Blincyto® (blinatumomab)
(Intravenous)

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I. Length of Authorization

- Relapsed or Refractory B-Cell Precursor Acute Lymphocytic Leukemia (ALL)
  - Initial coverage will be provided for 30 weeks for a total of five cycles (2 cycles of induction followed by 3 cycles of consolidation)
  - Continued coverage will be provided every 24 weeks for a maximum of two additional authorizations (4 cycles of continued therapy)
- MRD+ B-Cell Precursor Acute Lymphocytic Leukemia (ALL)
  - Initial coverage will be provided for 24 weeks for a total of four cycles (1 cycle of induction followed by 3 cycles of consolidation)
  - Continued coverage may not be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Blincyto 35 mcg powder for injection: 28 vials per 42 day supply

B. Max Units (per dose and over time) [Medical Benefit]:

- Relapsed or Refractory B-Cell Precursor Acute Lymphocytic Leukemia (ALL)
  Cycle 1 – 5 (Induction/Consolidation)
  - 980 billable units per 42 days
  Cycle 6 – 9 (Continuation Therapy)
  - 980 billable units per 84 days
- MRD+ B-Cell Precursor Acute Lymphocytic Leukemia (ALL)
  Cycle 1 – 4 (Induction/Consolidation)
  - 980 billable units per 42 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

B-Cell Precursor Acute Lymphocytic Leukemia (ALL) †

- Patient is at least 1 month old; **AND**
- Used as single agent therapy; **AND**
  - Patient has relapsed or refractory disease; **OR**
  - Used in patients with minimal residual disease positive (MRD+) as consolidation therapy following a complete response/remission to induction therapy

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria from section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Cytokine Release Syndrome (CRS); neurological toxicities; serious infections; pancreatitis; tumor lysis syndrome; neutropenia/febrile neutropenia; elevation of LFTs; leukoencephalopathy, etc.; **AND**
- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
  - Patient has not exceeded a total of 4 cycles of continued therapy or 9 total cycles of Blincyto for the treatment of relapsed or refractory disease; **OR**
  - Continued therapy for use in the treatment of MRD+ ALL may not be renewed.

V. Dosage/Administration

Indication	Dose
Acute Lymphoblastic Leukemia	**Relapsed/Refractory Disease*** ➢ Weight greater than or equal to 45 kg – Cycle 1 (induction): • 9 mcg daily x 7 days, then 28 mcg daily x 21 days in a 42 day cycle – Cycles 2-5 (consolidation): • 28 mcg daily x 28 days in a 42 day cycle. – Cycles 6-9 (maintenance): • 28 mcg daily x 28 days in an 84 day cycle. ➢ Weight less than 45 kg – Cycle 1(induction) : • 5 mcg/m2/day (not to exceed 9 mcg/day) x 7 days, then 15 mcg/m2/day (not to exceed 28 mcg/day) x 21 days in a 42 day cycle – Cycles 2-5 (consolidation): • 15 mcg/m2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle. – Cycles 6-9 (maintenance): • 15 mcg/m2/day (not to exceed 28 mcg/day) x 28 days in an 84 day cycle.

	**May repeat for up to 9 total cycles of therapy.*
	MRD+ Disease ➢ Weight greater than or equal to 45 kg – Cycle 1(induction) : • 28 mcg daily x 28 days in a 42-day cycle – Cycles 2-4 (consolidation): • 28 mcg daily x 28 days in a 42 day cycle. ➢ Weight less than 45 kg – Cycle 1(induction) : • 15 mcg/m2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle. – Cycles 2-4 (consolidation: • 15 mcg/m2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle.

VI. Billing Code/Availability Information

Jcode:

- J9039 - Injection, blinatumomab, 1 microgram; 1 billable unit = 1 microgram

NDC:

- Blincyto 35 mcg powder for injection: 55513-0160-xx

VII. References

1. Blincyto [package insert]. Thousand Oaks, CA; Amgen, March 2018. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) blinatumomab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC