Blincyto® (blinatumomab)
(Intravenous)

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I. Length of Authorization [1,9,10]

Acute Lymphoblastic Leukemia (ALL)

- Relapsed or refractory disease:
  - 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)
- Consolidation therapy (Adult) and MRD+ or less than complete response to induction therapy (Pediatric):
  - Coverage will be provided for 24 weeks for a total of four cycles (1 cycle of induction followed by 3 cycles of consolidation)
- Maintenance therapy (Adult):
  - Coverage will be provided for up to 30 weeks for a total of five cycles (1-2 cycles of induction followed by 3 cycles of consolidation)
- Infant ALL in combination with an Interfant regimen:
  - Coverage will be provided for 28 days

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]:

- Acute Lymphoblastic Leukemia (ALL) (Adult/Pediatric)
  Cycle 1 – 5 (Induction/Consolidation)

- 980 billable units per 42 days

Cycle 6 – 9 (Continued Therapy)

- 980 billable units per 84 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Universal Criteria [1]

- 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**

Acute Lymphoblastic Leukemia (ALL) – Adult* † ‡ Φ [1-8]

- Patient is at least 15 years of age; **AND**
- Patient has B-cell precursor ALL; **AND**
  - Used as consolidation therapy following a complete response to induction therapy; **AND**
    - Patient has positive minimal residual disease (MRD+) or persistent/rising MRD; **AND**
      - Used with or without a tyrosine kinase inhibitor (TKI§) for Philadelphia chromosome-positive (Ph+) disease; **OR**
      - Used as a single agent for Philadelphia chromosome-negative (Ph-) disease; **OR**
    - Patient has negative minimal residual disease (MRD-); **AND**
      - Used with a TKI§ for Ph+ disease in patients who are not candidates for multi-agent chemotherapy; **AND**
      - Used as a single agent for Ph- disease; **AND**
        - Patient received induction therapy with inotuzumab ozogamicin + mini-hyperCVD; **OR**
        - Patient is not a candidate for multi-agent chemotherapy; **OR**
    - Patient has MRD unavailable; **AND**
      - Used single agent for Ph- disease; **AND**
        - Patient received induction therapy with inotuzumab ozogamicin + mini-hyperCVD; **OR**
        - Patient is not a candidate for multi-agent chemotherapy; **OR**
  - Used as maintenance therapy; **AND**
    - Used as a single agent alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine) for Ph- disease; **AND**
    - Patient has negative minimal residual disease (MRD-) or MRD unavailable; **AND**

        - Used following a complete response to induction therapy with inotuzumab ozogamicin + mini-hyperCVD; **AND**
    - Patient has relapsed or refractory disease; **AND**
        - Used with or without a TKI§ for Ph+ disease; **OR**
        - Used as a single agent for Ph- disease; **OR**
        - Used in combination with inotuzumab ozogamicin + mini-hyperCVD for Ph+ or Ph- disease

**NCCN recommendations for ALL may be applicable to adolescent and young adult (AYA) patients within the age range of 15-39 years.*

§*TKI options include bosutinib, dasatinib, imatinib, nilotinib, or ponatinib.*

Pediatric Acute Lymphoblastic Leukemia (ALL) † ‡ Φ [1-9]

- Patient is at least 1 month of age; **AND**
    - Used as a single agent; **AND**
        - Patient has B-cell precursor ALL; **AND**
            - Patient has minimal residual disease positive (MRD+) ALL; **AND**
                - Patient is in first or second complete remission; **OR**
                - Used after or at the end of consolidation therapy; **OR**
            - Used for less than complete response at the end of consolidation therapy; **AND**
                - Patient has Philadelphia chromosome-positive (Ph+) disease; **OR**
            - Patient has relapsed or refractory disease; **OR**
    - Used in combination with an Interfant regimen (e.g., Interfant-06, Interfant-99, etc.) for infant ALL

**NCCN recommendations for Pediatric ALL may be applicable to certain adolescent and young adult (AYA) patients up to 30 years of age.*

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

IV. Renewal Criteria [1,2,9,10]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the 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: Cytokine Release Syndrome (CRS), neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome (TLS), 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**

Acute Lymphoblastic Leukemia (Adult/Pediatric) – Relapsed or refractory disease

- Patient has not exceeded 4 cycles of continued therapy or 9 total cycles of therapy for the treatment of relapsed or refractory disease

Adult Acute Lymphoblastic Leukemia – Consolidation and maintenance therapy

- Coverage may not be renewed

Pediatric Acute Lymphoblastic Leukemia – MRD+ or less than complete response to consolidation therapy

- Coverage may not be renewed

Pediatric Acute Lymphoblastic Leukemia – With an Interfant regimen

- Coverage may not be renewed

V. Dosage/Administration [1,9,10]

Indication	Dose
Adult ALL	**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 (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/m^2/day (not to exceed 9 mcg/day) x 7 days, then 15 mcg/m^2/day (not to exceed 28 mcg/day) x 21 days in a 42 day cycle – Cycles 2-5 (induction/consolidation): • 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle – Cycles 6-9 (continued therapy): • 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in an 84 day cycle **Up to 9 total cycles of therapy.*
	Consolidation Therapy* ➢ 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.*
	Maintenance Therapy* ➢ Weight greater than or equal to 45 kg – 1 to 2 cycles of induction until attainment of response: • 28 mcg daily x 28 days in a 42-day cycle – 3 cycles of consolidation: • 28 mcg daily x 28 days in a 42 day cycle ➢ Weight less than 45 kg – 1 to 2 cycles of induction until attainment of response: • 15 mcg/m²/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle – 3 cycles of consolidation: • 15 mcg/m²/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle **Up to 5 total cycles of therapy.*
Pediatric ALL	**Relapsed/Refractory Disease (single agent)*** ➢ 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+ or Less Than Complete Response to Consolidation (single agent)* ➢ 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.*
	<u>In Combination with an Interfant Regimen (Infant ALL):</u> 15 mcg/m²/day (not to exceed 28 mcg/day) x 28 days

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

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

<u>NDC:</u>

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

VII. References

1. Blincyto [package insert]. Thousand Oaks, CA; Amgen, February 2022. Accessed January 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) blinatumomab. National Comprehensive Cancer Network, 2023. 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 January 2023.
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 1.2023. National Comprehensive Cancer Network, 2023. 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 January 2023.

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.
9. Van Der Sluis IM, De Lorenzo P, Kotecha RS, et al. A phase 2 study to test the feasibility, safety and efficacy of the of the addition of blinatumomab to the Interfant06 backbone in infants with newly diagnosed KMT2A-rearranged acute lymphoblastic leukemia. a collaborative study of the Interfant Network. Blood 2021;138:361.
10. Advani AS, Moseley A, O'Dwyer KM, et al. SWOG 1318: A Phase II Trial of Blinatumomab Followed by POMP Maintenance in Older Patients With Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia. J Clin Oncol. 2022 May 10;40(14):1574-1582..

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: https://www.cms.gov/medicare-coverage-database/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

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- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Qualified interpreters
- Information written in other languages

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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- Information written in other languages

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).