Reference number(s)
4231-A

STANDARD MEDICARE PART B MANAGEMENT

BLINCYTO (blinatumomab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Blincyto is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children.
B. Blincyto is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For initial requests: Testing or analysis confirming CD19 protein on the surface of the B cell

III. CRITERIA FOR INITIAL APPROVAL

B-cell Precursor Acute Lymphoblastic Leukemia

Authorization of 9 months may be granted for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) when all of the following criteria are met:

A. The member meets one of the following:
    1. The member has Philadelphia chromosome positive disease and meets one of the following:
        a. Member has relapsed or refractory disease and had an inadequate response or intolerance to a tyrosine kinase inhibitor (TKI) (e.g., imatinib, dasatinib)
        b. Member has high-risk genetics
        c. Member has less than complete response following induction therapy
        d. Member has minimal residual disease positive (MRD+) at the end of consolidation therapy
    2. The member has Philadelphia chromosome negative disease and meets one of the following:
        a. Member has relapsed or refractory disease
        b. Blincyto will be used as consolidation therapy with minimal residual disease positive (MRD+) following a complete response to induction therapy
        c. Blincyto will be used for minimal residual disease positive (MRD+) after consolidation therapy
    3. The member has Philadelphia chromosome like disease that is minimal residual disease positive (MRD+) after consolidation therapy

B. Blincyto will be used as a single agent; corticosteroids will be given as premedication prior to Blincyto infusion
C. The B-cells must be CD19-positive as confirmed by testing or analysis

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Blincyto
2. Blincyto is being used to treat an indication enumerated in Section III
3. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen or
    ii. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2019.
2. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 23, 2019.
3. The NCCN Clinical Practice Guidelines in Oncology Acute Lymphoblastic Leukemia (Version 1.2018) 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 25, 2019.