Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 198.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Gamifant (emapalumab-lzsg)

I. Policy:
Gamifant (emapalumab-lzsg)

II. Purpose/Objective:
To provide a policy of coverage regarding Gamifant (emapalumab-lzsg)

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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:
Gamifant (emapalumab-lzsg) is an interferon gamma (IFNγ) blocking monoclonal antibody. IFNγ is hypersecreted in hemophagocytic lymphohistiocytosis (HLH); emapalumab binds to IFNγ and neutralizes it.

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

Gamifant (emapalumab-lzsg) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on one of the following:
    - A molecular diagnosis (HLH gene mutations) **OR**
    - A family history consistent with primary HLH (X-linked lymphoproliferative syndrome) **OR**
    - 5 out of the following 8 criteria fulfilled:
        - Fever ≥ 38.5ºC
        - Splenomegaly
        - Cytopenias affecting 2 of 3 lineages in the peripheral blood; hemoglobin <9 g/dL, platelets <100 x 10^9/L, neutrophils <1 x 10^9/L
        - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤1.5 g/dL)
        - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
        - Low or absent NK-cell activity
        - Ferritin ≥ 500 mcg/L
        - Soluble CD25 level (i.e. soluble IL-2 receptor) of ≥ 2,400 U/mL or two standard deviations above age-adjusted laboratory-specific norms

  AND
- Medical record documentation of refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g. etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

Authorization Duration (for members **without** a confirmed molecular diagnosis): Initial approval will be for 4 weeks or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis based on molecular diagnosis (HLH gene mutations). Subsequent approvals will be for an additional 6 months of less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

Authorization Duration (for members **with** a confirmed molecular diagnosis): 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 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

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: 5/21/19

Revised: 7/10/19 (CD25 level per DHS), 2/15/22 (per DHS corrected hypofibrinogenemia, CD25 deviations)

Reviewed: 2/1/20, 1/28/21, 1/21/22