I. Policy:
Blinicyto (blinatumomab)

II. Purpose/Objective:
To provide a policy of coverage regarding Blincyto (blinatumomab)

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:

- 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:
Blincyto (blinatumomab) is a bispecific T-cell engager (BiTE) which binds to CD19 expressed on B-cells and CD3 expressed on T-cells. It activates endogenous T cells by connecting CD3 in the T-cell receptor complex with CD19 on B-cells (malignant and benign), thus forming a cytolytic synapse between a cytotoxic T-cell and the cancer target B-cell. Blinatumomab mediates the production of cytolytic proteins, release of inflammatory cytokines, and proliferation of T cells, which result in lysis of CD19-positive cells.

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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Blincyto (blinatumomab) will be considered medically necessary when all of the following criteria are met per indication:

Relapsed or Refractory B-cell Precursor ALL
- Prescription written by an oncologist/hematologist AND
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Approval will be limited to one lifetime 9 cycle (20 month) course. Subsequent approval for treatment past the initial 9 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MRD-positive B-cell Precursor ALL
- Prescription written by an oncologist/hematologist AND
- Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second remission AND
- Medical record documentation of a minimal residual disease (MRD) greater than or equal to 0.1%

AUTHORIZATION DURATION: Approval will be limited to one lifetime 4 cycle (6 month) course. Subsequent approval for treatment past the initial 4 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

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: 2/27/15

Revised: 11/15/16 (updated criteria and duration), 9/19/17 (revised indication and duration), 5/15/18 (MRD-positive indication)

Reviewed: 3/31/16, 4/22/19, 1/1/20