Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 272.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Krystexxa (pegloticase)

I. Policy:
Krystexxa (pegloticase)

II. Purpose/Objective:
To provide a policy of coverage regarding Krystexxa (pegloticase)

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:
Krystexxa (pegloticase) is a pegylated recombinant form of urate-oxidase enzyme, also known as uricase (an enzyme normally absent in humans and high primates), which converts uric acid to allantoin (an inactive and water 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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Krystexxa (pegloticase) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Documentation of age greater than or equal to 18 years AND
- Prescribed by or in consultation with a rheumatologist AND
- Medical record documentation of a diagnosis of chronic, symptomatic gout AND
- Medical record documentation that Krystexxa is being given in combination with oral methotrexate (recommended dose 15 mg weekly) OR intolerance or contraindication to methotrexate AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary xanthine oxidase inhibitors (examples: allopurinol and febuxostat) at the maximum medically appropriate dose AND
- Medical record documentation that high-risk patients (e.g., patients of African, Mediterranean [including Southern European and Middle Eastern], and Southern Asian ancestry) have been screened for glucose-6-phosphate dehydrogenase (G6PD) deficiency AND
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression AND
- Ongoing uric acid level monitoring prior to each infusion. The two most recent uric acid levels (from within the past 8 weeks) must be submitted. In individuals whose uric acid level is above 6mg/dL for two consecutive lab draws, therapy should be discontinued, and reauthorization will not be approved.

The medication will no longer be covered if the patient experienced toxicity or worsening of disease.

QUANTITY LIMIT: 8 mg every 14 days

NOTE: The risk of infusion reactions, including anaphylaxis, is higher in patients who have lost therapeutic response. Serum uric acid levels should be monitored prior to each infusion and treatment with Krystexxa should be discontinued if levels increase to above 6 mg/dL, particularly when two consecutive levels above 6 mg/dL are observed.

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: 1/17/23

Revised:

Reviewed: