Reference number(s)
2228-A

SPECIALTY GUIDELINE 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

1. 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.
2. Blincyto is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Documentation of Philadelphia chromosome testing
B. 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 relapsed or refractory Philadelphia chromosome positive disease and had an inadequate response or intolerance to a tyrosine kinase inhibitor (TKI) (e.g., imatinib, dasatinib).
    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 for minimal residual disease positive (MRD+) following a complete response to induction therapy.
B. Blincyto will be used as monotherapy with corticosteroids as premedication prior to infusion
C. The B-cells must be CD19-positive as confirmed by testing or analysis

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced unacceptable toxicity or disease progression while on the current regimen.

Reference number(s)
2228-A

V. REFERENCES

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2018.
2. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 25, 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.