Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 180.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Kanuma (sebelipase alfa)

I. Policy:
Kanuma (sebelipase alfa)

II. Purpose/Objective:
To provide a policy of coverage regarding Kanuma (sebelipase alfa)

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:
Kanuma (sebelipase alfa) is a form of enzyme replacement therapy that binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebelipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol, and free fatty acids. In patients with lysosomal acid lipase (LAL) deficiency, replacement with sebelipase alfa, a recombinant form of LAL, results in improvement in disease-related hepatic and lipid parameters.

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

Kanuma (sebelipase alfa) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Must be prescribed by a provider specializing in genetics or metabolism **AND**
- Medical record documentation of Lysosomal Acid Lipase deficiency as either Wolman disease **OR** Cholesteryl ester storage disease (CESD) **AND**
- Medical record documentation of confirmed diagnosis in one of three ways: Dried Blood Spot (DBS) test, leucocyte testing, or genetic testing **AND**
- Medical record documentation that the member will receive a weight and diagnosis appropriate dosing regimen

QUANTITY LIMITS:

Rapidly progressing/Wolman disease (patients initially presenting within the first 6 months of life): Kanuma will initially be approved for quantity sufficient for up to 5 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.

Late onset/CESD: Patients 4 years of age and older will be approved for up to 3 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

AUTHORIZATION DURATION: Initial approval will be for a period of 3 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 medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

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: 7/17/18

Revised: 1/19/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment)**,** 2/20/23 (QL per PARP)

Reviewed: 5/31/19, 2/1/20, 1/28/21, 1/21/22