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.

A. FDA-Approved Indications
   1. Blincyto is indicated for the treatment of CD19-positive 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 CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

B. Compendial Uses
   1. Philadelphia chromosome negative or Philadelphia chromosome like B-cell precursor acute lymphoblastic leukemia (ALL) that is minimal residual disease positive (MRD+) after consolidation therapy
   2. Philadelphia chromosome negative B-cell precursor acute lymphoblastic leukemia (ALL) as consolidation therapy for minimal residual disease positive (MRD+) following a complete response to induction therapy
   3. Philadelphia chromosome positive (Ph-positive) B-cell precursor acute lymphoblastic leukemia (ALL) with less than complete response or MRD+ at end of consolidation
   4. Ph+ B-cell ALL as consolidation therapy for persistent/rising minimal residual disease (MRD) following a complete response to induction therapy

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: 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 both of the following criteria are met:
A. The member meets one of the following:
   1. The member has Philadelphia chromosome positive (Ph+) disease and meets one of the following:
      a. Member has relapsed or refractory disease and the requested medication will be used as a single agent or with a tyrosine kinase inhibitor (TKI) (e.g., imatinib, dasatinib)

b. Member will be using as consolidation therapy for persistent/rising minimal residual disease (MRD) following a complete response to induction therapy and the requested medication will be used as a single agent or with a TKI
c. Member has less than complete response or minimal residual disease positive (MRD+) at the end of consolidation therapy, and will be used as a single agent

2. The member has Philadelphia chromosome negative (Ph-) disease, the requested medication will be used as a single agent, and meets one of the following:
   a. Member has relapsed or refractory disease
   b. Member has minimal residual disease positive disease (MRD+)
3. The member has Philadelphia chromosome like (Ph-like) disease that is minimal residual disease positive (MRD+) after consolidation therapy and the requested medication will be used as a single agent

B. 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 III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 1, 2021.
3. The NCCN Clinical Practice Guidelines in Oncology Acute Lymphoblastic Leukemia (Version 1.2021) 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 1, 2021.