Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 29.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Elitek (rasburicase)

I. Policy:
Elitek (rasburicase)

II. Purpose/Objective:
To provide a policy of coverage regarding Elitek (rasburicase)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Elitek (rasburicase) is an intravenously administered recombinant urate-oxidase enzyme, which converts uric acid to allantoin (an inactive and soluble metabolite of uric acid); it does not inhibit the formation of uric acid.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Elitek (rasburicase) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Physician provided documentation verifies a diagnosis of lymphoma, leukemia or solid tumor malignancies; **AND**
- Physician provided documentation of high risk for tumor lysis syndrome characterized by the presence of ONE of the following "high risk" factors:
    - Renal disease or renal involvement by tumor
    - Serum uric acid level greater than or equal to 8 mg/dL
    - Spontaneous Tumor Lysis Syndrome (TLS)
    - Elevated White Blood Cell (WBC) count greater than 50 x 10^9/L
    - Bone Marrow involvement
    - Diagnosis of any of the following:
        - Burkitt's lymphoma or Burkitt's Leukemia
        - Lymphoblastic lymphoma
        - T-cell Non-Hodgkin's lymphoma
        - Plasma cell leukemia
        - Chronic lymphocytic leukemia (CLL) treated with venetoclax and lymph node ≥10 cm, or lymph node ≥5 cm and absolute lymphocyte count ≥25 x 10^9/L and elevated baseline uric acid.
        - Acute lymphoblastic leukemia (ALL) with WBC greater than or equal to 100 x 10^9/L and/or serum lactate dehydrogenase (LDH) greater than or equal to two times the upper limit of normal
        - Acute myeloid leukemia (AML) with WBC greater than or equal to 100 x 10^9/L
        - Adult T cell leukemia/lymphoma, diffuse large B-cell, transformed, and mantle cell lymphomas with serum LDH level above the upper limit of normal with a bulky tumor mass, or myeloma with extra medullary disease
        - Stage III/IV childhood diffuse large B-cell lymphoma with LDH ≥2 x ULN

    OR
- Physician provided documentation of therapeutic failure on, intolerance to, or contraindication to oral or injectable allopurinol

AUTHORIZATION DURATION: Elitek is limited to one course of treatment defined as: One infusion daily for 5 days. Authorization will be given to cover 5 total days of service (infusions). Additional administration of the drug will require another prior authorization

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/26/04

Revised: 9/05, 10/06, 2/10 (limitation added, criteria updated); 2/14 (add limitation), 1/20/15 (update formatting and references) 3/24/15 (auth duration), 10/14/20 (per DHS, risk factors), 7/27/22 (Medicaid PARP statement), 7/24/23 (LOB carve out, Medicaid business segment)

Reviewed: 11/07, 10/08; 2/12; 3/31/16, 1/31/17, 10/31/17, 8/30/18, 8/29/19, 8/26/20, 8/19/21