Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 189.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lumoxiti (moxetumomab pasudotox-tdfk)

I. Policy:
Lumoxiti (moxetumomab pasudotox-tdfk)

II. Purpose/Objective:
To provide a policy of coverage regarding Lumoxiti (moxetumomab pasudotox-tdfk)

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:
Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin composed of a recombinant murine immunoglobulin genetically fused to truncated Pseudomonas exotoxin (PE38). Moxetumomab pasudotox-tdfk binds CD22 on the cell surface of B-cells and is internalized. Moxetumomab pasudotox-tdfk internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death.

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

Lumoxiti (moxetumomab pasudotox-tdfk) will be considered medically necessary when ALL of the following criteria are met:

Hairy Cell Leukemia

- Prescription is written by a hematologist/oncologist **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory hairy cell leukemia (HCL) **AND**
- Medical record documentation that member has received at least two prior systemic therapies, one of which must be a purine nucleoside analog (e.g., cladribine, pentostatin (Nipent), etc.)

Note: FDA recommended treatment duration is for a maximum of 6 cycles (The recommended dose of Lumoxiti is 0.04 mg/kg administered as a 30-minute intravenous infusion on Days 1, 3, and 5 of each 28-day cycle)

AUTHORIZATION DURATION: Initial approval will be limited to 6 cycles (6 months) or less if the reviewing provider feels it is medically necessary. Subsequent approval for treatment past 6 cycles (6 months) will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

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: 1/15/19

Revised: 9/16/22 (Medicaid PARP statement)

Reviewed: 11/1/19, 9/30/20, 9/16/21