Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 128.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Blincyto (blinatumomab)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Blincyto (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
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:
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 for all lines of business 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 CD19-positive 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 CD19-positive 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.

Consolidation Phase B-cell Precursor ALL
- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) **AND**
- Medical record documentation of Philadelphia chromosome-negative disease **AND**
- Medical record documentation member is in the consolidation phase of multiphase chemotherapy

AUTHORIZATION DURATION:
For Adults: Approval will be limited to one lifetime 4 cycle (10 month) course. Subsequent approval for treatment past the 4 cycles of Blincyto will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
For Pediatrics: Approval will be limited to one lifetime 1 cycle (1 month) course. Subsequent approval for treatment past the 1 cycle of Blincyto will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

Note: For Consolidation Phase, in clinical trial E1910, patients received 2 cycles of Blincyto followed by 3 cycles of consolidation chemotherapy, then a third cycle of Blincyto followed by the fourth cycle of chemotherapy and a fourth cycle of Blincyto (total 8 cycles). In clinical trial 20120215, patients received Blincyto as the third cycle of consolidation, and then were to proceed to HSCT after this cycle.

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.

REFERENCES:

1. Blincyto [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2024.

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), 5/18/21 (CD19 positive), 3/31/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 8/19/24 (Consolidation Phase indication, LOB table, taglines)

Reviewed: 3/31/16, 4/22/19, 1/1/20, 1/1/21, 5/2/22 (Medicaid PARP statement), 3/18/24, 3/13/25

MA UM Committee approval: 12/31/23, 11/8/24, 4/29/25

DHS PARP approval: 4/3/25