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) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- Relapsed or Refractory B-Cell Precursor Acute Lymphocytic Leukemia (ALL)
  Cycle 1 – 5 (Induction/Consolidation)
  - 980 billable units per 42 days
  Cycle 6 – 9 (Continued 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 [1]

Coverage is provided in the following conditions:

- Patient is at least 1 month old; **AND**

Universal Criteria [1]

- Used as single agent therapy; **AND**
- Patient has not received a live vaccine within 2 weeks prior to initiating therapy and will not receive concurrent treatment with lives vaccine while on therapy; **AND**

B-Cell Precursor Acute Lymphocytic Leukemia (ALL) † Φ [1-8]

- Patient has relapsed or refractory disease (Philadelphia chromosome [Ph]-positive patients must be TKI intolerant/refractory); **OR**
- Used as consolidation therapy in patients with minimal residual disease positive (MRD+) following a complete response/remission to induction therapy; **OR**
- Used in patients that are MRD+ after consolidation therapy ‡; **OR**
- Used in patients that are Ph-positive with less than complete response after induction therapy ‡

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in 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, elevated liver enzymes, 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 4 cycles of continued therapy or 9 total cycles of therapy 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 [1]

Indication	Dose
	Relapsed/Refractory Disease*

Acute Lymphoblastic Leukemia	➢ 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 (induction/consolidation): • 28 mcg daily x 28 days in a 42 day cycle – Cycles 6-9 (continued therapy): • 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 (induction/consolidation): • 15 mcg/m²/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle – Cycles 6-9 (continued therapy): • 15 mcg/m²/day (not to exceed 28 mcg/day) x 28 days in an 84 day cycle **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 **Up to 4 total cycles of therapy.*

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

1. Blincyto [package insert]. Thousand Oaks, CA; Amgen, March 2020. Accessed February 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) blinatumomab. National Comprehensive Cancer Network, 2021. 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 February 2021.

3. Jen EY, Xu Q, Schetter A, Przepiorka D, et al. FDA Approval: Blinatumomab for Patients with B-cell Precursor Acute Lymphoblastic Leukemia in Morphologic Remission with Minimal Residual Disease. Clin Cancer Res. 2019 Jan 15;25(2):473-477. doi: 10.1158/1078-0432.CCR-18-2337. Epub 2018 Sep 25.
4. Kantarjian H, Stein A, Gökbuget N, et al. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. N Engl J Med. 2017 Mar 2;376(9):836-847. doi: 10.1056/NEJMoa1609783.
5. Martinelli G, Boissel N, Chevallier P, et al. Complete Hematologic and Molecular Response in Adult Patients With Relapsed/Refractory Philadelphia Chromosome-Positive B-Precursor Acute Lymphoblastic Leukemia Following Treatment With Blinatumomab: Results From a Phase II, Single-Arm, Multicenter Study. J Clin Oncol. 2017 Jun 1;35(16):1795-1802. doi: 10.1200/JCO.2016.69.3531. Epub 2017 Mar 29. Erratum in: J Clin Oncol. 2017 Aug 10;35(23):2722. J Clin Oncol. 2017 Aug 20;35(24):2856.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Pediatric Acute Lymphoblastic Leukemia 2.2021. National Comprehensive Cancer Network, 2021. 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 February 2021.
7. Topp MS, Gökbuget N, Stein AS, et al. Safety and activity of blinatumomab for adult patients with relapsed or refractory B-precursor acute lymphoblastic leukaemia: a multicentre, single-arm, phase 2 study. Lancet Oncol. 2015;16(1):57-66.
8. von Stackelberg A, Locatelli F, Zugmaier G, et al. Phase I/Phase II Study of Blinatumomab in Pediatric Patients With Relapsed/Refractory Acute Lymphoblastic Leukemia. J Clin Oncol. 2016;34(36):4381-4389.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.50	Lymphoblastic (diffuse) lymphoma unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma spleen

C83.58	Lymphoblastic (diffuse) lymphoma lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma extranodal and solid organ sites
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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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