

Billing and Coding Considerations for BLINCYTO®

This Information Sheet is intended to help healthcare professionals understand the key billing and coding considerations for BLINCYTO® and its related services and supplies when using the Food and Drug Administration (FDA)-approved dosing options across treatment settings.

Updates regarding Medicare Home Infusion Therapy Benefit:

1. Starting January 1, 2021, Medicare implemented the permanent home infusion therapy benefit that provides separate Part B coverage and payment for qualified home infusion therapy services¹

- Medicare updated the codes used to report the provision of home infusion therapy services
- The new codes differentiate new visits vs subsequent visits for home infusion therapy services
- Claims for home infusion therapy services will be billed separately from the drug, pump, and other supplies. These services must be reported to the A/B Medicare Administrative Contractor (MAC), and are reimbursed by Medicare at rates set by the Medicare Physician Fee Schedule. Claims for the drug, pump, and supplies should continue being sent to the Durable Medical Equipment (DME) MAC and are payable under the Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule^{1,2}
- Home infusion therapy services are equal to 5 hours per calendar day, billed in 15 minute increments

Please see pages 10 and 11 for sample claim forms showing coding changes that may be appropriate to report services for Medicare beneficiaries receiving BLINCYTO® treatment via home infusion

2. Due to COVID-19 Public Health Emergency (PHE), Medicare temporarily revised the definition of direct supervision to include the virtual presence of the supervising physician or other qualified healthcare provider using real-time, interactive audio and video telecommunications technology through to December 31, 2025³

Medicare sequestration has been fully reinstated beginning with the third quarter of 2022 and as such, the Medicare portion of payment rates are reduced by 2%.⁴

Please note that the information in this resource is intended to be educational and is not a guarantee of reimbursement. Coverage, coding, and billing requirements vary by health plan so be sure to check with individual payers for detailed guidance.

INDICATIONS

BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients one month and older with:

- Philadelphia chromosome-negative disease in the consolidation phase of multiphase chemotherapy
- Minimal residual disease (MRD) greater than or equal to 0.1% in first or second complete remission
- Relapsed or refractory disease

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.**

[Click here](#) to see BLINCYTO® full Prescribing Information, including **BOXED WARNINGS**.
Please see additional Important Safety Information on pages 18-19.

BLINCYTO®

Billing Information Sheet



Hospital Inpatient (HIP) Site of Service - Multiple Payers (Medicare and Non-Medicare)

Item	Revenue Code ^{5,6,*}	Coding Information (ICD-10-CM ⁷ /HCPCS ⁸ /CPT ⁹ /ICD-10-PCS ¹⁰)	Notes
Diagnosis: Encounter for drug therapy and ALL	N/A	Z51.12 Encounter for antineoplastic immunotherapy AND C91.00 Acute lymphoblastic leukemia not having achieved remission/failed remission OR C91.01 Acute lymphoblastic leukemia, in remission OR C91.02 Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition.
Drug: BLINCYTO® and external infusion pump (EIP)	Report the appropriate revenue code for the cost center in which the service is performed; eg, • Medicare: 0250 General pharmacy • Other payers: 0250 or 0636 Drugs requiring detailed coding (if required by a given payer)	J9039 Injection, blinatumomab, 1 mcg	
	Report the appropriate revenue code for the cost center in which the service is performed; eg, • 0290 DME	E0791 Parenteral infusion pump, stationary, single or multi-channel E0776 IV pole	
Administration: Continuous intravenous infusion (CIVI) via EIP	Report the appropriate revenue code for the cost center in which the service is performed; eg, • 0261 IV therapy: Infusion pump	3E03305 Introduction of other antineoplastic into peripheral vein, percutaneous approach† OR 3E04305 Introduction of other antineoplastic into central vein, percutaneous approach† 96416 Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR 96521 Refilling and maintenance of a portable pump	

Coding Information Definitions:

ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification

HCPCS – Healthcare Common Procedure Coding System

CPT – Current Procedural Terminology

ICD-10-PCS – International Classification of Diseases, 10th Revision, Procedure Coding System

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

†The previous ICD-10-PCS codes that described the administration of BLINCYTO® (XW03351 and XW04351) have been deleted and should not be used for dates of service on or after October 1, 2021.

BLINCYTO®

Billing Information Sheet



Sample UB-04 (CMS-1450) Form: Hospital Inpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTRL. # b. MED. REC. # 5 FED. TAX ID		4 TYPE OF BILL	
8 PATIENT NAME a. Smith, Jane				9 PATIENT ADDRESS a. 123 Main Street, Anytown, Anystate 12345			
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR	
17 STAY		18		19		20	
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SERVICE UNITS (Field 46):
Report units of service for units administered.
BLINCYTO® dose reported as 1 unit per mcg

REVENUE CODES* (Field 42) and DESCRIPTIONS (Field 43):
Product
Use revenue code **0250** General pharmacy
Related supplies and administration procedure
Use the most appropriate revenue code for cost center for services (eg, **0290** Use of DME for EIP and IV pole; eg, **0261** for CIVI therapy [initiation or refill] via EIP)
Check payer-specific guidance for additional revenue codes

PRODUCT AND PROCEDURE CODES (Field 44):
HCPCS codes are only required in outpatient setting
Product
Enter the HCPCS code representing BLINCYTO® administered through EIP; eg, **J9039** (blinatumomab) per 1 mcg
96416 for CIVI
EIP: Enter the HCPCS code representing the EIP and supplies used; eg,
• **E0791** Parenteral infusion pump, stationary, single or multi-channel
• **E0776** IV pole

DIAGNOSIS CODES* (Field 67 and 67A-Q):
Enter the appropriate diagnosis code; eg, ICD-10-CM:
• **Z51.12** Encounter for antineoplastic immunotherapy **AND**
• **C91.00** Acute lymphoblastic leukemia not having achieved remission **OR**
• **C91.01** Acute lymphoblastic leukemia, in remission **OR**
• **C91.02** Acute lymphoblastic leukemia, in relapse
Final codes depend on medical record documentation and payer requirements

PRINCIPAL PROCEDURE (Field 74):
Enter principal ICD-10-PCS procedure code
• **3E03305** Introduction of other antineoplastic into peripheral vein, percutaneous approach† **OR**
• **3E04305** Introduction of other antineoplastic into central vein, percutaneous approach†

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

†The previous ICD-10-PCS codes that described the administration of BLINCYTO® (XW03351 and XW04351) have been deleted and should not be used for dates of service on or after October 1, 2021.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO®

Billing Information Sheet



Hospital Outpatient Department (HOPD) - Multiple Payers (Medicare and Non-Medicare)

Item	Revenue Code ^{5,6,*}	Coding Information (ICD-10-CM ⁷ /CPT ⁹ /HCPCS ⁸ /NDC ¹¹)	Notes
Diagnosis: Encounter for drug therapy and ALL	N/A	Z51.12 Encounter for antineoplastic immunotherapy AND C91.00 Acute lymphoblastic leukemia not having achieved remission OR C91.01 Acute lymphoblastic leukemia, in remission OR C91.02 Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition.
Procedure: Administration via CIVI using an EIP	Report the appropriate revenue code for the cost center in which the service is performed; eg, • 0261 IV therapy: Infusion pump • 026x IV therapy	96416 Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR 96521 Refilling and maintenance of portable pump OR G0498 Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion	CPT codes may be used to report the CIVI procedures associated with BLINCYTO® to the Part A/B MAC and non-Medicare payers. For Medicare patients, HCPCS code G0498 will replace CPT and HCPCS codes (96416, E0781, and 99211–99215) previously used to bill for prolonged infusion services when the CIVI is started in the HOPD. It does not apply to BLINCYTO® when the CIVI is started in the inpatient setting or via home infusion. ^{8,9,12} Certain payers may not recognize G0498 and require itemization of specific items, instead. The healthcare provider should consult the payer or MAC to determine which code is most appropriate for administration of BLINCYTO®. If the clinic bills the G-code to the MAC, the cost of the pump and supplies is bundled and should not be billed separately to the DME MAC. ¹³
Drug: BLINCYTO®	Report the appropriate revenue code for the cost center in which the service is performed; eg, • Medicare: 0636 Drug requiring detailed coding • Other payers: 0250 or 0636 General pharmacy (if required by a given payer)	J9039 Injection, blinatumomab, 1 mcg JW Discarded drug/not administered to any patient JZ Zero drug amount discarded/not administered to any patient JG Drug or biological acquired with 340B Drug Pricing Program discount TB Drug or biological acquired with 340B Drug Pricing Program discount	Medicare policies reflect the code for BLINCYTO® (J9039 per 1 mcg) and has a maximum utilization of 210 units per date of service (based on prescribing information). ¹⁴ However, coding and coverage requirements may vary by payer. Like many payers, Medicare requires the use of the modifier JW and JZ, which provides payment for the amount of drug or biologic discarded, as well as for the dose administered, up to the amount of the drug or biologic as indicated on the vial or label for a single-dose vial (SDV). ¹⁵ Note: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers. [†] Starting January 1, 2024, CMS is requiring all 340B covered entities, including hospital-based and nonhospital-based entities, that submit claims for separately payable Part B drugs and biologicals to report modifier "JG" or "TB" on claim lines for drugs acquired through the 340B Drug Pricing Program. Starting January 1, 2025, 340B covered entities must report the "TB" modifier on claims. ¹⁶
	N/A	NDC: 55513016001 BLINCYTO® 35 mcg lyophilized powder, SDV IV solution stabilizer, 10 mL SDV	Some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format. ¹⁷ Insert a leading zero in the appropriate section to complete the 5-4-2 digit format. Remove the dashes prior to entering the NDC on the claim form.

Coding Information Definition:
NDC – National Drug Code

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

†Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

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Billing Information Sheet



Hospital Outpatient Department (HOPD) - Multiple Payers (Medicare and Non-Medicare) (continued)

Item	Revenue Code ^{5,6,*}	Coding Information (HCPCS ²)	Notes
DME: EIP and supplies	Report the appropriate revenue code for the cost center in which the service is performed; eg, 0290 DME	<p>E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater OR</p> <p>E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient OR</p> <p>A4222 Infusion supplies for external drug infusion pump, per cassette or bag</p> <p>Modifiers for use with E-codes for IV pump</p> <p>-KD Drug or biologic infused through DME</p> <p>-RR Rental</p> <p>-KH DMEPOS item, initial claim, purchase or first rental month</p> <p>-KI DMEPOS item, second or third rental months</p> <p>-KJ DMEPOS item, parenteral enteral nutrition (pen) pump or capped rental, fourth to 15th rental months</p>	<p>Please note that Medicare specifically requires DMEPOS accreditation in order to bill a DME MAC. Non-Medicare payers may allow billing for all services and supplies under a medical or other benefit.</p> <p>Report the appropriate EIP code and appropriate modifier(s) as documented in the medical record.</p> <p>Modifiers may be used to provide additional detail when billing for the EIP to the DME MAC.⁸</p> <p>Note: Drug administration codes may get billed to the MAC and the E-codes may get billed separately to the DME MAC.</p> <p>Report any supplies as necessary.</p>

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

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Billing Information Sheet



Sample UB-04 (CMS-1450) Form: Hospital Outpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTL # b. MED. REC. #		4 TYPE OF BILL	
5 PATIENT NAME Smith, Jane		6 PATIENT ADDRESS 123 Main Street, Anytown, Anystate 12345		7 STATEMENT COVERED PERIOD FROM THROUGH		8	
9 BIRTHDATE		10 SEX		11 DATE		12	
13 ADMISSION 13 HR 14 TYPE 15 SRC		16 DHR		17 STAY		18	
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BLINCYTO®

Billing Information Sheet



Physician Office - Multiple Payers (Medicare and Non-Medicare)

Item	Coding Information (ICD-10-CM ⁷ /CPT ⁹ /HCPCS ⁸ /NDC ¹¹)	Notes
Diagnosis: Encounter for drug therapy and ALL	Z51.12 Encounter for antineoplastic immunotherapy AND C91.00 Acute lymphoblastic leukemia not having achieved remission OR C91.01 Acute lymphoblastic leukemia, in remission OR C91.02 Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM code(s) to describe the patient's condition.
Procedure: Administration via CIVI using an EIP	96416 Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR 96521 Refilling and maintenance of portable pump OR G0498 Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion	CPT codes may be used to report the CIVI procedures associated with BLINCYTO® to the Part A/B MAC and non-Medicare payers. For Medicare patients, HCPCS code G0498 will replace CPT codes and HCPCS (96416, E0781, and 99211–99215) previously used to bill for prolonged infusion services when the CIVI is started in the physician office. It does not apply to BLINCYTO® when the CIVI is started in the inpatient setting or via home infusion. ^{8,9,12} Some payers may not recognize G0498 and require itemization of specific items, instead. The healthcare provider should consult the payer or MAC to determine which code is most appropriate for administration of BLINCYTO®.
Drug: BLINCYTO®	J9039 Injection, blinatumomab, 1 mcg JW Discarded drug/not administered to any patient JZ Zero drug amount discarded/not administered to any patient	Medicare requires use of the HCPCS code in the physician office setting ¹⁸ and has a maximum utilization of 210 units per date of service (based on prescribing information). ¹⁹ However, coding requirements may vary by payer. Like many payers, Medicare requires the use of the modifier JW and JZ, which provides payment for the amount of drug or biologic discarded, as well as for the dose administered, up to the amount of the drug or biologic as indicated on the vial or label for an SDV. ¹⁵ Note: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
	NDC: 55513016001 BLINCYTO® 35 mcg lyophilized powder, SDV IV solution stabilizer, 10 mL SDV	Some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format. ¹⁷ Insert a leading zero in the appropriate section to complete the 5-4-2 digit format. Remove the dashes prior to entering the NDC on the claim form.
DME: EIP and supplies	E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater ²² E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient ²² G0498 Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion A4222 Infusion supplies for external drug infusion pump, per cassette or bag Modifiers for EIP -KD Drug or biologic infused through DME -RR Rental -KH DMEPOS item, initial claim or first rental month -KI DMEPOS item, second or third rental months -KJ DMEPOS item, fourth to 15th rental months	Report the appropriate EIP code and appropriate modifier(s) as documented in the medical record. Modifiers may be used to provide additional detail when billing for the EIP to the DME MAC. ⁸ Note: Drug administration codes may get billed to the MAC and the E-codes may get billed separately to the DME MAC. If the office bills the G-code to the MAC, the cost of the pump and supplies is bundled and should not be billed separately to the DME MAC. ¹³ Report any supplies as necessary.

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

BLINCYTO®

Billing Information Sheet



Sample CMS-1500 Form: Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA		PICA	
1. MEDICARE (Medicare#)	MEDICAID (Medicaid#)	TRICARE (ID#DoD#)	CHAMPVA (Member ID#)
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY	SEX M F
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other	7. INSURED'S ADDRESS (No., Street)
CITY	STATE	CITY	STATE
ZIP CODE	TELEPHONE (Include Area Code)	ZIP CODE	TELEPHONE (Include Area Code)
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	11. INSURED'S POLICY GROUP OR FECA NUMBER	
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES NO	a. INSURED'S DATE OF BIRTH MM DD YY	
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES NO	SEX M F	
d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODE	b. OTHER CLAIM ID (Designated by NUCC)	

NDC (BOX 24A SHADED AREA): When reporting BLINCYTO®, some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. When required by the payer, report the NDC qualifier "N4," indicating that an NDC follows, and the NDC in the 11-digit format. The unit of measure can also be reported, 3 spaces after the NDC, as UNX (X = the number of vials). Verify the payer-specific claim submission requirements

DIAGNOSIS (BOX 21): Enter the appropriate diagnosis code; eg, ICD-10-CM:

- **Z51.12** Encounter for antineoplastic immunotherapy **AND**
- **C91.00** Acute lymphoblastic leukemia not having achieved remission **OR**
- **C91.01** Acute lymphoblastic leukemia, in remission **OR**
- **C91.02** Acute lymphoblastic leukemia, in relapse

Final codes depend on medical record documentation

DIAGNOSIS POINTER (Box 24E): Enter the letter (A–L) that corresponds to the diagnosis in Box 21

UNITS (Box 24G): Report units of service for both units administered and amount of discarded drug. BLINCYTO® dose reported as 1 unit per mcg. Report 1 unit for initiation of CIVI via EIP or refill of EIP

PLACE OF SERVICE (Box 24B): Enter the appropriate 2-digit place of service code that corresponds to the location where services are rendered; eg, • **11** Physician office

PROCEDURES/SERVICES/SUPPLIES (Box 24D): Enter the appropriate administration procedure. Use the CPT code representing the procedure performed, such as initiation OR refill; eg, **96416** Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump **OR** **96521** Refilling and maintenance of portable pump **OR** **G0498** Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion

JW/JZ Discard Modifier: JW or JZ modifier required for Medicare Part B claims for drugs in single-use containers

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information for BLINCYTO® on pages 18–19.

BLINCYTO®

Billing Information Sheet



Home Infusion - Multiple Payers (Medicare and Non-Medicare)

Item	Coding Information (ICD-10-CM ⁷ /CPT ⁹ /HCPCS ⁸ /NDC ¹¹)	Notes
Diagnosis: Encounter for drug therapy and ALL	Z51.12 Encounter for antineoplastic immunotherapy AND C91.00 Acute lymphoblastic leukemia not having achieved remission OR C91.01 Acute lymphoblastic leukemia, in remission OR C91.02 Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM code(s) to describe the patient's condition.
Procedure: Administration via CIVI using an EIP	G0090 Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes ¹ G0070 Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes ¹ 99601 Home infusion/specialty drug administration, per visit (up to 2 hours) 99602 Each additional hour S9329 Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9330 Home infusion therapy, continuous (24 hours or more) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9338 Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9379 Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Home infusion therapy services for Medicare beneficiaries receiving BLINCYTO® should be billed using G0090 for an initial visit and G0070 for subsequent visits. Some or all Medicare contractors may reject chemotherapy CPT codes with the availability of G0070 and G0090. These services must be reported to the A/B MAC, and are reimbursed by Medicare at rates set by the Medicare Physician Fee Schedule. They are billed and paid separately from the external infusion pump and drug, which are billed to the DME MAC and reimbursed under the DMEPOS Fee Schedule. Medicare requires that a claim for BLINCYTO® be billed no more than 30 days prior to the visit. Otherwise, payment for the home infusion therapy service will be denied. ¹ These services may be covered by Medicaid, commercial plans, or Medicare Advantage plans. ²⁰ CPT codes 99601 and 99602, as well as certain S-codes, may be used to report home infusion therapy services to other payer types other than FFS Medicare. Please note that FFS Medicare does not recognize S-codes, although other payers might. ²⁰
Drug: BLINCYTO®	J9039 Injection, blinatumomab, 1 mcg JW Discarded drug/not administered to any patient JZ Zero drug amount discarded/not administered to any patient	Medicare requires that claims for BLINCYTO®, the pump, and supplies be sent to the DME MACs. Claims for home infusion therapy services must now be submitted separately and are processed by Part A/B MACs. ¹ <u>Medicare sets maximum utilization at 875 units of service (UOS), which is equivalent to 25 vials per month in this site of care.</u> ²¹ Many payers require the use of the modifier JW and JZ, which provides payment for the amount of drug or biologic discarded, as well as for the dose administered, up to the amount of the drug or biologic as indicated on the vial or label for an SDV. ¹⁵ Note: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
	NDC: 55513016001 BLINCYTO® 35 mcg lyophilized powder, SDV IV solution stabilizer, 10 mL SDV	Some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format. ¹⁷ Insert a leading zero in the appropriate section to complete the 5-4-2 digit format. Remove the dashes prior to entering the NDC on the claim form.
DME: EIP and supplies	E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater ²² E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient ²² A4222 Infusion supplies for external drug infusion pump, per cassette or bag Modifiers for EIP -KD Drug or biologic infused through DME -RR Rental -KH DMEPOS item, initial claim or first rental month -KI DMEPOS item, second or third rental months -KJ DMEPOS item, fourth to 15th rental months	Report the appropriate EIP code and appropriate modifier(s) as documented in the medical record. Modifiers may be used to provide additional detail when billing for the EIP to the DME MAC. ⁸ Report any supplies as necessary.

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Please see Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO®

Billing Information Sheet



Sample CMS-1500 Form: Medicare DME MAC for BLINCYTO®, Pump, and Related Supplies by DME Supplier

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) (02/12)

1. MEDICARE **MEDICAID** **TRICARE** **CHAMPVA** **GROUP HEALTH PLAN** **FECA BLK LUNG** **OTHER**
(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY **SEX** M ☐ F ☐

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. INSURED'S ADDRESS (No., Street) **CITY** **STATE** **ZIP CODE** **TELEPHONE** (Include Area Code)

6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐

7. INSURED'S DATE OF BIRTH MM DD YY **SEX** M ☐ F ☐

8. RESERVED FOR NUCC USE

9. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) ☐ YES ☐ NO b. AUTO ACCIDENT? ☐ YES ☐ NO c. OTHER ACCIDENT? ☐ YES ☐ NO

10. INSURED'S POLICY GROUP OR FECA NUMBER

11. INSURED'S DATE OF BIRTH MM DD YY **SEX** M ☐ F ☐

12. OTHER CLAIM ID (Designated by NUCC)

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE **SIGNED**

15. OTHER DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

18. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

19. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to 21

20. DATE(S) OF SERVICE From MM DD YY To MM DD YY

21. PLACE OF SERVICE A. 12 Home

22. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER

23. DIAGNOSIS POINTER A B

24. \$ CHARGES XXX XX X

25. DAYS OR UNITS XX X

26. PSCT NPI

27. QUAL NPI

28. UNITS (Box 24G): Report units of service for both units administered and amount of discarded drug. BLINCYTO® dose reported as 1 unit per mcg. Report 1 unit each for IEP and other supplies. Reminder: Billing cap of 25 vials per month applies²¹

29. DIAGNOSIS POINTER (Box 24E): Enter the letter (A-L) that corresponds to the diagnosis in Box 21

30. PROCEDURES/SERVICES/SUPPLIES (Box 24D): Enter the appropriate CPT/HCPCS codes and modifiers; eg, Drug: J9039 for BLINCYTO® JW/JZ Discard Modifier: JW or JZ modifier required for Medicare DME external infusion pump claims including infused drugs in single-use containers IV Pump: E0781 Ambulatory infusion pump A4222 Infusion supplies for external drug infusion pump, per cassette or infusion option Other codes may be appropriate. Check with individual Medicare DME MACs for detailed guidance

31. PLACE OF SERVICE (Box 24B): Enter the appropriate 2-digit place of service code that corresponds to the location where services are rendered; eg, 12 Home

32. SIGNED **DATE**

33. NUCC Instruction Manual available at: www.nucc.org

34. FORM 1500 (02-12)

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO®

Billing Information Sheet



Sample CMS-1500 form: Medicare A/B MAC for Home Infusion Therapy Services by Home Infusion Therapy Supplier

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

☐ ☐ PICA

1. MEDICARE <small>(Medicare#)</small>	MEDICAID <small>(Medicaid#)</small>	TRICARE <small>(ID#/DoD#)</small>	CHAMPVA <small>(Member ID#)</small>	GROUP HEALTH PLAN <small>(ID#)</small>	FECA BLK (LUNG) <small>(ID#)</small>	OTHER <small>(ID#)</small>
---	--	--------------------------------------	--	---	---	-------------------------------

1a. INSURED'S I.D. NUMBER (For Program In Item 1)
 4. INSURED'S NAME (Last Name, First Name, Middle Initial)
 7. INSURED'S ADDRESS (No., Street)
 CITY
 STATE
 ZIP CODE
 TELEPHONE (Include Area Code)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
 3. PATIENT'S BIRTH DATE
 MM DD YY
 SEX
 M ☐ F ☐
 6. PATIENT RELATIONSHIP TO INSURED
 Self ☐ Spouse ☐ Child ☐ Other ☐
 8. RESERVED FOR NUCC USE

10. IS PATIENT'S CONDITION RELATED TO:
 a. EMPLOYMENT? (Current or Previous)
 YES ☐ NO ☐
 b. AUTO ACCIDENT?
 YES ☐ NO ☐
 c. OTHER ACCIDENT?
 YES ☐ NO ☐
 11. INSURED'S POLICY GROUP OR FECA NUMBER
 a. INSURED'S DATE OF BIRTH
 MM DD YY
 SEX
 M ☐ F ☐
 b. OTHER CLAIM ID (Designated by NUCC)
 c. INSURANCE PLAN NAME OR PROGRAM NAME
 d. IS THERE ANOTHER HEALTH BENEFIT PLAN?
 YES ☐ NO ☐ If yes, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
 SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
 SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)
 MM DD YY
 QUAL. _____
 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to 3.
 A. Z51.12 B. C91.02
 C. _____ D. _____
 E. _____ F. _____
 G. _____ H. _____
 I. _____ J. _____
 K. _____ L. _____

DIAGNOSIS (BOX 21):
 Enter the appropriate diagnosis code; eg, ICD-10-CM:
Z51.12 Encounter for antineoplastic immunotherapy **AND**
C91.00 Acute lymphoblastic leukemia not having achieved remission **OR**
C91.01 Acute lymphoblastic leukemia, in remission **OR**
C91.02 Acute lymphoblastic leukemia, in relapse
 Final codes depend on medical record documentation

24. A.	DATE(S) OF SERVICE	B.	PLACE OF SERVICE	C.	PROCEDURES, SERVICES, OR SUPPLIES	E.	DIAGNOSIS POINTER	F.	\$ CHARGES	G.	DAYS (or UNITS)	H.	PSCT (or UNITS)	I.	QUAL.
1	MM DD YY	MM DD YY	12	EMG	CPT/HCPCS	MODIFIER	A B	XXX XX	X						
2	MM DD YY	MM DD YY	12		J9039		A B	0 00	X						
3															
4															

PLACE OF SERVICE (Box 24B):
 Enter the appropriate 2-digit place of service code that corresponds to the location where services are rendered; eg,
 • 12 Home

DIAGNOSIS POINTER (Box 24E): Enter the letter (A-L) that corresponds to the diagnosis in Box 21

UNITS (Box 24G):
 Report units of service for the administration of BLINCYTO®, reported as 1 unit per 15 minutes of time of IV infusion

PROCEDURES/SERVICES/SUPPLIES (Box 24D):
 Enter the appropriate CPT/HCPCS codes and modifiers; eg,
 • IV Infusion: **G0090** for IV infusion of BLINCYTO®, initial visit
 • Drug: **J9039** is added to identify BLINCYTO® as the drug related to the administration service;
 List a zero charge to indicate that no reimbursement for the drug is expected
 Other codes may be appropriate. Check with individual Medicare A/B MAC for detailed guidance

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
 SIGNED _____ DATE _____

NUCC Instruction Manual available at: www.nucc.org

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO®

Billing Information Sheet



Sample CMS-1500 Form: Non-Medicare Payer by Home Infusion Provider



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA <input type="checkbox"/>		PICA <input type="checkbox"/>	
1. MEDICARE <input type="checkbox"/> (Medicare#)	MEDICAID <input type="checkbox"/> (Medicaid#)	TRICARE <input type="checkbox"/> (ID#/DoD#)	CHAMPVA <input type="checkbox"/> (Member ID#)
GROUP HEALTH PLAN <input type="checkbox"/> (ID#)		FECA BLK (LUNG) <input type="checkbox"/> (ID#)	OTHER <input type="checkbox"/> (ID#)
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED	
CITY		Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
STATE		8. RESERVED FOR NUCC USE	
ZIP CODE		CITY	
TELEPHONE (Include Area Code)		STATE	
()		()	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous)	
b. RESERVED FOR NUCC USE		YES <input type="checkbox"/> NO <input type="checkbox"/>	
c. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE		11. INSURED'S POLICY GROUP OR FECA NUMBER	
I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment.		a. INSURED'S DATE OF BIRTH MM DD YY	
		SEX M <input type="checkbox"/> F <input type="checkbox"/>	
		b. OTHER CLAIM ID (Designated by NUCC)	
		c. INSURANCE PLAN NAME OR PROGRAM NAME	
		d. IS THERE ANOTHER HEALTH BENEFIT PLAN?	
		YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 8, 9a, and 9d.	
		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE	
		I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
		SIGNED	
		DATE	
		MM DD YY	
		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION	
		FROM MM DD YY TO MM DD YY	

NDC (BOX 24A SHADED AREA): When required by the payer, report the NDC qualifier "N4," indicating that an NDC follows, and the NDC in the 11-digit format. The unit of measure can also be reported, 3 spaces after the NDC, as UNX (X = the number of vials). Verify the payer-specific claim submission requirements

DIAGNOSIS (BOX 21): Enter the appropriate diagnosis code; eg, ICD-10-CM:

- Z51.12 Encounter for antineoplastic immunotherapy AND
- C91.00 Acute lymphoblastic leukemia not having achieved remission OR
- C91.01 Acute lymphoblastic leukemia, in remission OR
- C91.02 Acute lymphoblastic leukemia, in relapse

Final codes depend on medical record documentation

DIAGNOSIS POINTER (Box 24E): Enter the letter (A-L) that corresponds to the diagnosis in Box 21

UNITS (Box 24G): Report units of service for both units of drug administered and amount of discarded drug. BLINCYTO® dose reported with 1 unit per 1 mcg

PLACE OF SERVICE (Box 24B): Enter the appropriate 2-digit place of service code that corresponds to the location where services are rendered; eg,

- 12 Home

PROCEDURES/SERVICES/SUPPLIES (Box 24D): Enter the appropriate CPT/HCPSC codes and modifiers; eg,

- Drug: J9039 for BLINCYTO®
- 99601 Home infusion/specialty drug administration, per visit (up to 2 hours)
- A4222 Infusion supplies for external drug infusion pump, per cassette or infusion option

Other codes may be appropriate. Check with individual payers for detailed guidance

NOTE: Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

BLINCYTO® Dosing Options¹¹

Dosing option	Dose per vial X number of SDVs*	Number of billing units
24-hour	35 mcg X 1 vial	35
48-hour	35 mcg X 1-2 vials	35-70
72-hour^{1†}	35 mcg X 1-3 vials	35-105
96-hour^{1†}	35 mcg X 1-4 vials	35-140
7-day^{1‡}	35 mcg X 1-6 vials	35-210

*Number of SDVs depends on dose, infusion duration, and patient's weight.¹¹

[†]The administration of BLINCYTO as a 72-hour, 96-hour, and 7-day infusion is not recommended for patients weighing less than 5.4 kg.¹¹

[‡]Prepared with Bacteriostatic 0.9% Sodium Chloride Injection (containing 0.9% benzyl alcohol).¹¹

Key Considerations for the BLINCYTO® 7-day Infusion Option (7-DIO)



Minor variations are expected in coding, billing, and claims filing for the BLINCYTO® 7-DIO.²⁰



The 7-DIO requires 6 vials of BLINCYTO® and 1 vial of IV Solution Stabilizer for patients ≥ 45 kg. For patients weighing between 5.4 kg and less than 45 kg, 1 to 5 vials are required. The safety of the administration of BLINCYTO® at a BSA of less than 0.4 m² has not been established.¹¹ Refer to the Prescribing Information for details on handling and preparation.



If the units field on a claim form cannot accommodate more than 99 units, utilize multiple lines to capture all units (eg, 99+98+13). Payers may require separate reporting of drug units administered and discarded.²⁰



Less frequent claim submissions are expected with utilization of the 7-DIO. Typically the entire 7-DIO can be billed on the day of administration/refill. However, be sure to refer to payer guidelines for maximum daily quantity limits. Apply the appropriate dates of service as needed.²⁰



If the 7-DIO is interrupted mid-treatment, refer to payer guidelines for reporting and documentation in these cases. If full reimbursement is withheld by the payer, refer to Amgen's Product Return Policy for assistance.



Existing codes and modifiers are adequate to report BLINCYTO® and its related services; however, payer requirements may vary with respect to:²⁰

- The entities that can bill for DME and the associated supplies
- The number of units billed for BLINCYTO® J9039 (HCPCS units vs number of vials)
- Covered diagnosis codes
- Covered nursing services (eg, infusion services at patient's home)
- Drug claim submission options (eg, 1 or more dates of service on claims)
- Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

UNDERSTANDING EXAMPLES OF



REIMBURSEMENT ACROSS SITES OF CARE

A BLINCYTO® patient transitions through multiple sites of care. This guide shows how major payers in the United States (commercial plans, Medicare, and Medicaid) offer coverage in each setting and reimburse for each component of care:



Drug



Pump and Supplies



Hospitalization



Professional Services (ie, drug administration)

INDICATIONS

BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients one month and older with:

- Philadelphia chromosome-negative disease in the consolidation phase of multiphase chemotherapy
- Minimal residual disease (MRD) greater than or equal to 0.1% in first or second complete remission
- Relapsed or refractory disease

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

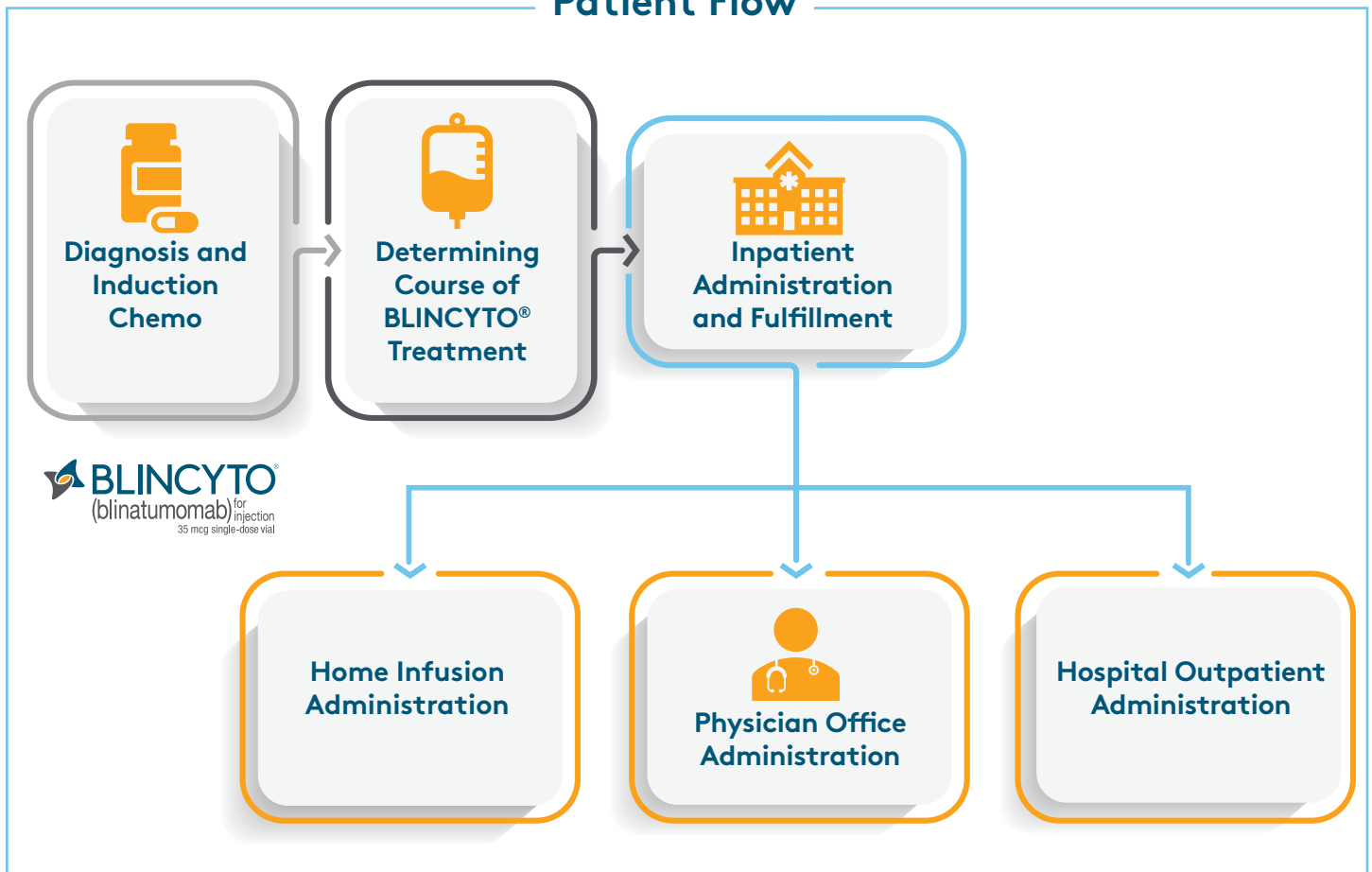
- Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.
- Neurological toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.

Please see additional Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO® (blinatumomab) Reimbursement Process

Coverage of BLINCYTO® and its administration is required in all these sites of care to avoid interruption in treatment.

Patient Flow







The scenarios depicted above illustrate the most common ones for accessing BLINCYTO® via the buy-and-bill acquisition process, where the entity that acquires the product also administers it to the patient.

BLINCYTO® can also be acquired via a specialty pharmacy provider, including:




- Third-party specialty pharmacies that contract with a payer to supply specialty products covered under the medical benefit
- Specialty pharmacies owned by hospitals, physician offices, ambulatory infusion clinics, and/or home infusion companies that may also administer the medication

BLINCYTO® Reimbursement Across Transitions in Site of Care

BLINCYTO®-eligible patients need coverage for the following: Drug + Pump + Hospitalization + Administration

Inpatient Hospital			
Components of BLINCYTO® Care	Commercially Insured Patients	FFS Medicare Patients	FFS Medicaid Patients
BLINCYTO® 	MS-DRG-based or global payment; typically includes BLINCYTO® ²³ Reimbursement varies by contracts between providers and payers	MS-DRG payment includes BLINCYTO® ²⁴ Covered under Medicare Part A benefit ²⁵ Hospital may be eligible for outlier payments if cost of admission exceeds certain threshold Reimbursement varies for the 11 IPPS-Exempt Cancer Hospitals ²⁶	APR-DRG-based payment; typically includes BLINCYTO® ²⁷ Reimbursement varies by state; may follow Medicare allowable amounts
Pump and Supplies 	Some hospitals, in their contracts with managed care organizations, may negotiate a “carve out” benefit for drugs such as BLINCYTO® <ul style="list-style-type: none"> May allow separate payment of such drugs outside of the bundled payment for inpatient services 		
Hospitalization 			
Professional Services 	Physician services may be covered separately outside of the bundled payment	Physician services may be covered and reimbursed according to the MPFS under Medicare Part B benefit	Physician services may be covered and paid outside of the bundled payment




Key: APR-DRG – All Patient-Refined Diagnosis Related Groups; FFS – fee-for-service; IPPS – Inpatient Prospective Payment System; MPFS – Medicare Physician Fee Schedule; MS-DRG – Medicare Severity Diagnosis-Related Group.

Outpatient Hospital			
Components of BLINCYTO® Care	Commercially Insured Patients	FFS Medicare Patients	FFS Medicaid Patients
BLINCYTO® 	Reimbursed based on contracted rates; methodology varies Examples: ²⁸ <ul style="list-style-type: none"> ASP + X% WAC + X% AWP – X% May need prior authorization	Covered under Medicare Part B benefit Typically reimbursed based on ASP + 6% when administered in a 340B hospital setting (with 2% sequestration reduction) ^{29,30} MUE cap of 210 units (approx. 6 vials) per date of service applies ^{31,8}	Reimbursement may be similar to Medicare OR State-defined limit (eg, California uses a federal upper limit) ³² May need prior authorization
Pump and Supplies 	Reimbursement is bundled into the payment for the infusion service	Covered under Medicare Part B benefit Reimbursement is bundled into the payment for the infusion service	Reimbursed based on fee schedule or bundled into the payment for the infusion service Rates vary by state
Professional Services 	Reimbursed based on contracted rate	Reimbursed based on the Medicare OPFS	

Key: ASP – average sales price; AWP – average wholesale price; FFS – fee-for-service; MUE – medically unlikely edit; OPFS – Outpatient Prospective Payment System; WAC – wholesale acquisition cost.




Note: The information here describes coverage and payment for BLINCYTO® under FFS Medicare and FFS Medicaid. Coverage and payment for patients enrolled in Medicare Advantage and/or Medicaid managed care organizations varies widely and is often similar to commercial insurance.

Physician Office

Components of BLINCYTO® Care	Commercially Insured Patients	FFS Medicare Patients	FFS Medicaid Patients
BLINCYTO® 	Reimbursed based on contracted rates; methodology varies Examples: ²⁸ <ul style="list-style-type: none"> • ASP + X% • WAC + X% • AWP – X% May need prior authorization	Covered under Medicare Part B benefit Typically reimbursed based on ASP + 6% (with 2% sequestration reduction) ^{30,33} MUE cap of 210 units (approx. 6 vials) per date of service applies ^{8,19}	Reimbursement may be similar to Medicare OR State-defined limit (eg, California uses a federal upper limit) ³² May need prior authorization
Pump and Supplies 	Reimbursed based on contracted rate and bundled into payment for the infusion service	Covered under Medicare Part B benefit Reimbursement is bundled into the payment for the infusion service	Typically reimbursed based on fee schedule or bundled into the payment for the infusion service Rates vary by state
Professional Services 	Reimbursed based on contracted rate	Reimbursed based on the MPFS	

Key: ASP – average sales price; AWP – average wholesale price; FFS – fee-for-service; MPFS – Medicare Physician Fee Schedule; MUE – medically unlikely edit; WAC – wholesale acquisition cost.

Home Infusion

Components of BLINCYTO® Care	Commercially Insured Patients	FFS Medicare Patients	FFS Medicaid Patients
BLINCYTO® 	Reimbursed based on contracted rates; methodology varies Examples: ²⁸ <ul style="list-style-type: none"> • ASP + X% • WAC + X% • AWP – X% May need prior authorization	Covered under Medicare Part B as long as it is supplied in a covered external infusion pump and the IV is initiated in home infusion setting ³⁴ Typically reimbursed based on ASP + 6% (with 2% sequestration reduction) ^{30,33} Billing cap of 25 vials per month applies ²¹	Reimbursement may be similar to Medicare OR State-defined limit (eg, California uses a federal upper limit) ³⁷ May need prior authorization
Pump and Supplies 	Reimbursed based on contracted rate	Covered under Medicare Part B benefit Reimbursed as part of the Medicare DMEPOS Fee Schedule ³⁵	Typically reimbursed based on fee schedule Rates vary by state
Professional Services 	Reimbursed based on contracted rate	Covered under Part B Reimbursed under the home infusion therapy services benefit in 15-minute increments for applicable providers ³⁶	

Key: ASP – average sales price; AWP – average wholesale price; DMEPOS – Durable Medical Equipment Prosthetics, Orthotics, and Supplies; FFS – fee-for-service; WAC – wholesale acquisition cost.

Note: Medicare home infusion benefit is distinct and separate from the Medicare home health benefit.

Please see Important Safety Information for BLINCYTO® on pages 18-19.

BLINCYTO®

Indications and Important Safety Information



INDICATIONS

BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients one month and older with:

- Philadelphia chromosome-negative disease in the consolidation phase of multiphase chemotherapy
- Minimal residual disease (MRD) greater than or equal to 0.1% in first or second complete remission
- Relapsed or refractory disease

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.**

Contraindications

BLINCYTO® is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- **Cytokine Release Syndrome (CRS):** CRS, which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. The median time to onset of CRS is 2 days after the start of infusion and the median time to resolution of CRS was 5 days among cases that resolved. Closely monitor and advise patients to contact their healthcare professional for signs and symptoms of serious adverse events such as fever, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin, and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO® overlap with those of infusion reactions, capillary leak syndrome (CLS), and hemophagocytic histiocytosis/macrophage activation syndrome (MAS). Using all of these terms to define CRS in clinical trials of BLINCYTO, CRS was reported in 15% of patients with R/R ALL, in 7% of patients with MRD-positive ALL, and in 16% of patients receiving BLINCYTO® cycles in the consolidation phase of therapy. If severe CRS occurs, interrupt BLINCYTO® until CRS resolves. Discontinue BLINCYTO® permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.

- **Neurological Toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome:** BLINCYTO® can cause serious or life-threatening neurologic toxicity, including ICANS. The incidence of neurologic toxicities in clinical trials was approximately 65%. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment. The most common ($\geq 10\%$) manifestations of neurologic toxicity were headache and tremor. Grade 3 or higher neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. The majority of neurologic toxicities resolved following interruption of BLINCYTO®, but some resulted in treatment discontinuation.

The incidence of signs and symptoms consistent with ICANS in clinical trials was 7.5%. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. There is limited experience with BLINCYTO® in patients with active ALL in the central nervous system (CNS) or a history of neurologic events. Patients with a history or presence of clinically relevant CNS pathology were excluded from clinical studies. Patients with Down Syndrome may have a higher risk of seizures with BLINCYTO® therapy; consider seizure prophylaxis prior to initiation of BLINCYTO® for these patients.

Monitor patients for signs and symptoms of neurological toxicities, including ICANS, and interrupt or discontinue BLINCYTO® and/or treat with corticosteroids as outlined in the PI. Advise outpatients to contact their healthcare professional if they develop signs or symptoms of neurological toxicities.

- **Infections:** Approximately 25% of patients receiving BLINCYTO® in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO® as needed.
- **Tumor Lysis Syndrome (TLS),** which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cyto reduction and on-treatment hydration, should be used during BLINCYTO® treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO® as needed to manage these events.
- **Neutropenia and Febrile Neutropenia,** including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO® infusion and interrupt BLINCYTO® if prolonged neutropenia occurs.
- **Effects on Ability to Drive and Use Machines:** Due to the possibility of neurological events, including seizures and ICANS, patients receiving BLINCYTO® are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO® is being administered.
- **Elevated Liver Enzymes:** Transient elevations in liver enzymes have been associated with BLINCYTO® treatment with a median time to onset of 3 days. In patients receiving BLINCYTO®, although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations

IMPORTANT SAFETY INFORMATION (continued)

in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and total blood bilirubin prior to the start of and during BLINCYTO[®] treatment. BLINCYTO[®] treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if total bilirubin rises to > 3 times ULN.

- **Pancreatitis:** Fatal pancreatitis has been reported in patients receiving BLINCYTO[®] in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO[®] and dexamethasone as needed.
- **Leukoencephalopathy:** Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO[®], especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- **Preparation and administration** errors have occurred with BLINCYTO[®] treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).
- **Immunization:** Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO[®] treatment, during treatment, and until immune recovery following last cycle of BLINCYTO[®].
- **Benzyl Alcohol Toxicity in Neonates:** Serious adverse reactions, including fatal reactions and the “gasping syndrome,” have been reported in very low birth weight (VLBW) neonates born weighing less than 1500 g, and early preterm neonates (infants born less than 34 weeks gestational age) who received intravenous drugs containing benzyl alcohol as a preservative. Early preterm VLBW neonates may be more likely to develop these reactions because they may be less able to metabolize benzyl alcohol.

Use the preservative-free preparations of BLINCYTO[®] where possible in neonates. When prescribing BLINCYTO[®] (with preservative) for neonatal patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO[®] (with preservative), other products containing benzyl alcohol or other excipients (e.g., ethanol, propylene glycol) which compete with benzyl alcohol for the same metabolic pathway.

Monitor neonatal patients receiving BLINCYTO[®] (with preservative) for new or worsening metabolic acidosis. The minimum amount of benzyl alcohol at which serious adverse reactions may occur in neonates is not known. The BLINCYTO[®] 72-Hour bag (with preservative) and 96-Hour bag (with preservative) contain 2.5 mg of benzyl alcohol per mL, and the 7-Day bag (with preservative) contains 7.4 mg of benzyl alcohol per mL.

- **Embryo-Fetal Toxicity:** Based on its mechanism of action, BLINCYTO[®] may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with BLINCYTO[®] and for 48 hours after the last dose.

Adverse Reactions

- The safety of BLINCYTO[®] in adult and pediatric patients one month and older with MRD-positive B-cell precursor ALL (n=137), relapsed or refractory B-cell precursor ALL (n=267), and Philadelphia chromosome-negative B cell precursor ALL in consolidation (n=165) was evaluated in clinical studies. The most common adverse reactions (≥ 20%) to BLINCYTO[®] in this pooled population were pyrexia, infusion-related reactions, headache, infection, musculoskeletal pain, neutropenia, nausea, anemia, thrombocytopenia, and diarrhea.

Dosage and Administration Guidelines

- BLINCYTO[®] is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see accompanying BLINCYTO[®] **full Prescribing Information**, including **BOXED WARNINGS**.

Please note: The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for their own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

We're right here, right when you need us

**HCP Support Center**

Our Amgen SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Benefits Verification

• Verify patient's insurance plan coverage details

Prior Authorization Requirements

• Provide payer-specific prior authorization forms

Amgen SupportPlus Customer Portal

• A tool for managing patient benefits verification and more
• Submit, store, and retrieve benefit verifications electronically

**Amgen® Patient Navigator**

A single point of contact to help answer questions about access and reimbursement, navigating treatment logistics, and to provide supplemental resources as your patients transition from hospital to outpatient care.

Amgen Patient Navigators can help with:

• Benefits verification and understanding coverage
• Prior authorization process
• Reimbursement and access resources

The Amgen Patient Navigator is not part of a patient's treatment team and does not provide medical advice or case management services. The Amgen Patient Navigator does not administer Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

AMGEN® TherapyLocator[®]

Visit **AmgenTherapyLocator.com** to locate alternative sites where BLINCYTO[®] can be administered to your patients*

*The information on this website is reported by independent third-party sites that administer or deliver treatment to patients. It is not comprehensive of all sites that handle the therapies listed, and Amgen does not confirm accuracy or otherwise endorse any of these sites.

Note: Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. This information is not a guarantee of coverage or reimbursement.

**AMGEN Support⁺ | Co-Pay Program**

The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.

- Pay as little as **\$0 out-of-pocket** for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment†
- No income eligibility requirement

†Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay

What if my patient doesn't have private or commercial insurance?

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.‡

‡Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

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