Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 163.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Mylotarg (gemtuzumab ozogamicin)

I. Policy:
Mylotarg (gemtuzumab ozogamicin)

II. Purpose/Objective:
To provide a policy of coverage regarding Mylotarg (gemtuzumab ozogamicin)

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:
Mylotarg (gemtuzumab ozogamicin) is a humanized CD-33 directed monoclonal antibody-drug conjugate, which is composed of the IgG4 kappa antibody gemtuzumab linked to a cytotoxic calicheamicin derivative. CD33 is expressed on leukemic cells in over 80% of patients with AML (Castaigne 2012). Gemtuzumab ozogamicin binds to the CD33 antigen, resulting in internalization of the antibody-antigen complex. Following internalization, the calicheamicin derivative is released inside the myeloid cell. The calicheamicin derivative binds to DNA resulting in double strand breaks, inducing cell cycle arrest and apoptosis.

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

Mylotarg (gemtuzumab ozogamicin) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Newly diagnosed CD33-positive Acute Myeloid Leukemia
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of newly diagnosed CD33-positive Acute Myeloid Leukemia **AND**
- Medical record documentation of one of the following:
    - o Documentation of the member being ≥ 18 years

    OR
    - o Documentation of member being ≥ 1 month of age and < 18 years of age **AND**
    - o Documentation that Mylotarg will be used in combination with standard chemotherapy.

Relapsed or refractory CD33-positive Acute Myeloid Leukemia
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of relapsed or refractory CD33-positive Acute Myeloid Leukemia **AND**
- Medical record documentation of the member being ≥ 2 years

AUTHORIZATION DURATION:
For newly diagnosed CD33 positive Acute Myeloid Leukemia in patients ≥ 1 month of age and < 18 years of age:
Maximum of two (2) doses for a six (6) month authorization duration

For all other indications: Maximum of nine (9) cycles for a 12 month authorization duration
For requests exceeding the above limits, medical record documentation of the following is required:
- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

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: 1/16/18

Revised: 8/27/20 (age), 8/22/22 (Medicaid PARP statement), 8/22/23 (LOB carve out, Medicaid business segment)

Reviewed: 10/31/18, 8/29/19, 8/23/21