, chemoimmunotherapy, lenalidomide, and obinutuzumab)
- Progressive disease after small-molecule inhibitor therapy
- Patient with bulky disease or large tumor burden (i.e., any lymph node ≥10 cm; elevated LDH ≥2x ULN; absolute lymphocyte count ≥25,000/mcL; white blood cell count >50,000/mcL; organ infiltration; or bone marrow involvement)
- Spontaneous tumor lysis syndrome development
- Dehydration, volume depletion, or situations where adequate hydration may be difficult or impossible
- Renal disease or renal involvement by tumor (i.e., pre-existing nephropathy or exposure to nephrotoxins, oliguria and/or acidic urine)
- Pre-existing hyperuricemia (serum/plasma uric acid > 7.5mg/dl) or hyperphosphatemia (serum/plasma phosphate >4.5 mg/dL)

IV. Renewal Criteria [1]

Coverage may not be renewed.

V. Dosage/Administration [1,6-15]

Indication	Dose
Hyperuricemia due to Tumor Lysis	Administer 0.2 mg/kg intravenously daily for up to 5 days Note: Dosing beyond 5 days or administration of more than one course is not recommended. Elitek is indicated only for a single course of treatment. Alternative dosing: A single fixed-dose of rasburicase (3 to 6 mg) is usually adequate in adult patients based on literature support. One dose is frequently adequate. However, additional doses should be considered based upon tumor bulk, hydration status, and presence of acute renal failure.

VI. Billing Code/Availability Information

HCPCS Code:

- J2783 – Injection, rasburicase, 0.5 mg; 1 billable unit = 0.5 mg

NDC(s):

- Elitek 1.5 mg single-dose vial: 00024-5150-xx
- Elitek 7.5 mg single-dose vial: 00024-5151-xx

VII. References

1. Elitek [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC.; December 2022. Accessed May 2024.

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6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Guidelines Version 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2024.
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11. Hutcherson DA, Gammon DC, Bhatt MS, et al: Reduced-dose rasburicase in the treatment of adults with hyperuricemia associated with malignancy. Pharmacotherapy 26: 242– 247,2006.
12. Hummel M, Reiter S, Adam K, et al: Effective treatment and prophylaxis of hyperuricemia and impaired renal function in tumor lysis syndrome with low doses of rasburicase. Eur J Haematol 80: 331– 336,2008.
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15. Trifilio SM, Pi J, Zook J, et al: Effectiveness of a single 3-mg rasburicase dose for the management of hyperuricemia in patients with hematological malignancies. Bone Marrow Transplant. 2011 Jun;46(6):800-5. Doi: 10.1038/bmt.2010.212.

16. Larson RA, Pui CH (Feb 2024). Tumor lysis syndrome: Pathogenesis, clinical manifestations, definition, etiology and risk factors. Drews RE, Freedman AS, Poplack DG, Rosmarin AG (Eds.). In UpToDate. Last updated: Feb 09, 2024. Accessed: May 6, 2024. Available from: https://www.uptodate.com/contents/tumor-lysis-syndrome-pathogenesis-clinical-manifestations-definition-etiology-and-risk- factors?search=Tumor%20lysis%20syndrome:%20Pathogenesis,%20clinical%20manifestations,%20definition,%20etiology%20and%20risk%20factors&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E88.3	Tumor lysis syndrome

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC