Blincyto® (blinatumomab)
(Intravenous)

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I. Length of Authorization [1,9-11,17-20]

- Relapsed or refractory disease (single agent or with a TKI) (Adult/Pediatric):
  - Initial: Prior authorization validity will be provided initially for 30 weeks for a total of five cycles (2 cycles of induction followed by 3 cycles of consolidation)
  - Renewal: Prior authorization validity may be renewed every 24 weeks for a maximum of two additional authorizations (4 cycles of continued therapy)
- Relapsed or refractory disease (as a component of COG ALL1331 regimen) (Pediatric):
  - Initial: Prior authorization validity will be provided initially for a maximum of 24 weeks (three 56-day cycles)
  - Renewal: Prior authorization validity may NOT be renewed
- Frontline induction therapy (in combination with TKI) (Adult):
  - Initial: Prior authorization validity will be provided initially for 4 weeks
  - Renewal: Prior authorization validity may NOT be renewed
- Consolidation therapy (Adult/Pediatric)
  - Initial: Prior authorization validity will be provided initially for 30 weeks (five 42-day cycles)
  - Renewal: Prior authorization validity may NOT be renewed
- MRD+ (Adult/Pediatric):
  - Initial: Prior authorization validity will be provided initially for 24 weeks for a total of four cycles (1 cycle of induction followed by 3 cycles of consolidation)
  - Renewal: Prior authorization validity may NOT be renewed

- Maintenance therapy (alternating with POMP) (Adult):
  - Initial: Prior authorization validity will be provided initially for 24 weeks (one 42-day cycle)
  - Renewal: Prior authorization validity may be renewed every 24 weeks for a maximum of 4 additional authorizations (four 42-day cycles)
- Infant ALL in combination with an Interfant regimen:
  - Initial: Prior authorization validity will be provided initially for 28 days
  - Renewal: Prior authorization validity may NOT be renewed

II. Dosing Limits

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

- Acute Lymphoblastic Leukemia (ALL) (Adult/Pediatric)
  - 980 billable units per 42 days

III. Initial Approval Criteria [1]

Prior authorization validity 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 [1,2,16,6e]

- Patient is at least 18 years of age*; **AND**
- Patient has B-cell precursor ALL; **AND**
  - Patient has positive minimal residual disease (MRD+) greater than or equal to 0.1% **†**; **AND**
    - Used as a single agent for patients in first or second complete remission (CR); **OR**
  - Used as frontline induction therapy; **AND**
    - Used in combination with a tyrosine kinase inhibitor (TKI)**§** for Philadelphia chromosome-positive (Ph+) disease; **OR**
  - Used as part of consolidation therapy; **AND**
    - Used for Philadelphia chromosome-negative (Ph-) disease **†**; **AND**
      - Used with multiagent chemotherapy; **OR**
    - Used for Ph+ disease; **AND**
      - Used as a single agent as a component of inotuzumab ozogamicin + mini-hyperCVD regimen if refractory to TKIs; **OR**
      - Used in combination with a TKI**§**; **OR**

- Used as maintenance therapy; **AND**
  - Used as a single agent alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine); **AND**
    - Patient has Ph+ disease; **AND**
      - Patient is refractory to TKIs; **OR**
    - Patient has Ph- disease; **OR**
- Patient has relapsed or refractory 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. Refer to NCCN guidelines for TKI/mutation contraindications.*

Pediatric Acute Lymphoblastic Leukemia (ALL) † ‡ Φ [1,2,6]

- Patient is at least 1 month of age*; **AND**
  - Patient has infant ALL; **AND**
    - Used in combination with an interfant regimen (e.g., Interfant-06, Interfant-99, etc.) as consolidation therapy; **OR**
  - Patient has B-cell precursor ALL; **AND**
    - Used for MRD+ ALL as a single agent for first or second complete remission with MRD greater than or equal to 0.1% †; **OR**
    - Used as part of consolidation therapy; **AND**
      - Used for Ph+ (BCR::ABL1-positive) disease in combination with a TKI^ (with or without chemotherapy); **OR**
      - Used for Ph- (BCR::ABL1-negative) disease; **AND**
        - Used with multiagent chemotherapy; **OR**
      - Used for Ph-like (BCR::ABL1-like) disease; **AND**
        - Used as a single agent; **OR**
        - Used in combination with chemotherapy (*Note: may also be used with a TKI^ or ruxolitinib*); **OR**
    - Used for relapsed or refractory disease; **AND**
      - Used as a single agent †; **AND**
        - Used for Ph- (BCR::ABL1-negative) disease; **OR**
        - Used for Ph+ (BCR::ABL1-positive) disease intolerant/refractory to TKI; **OR**
      - Used as a component of COG AALL1331 regimen; **AND**
        - Used as a single agent for Ph- (BCR::ABL1-negative) disease; **OR**

- Used in combination with a TKI^ for Ph+ (BCR::ABL1-positive) disease

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

^*TKI options include dasatinib or imatinib. Refer to NCCN guidelines for regimens.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

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

Prior authorization validity 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**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: Cytokine Release Syndrome (CRS), neurological toxicities [including Immune Effector Cell-Associated Neurotoxicity (ICANS)], serious infections, pancreatitis, tumor lysis syndrome (TLS), neutropenia/febrile neutropenia, elevated liver enzyme, leukoencephalopathy, etc.; **AND**
- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

V. Dosage/Administration [1,9-11,14,15,17-20]

Indication	Dose
Adult ALL	**MRD+ Disease in first or second CR** ➢ 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/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle – Cycles 2-4 (consolidation): • 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle **Up to 4 total cycles of therapy*
	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/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.*
	Frontline Induction Therapy (in combination with TKI) ➢ Up to 9 mcg/day x 7 days, then up to 28 mcg/day x 21 days
	Consolidation Therapy* ** ➢ Weight greater than or equal to 45 kg – 28 mcg daily x 28 days in a 42-day cycle ➢ Weight less than 45 kg – 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle **Up to 5 total cycles of therapy*

	*** **Note**: dosing and dosing schedules are highly variable and dependent on regimen used, please refer to NCCN for additional protocols.*
	Maintenance Therapy* ➢ Up to 28 mcg daily x 28 days in a 42-day cycle for a maximum of 5 cycles (*Note: this regimen includes up to 15 cycles of alternating blocks of three cycles of POMP chemotherapy and one of blinatumomab. Cycle length is 6 weeks.*)
Pediatric ALL	**Relapsed/Refractory Disease:** Used as a 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/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.* Used as a component of COG AALL1331 regimen: – Cycles 1-3 (continuation and maintenance therapy): • 15 mcg/m^2/day x 28 days in a 56 day cycle
	Consolidation Therapy* ** ** ➢ Weight greater than or equal to 45 kg – 28 mcg daily x 28 days in a 42-day cycle ➢ Weight less than 45 kg – 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle **Up to 5 total cycles of therapy* ***Note: dosing and dosing schedules are highly variable and dependent on regimen used, please refer to NCCN for additional protocols.*
	MRD+ (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/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle – Cycles 2-4 (consolidation): • 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days in a 42 day cycle **Up to 4 total cycles of therapy.*
	In Combination with an Interfant Regimen (Infant ALL): ➢ 15 mcg/m^2/day (not to exceed 28 mcg/day) x 28 days

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References (STANDARD)

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2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) blinatumomab. National Comprehensive Cancer Network, 2025. 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 August 2025.
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6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Pediatric Acute Lymphoblastic Leukemia 3.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
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VIII. References (ENHANCED)

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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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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