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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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:

- appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- in accordance with current standards good medical treatment practiced by the general medical community;
- not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- 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:
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 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 the member being ≥ 18 years

**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: If approved, authorization should be for a maximum of 9 cycles for an authorization duration of 12 months.

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.

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

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