**Blincyto™ (blinatumomab)**

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**Definitions**

Blincyto (blinatumomab) is a bispecific T-cell engager designed to promote the lysis of cancer cells by binding simultaneously with both the CD3 protein on cytotoxic T-cells and the CD19 protein, a B-cell specific lymphocyte antigen expressed in specific types of acute lymphocytic leukemia (ALL).

**Dosing**

Max units (per dose and over time)

- **ALL, relapsed or refractory:**
  - Induction (cycle 1): 9 billable units per day on day 1-7, and 28 billable units per day on day 8-28 of a 42 day cycle
  - Induction (cycle 2): 28 billable units per day on day 1-28 of a 42 day cycle
  - Consolidation (cycle 3-5): 28 billable units per day on day 1-28 of a 42 day cycle
  - Continuation (cycle 6-9): 28 billable units per day on day 1-28 of an 84 day cycle
- **ALL, MRD+**:
  - Induction (cycle 1): 28 billable units per day on day 1-28 of a 42 day cycle
  - Consolidation (cycle 2-4): 28 billable units per day on day 1-28 of a 42 day cycle

**Guideline**

Blincyto (blinatumomab) is considered medically necessary for the following diagnoses when the subsequent criteria are met:

- **B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:**
  - Patient’s disease is CD19+; **AND**
• Patient’s disease is Philadelphia chromosome-negative OR Philadelphia chromosome-positive and refractory to tyrosine kinase inhibitor (TKI) therapy; AND
• Blincyto will be administered as a single-agent; AND
• There is no evidence of active central nervous system involvement

B-cell precursor acute lymphocytic leukemia (ALL), minimal residual disease (MRD)-positive:
• Patient’s disease is CD19+; AND
• Patient’s disease is in first or second complete remission; AND
• Patient has minimal residual disease greater than or equal to 0.1%

Coverage for Blincyto (blinatumomab) may be renewed for the following diagnoses when subsequent criteria are met:

B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:
• Patient continues to meet initial approval criteria; AND
• Disease response or stabilization; AND
• Absence of unacceptable toxicity from the drug, including cytokine release syndrome, neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome, neutropenia/febrile neutropenia, elevation of LFTs, leukoencephalopathy.

Limitations/Exclusions

• Approval will be granted for 30 weeks for a diagnosis of relapsed or refractory ALL and may be renewed twice for 24 weeks
• Approval will be granted for 24 weeks for a diagnosis of MRD+ ALL and may not be renewed

Applicable Procedure Codes

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9039</td>
<td>Injection, blinatumomab, 1 microgram</td>
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Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C91.00</td>
<td>Acute lymphoblastic leukemia not having achieved remission</td>
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<tr>
<td>C91.02</td>
<td>Acute lymphoblastic leukemia, in relapse</td>
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Revision History

<table>
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<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>10/8/2019</td>
<td>Annual Review</td>
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<tr>
<td>09/06/2018</td>
<td>Added coverage for MRD+ ALL, added approval durations, renewal criteria, and dosing</td>
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<tr>
<td>05/01/2018</td>
<td>“CD19+” descriptive added to refractory B-cell ALL</td>
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References


