# BLINCYTO®
# Billing Information Sheet

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

## 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 services[1]

- 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, 2024[3]

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.

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## 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**<br>**C91.00** Acute lymphoblastic leukemia not having achieved remission/failed remission **OR**<br>**C91.01** Acute lymphoblastic leukemia, in remission **OR**<br>**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,<br>• **Medicare: 0250** General pharmacy<br>• **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,<br>• **0290** DME | **E0791** Parenteral infusion pump, stationary, single or multi-channel<br>**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,<br>• **0261** IV therapy: Infusion pump | **3E03305** Introduction of other antineoplastic into peripheral vein, percutaneous approach† **OR**<br>**3E04305** Introduction of other antineoplastic into central vein, percutaneous approach†<br>**96416** Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump **OR**<br>**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.

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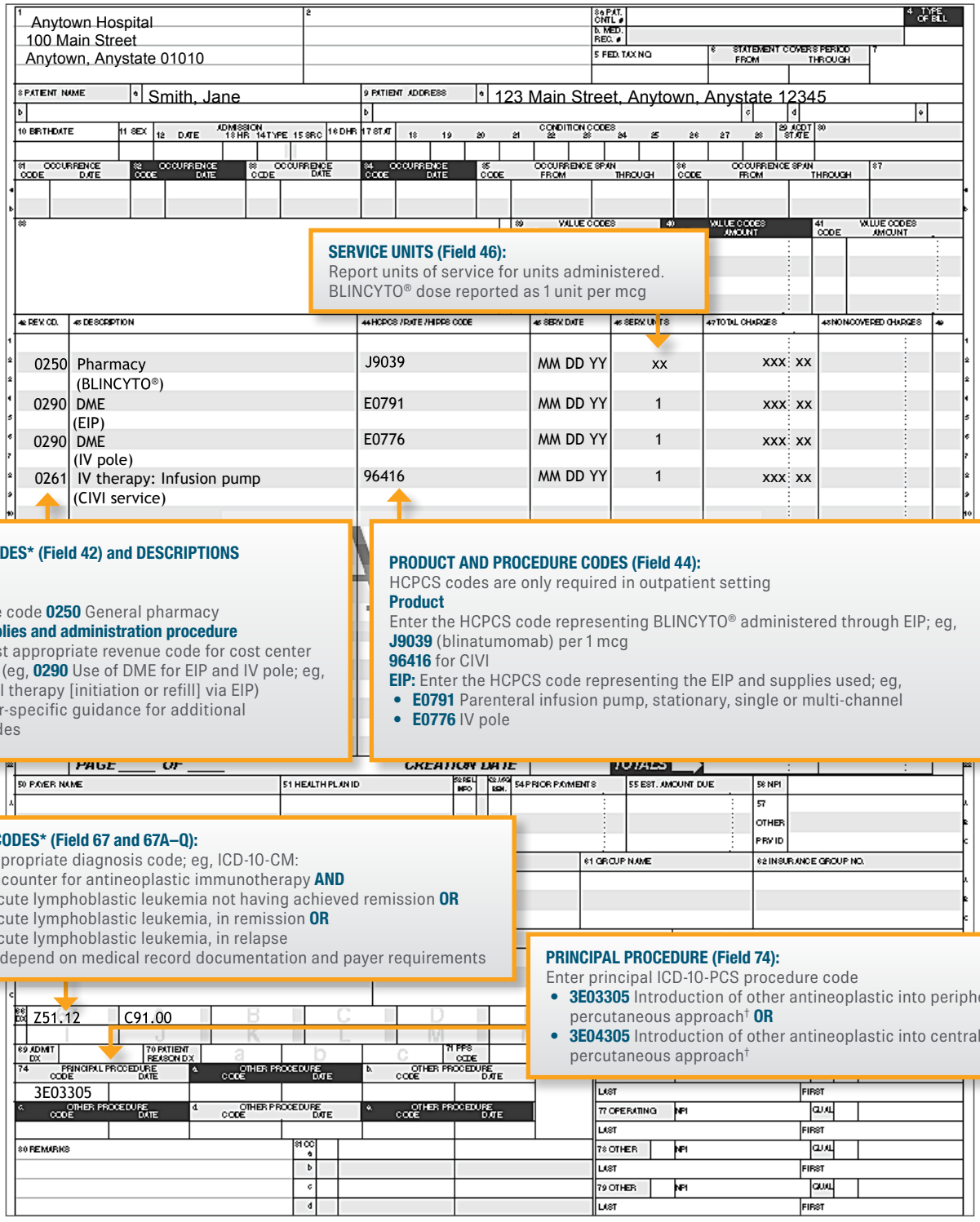
## Sample UB-04 (CMS-1450) Form: Hospital Inpatient Administration




**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.

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## 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**<br>**C91.00** Acute lymphoblastic leukemia not having achieved remission **OR**<br>**C91.01** Acute lymphoblastic leukemia, in remission **OR**<br>**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,<br>• **0261** IV therapy: Infusion pump<br>• **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**<br>**96521** Refilling and maintenance of portable pump **OR**<br>**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]<br>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®.<br>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,<br>• **Medicare: 0636** Drug requiring detailed coding<br>• **Other payers: 0250 or 0636** General pharmacy (if required by a given payer) | **J9039** Injection, blinatumomab, 1 mcg<br>**JW** Discarded drug/not administered to any patient<br>**JZ** Zero drug amount discarded/not administered to any patient<br>**JG** Drug or biological acquired with 340B Drug Pricing Program discount<br>**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.<br>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]<br>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.†<br>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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## Hospital Outpatient Department (HOPD) - Multiple Payers (Medicare and Non-Medicare) *(continued)*

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

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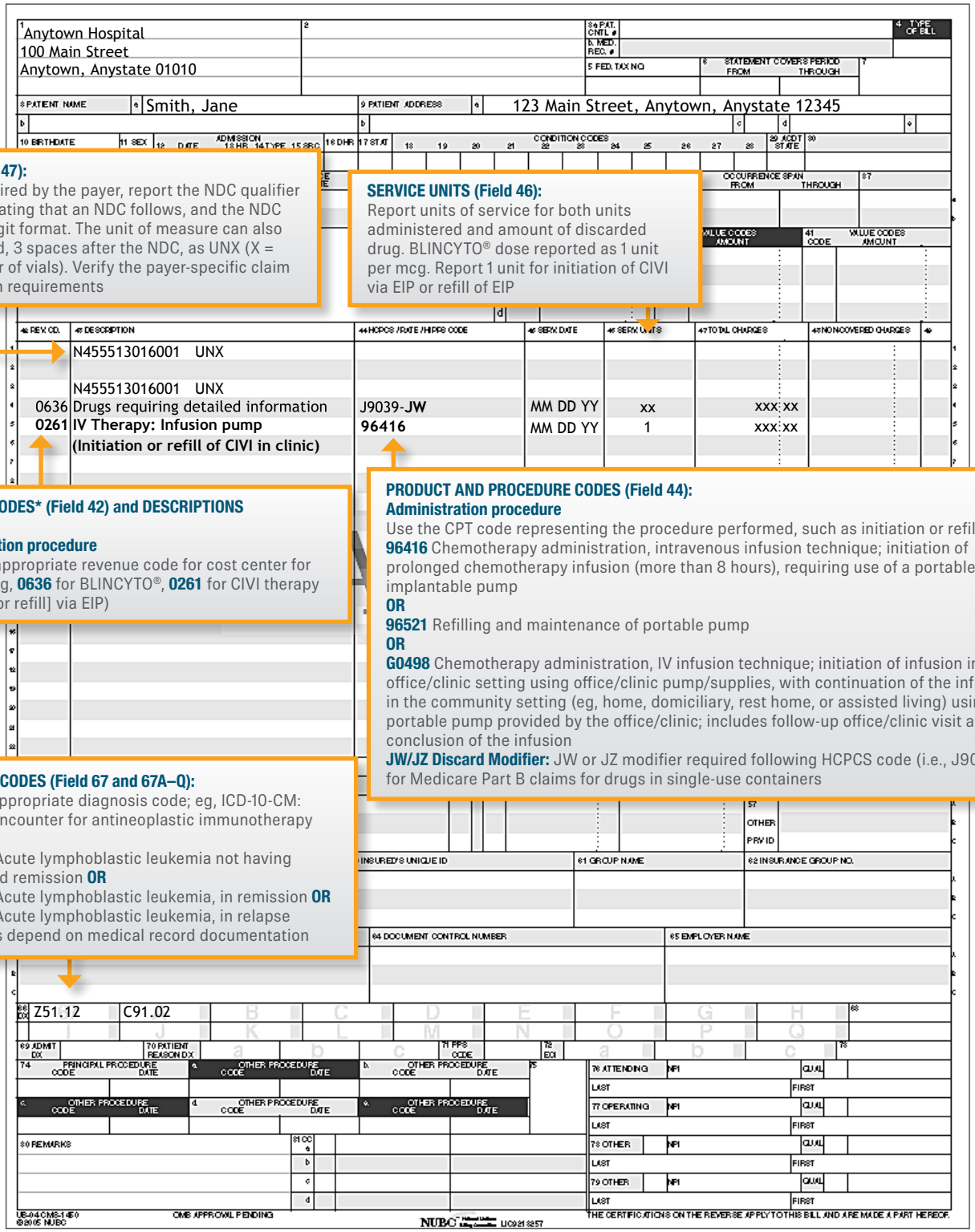
## Sample UB-04 (CMS-1450) Form: Hospital Outpatient Administration




*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.

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.

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## 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**<br>**C91.00** Acute lymphoblastic leukemia not having achieved remission **OR**<br>**C91.01** Acute lymphoblastic leukemia, in remission **OR**<br>**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**<br>**96521** Refilling and maintenance of portable pump **OR**<br>**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]<br>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<br>**JW** Discarded drug/not administered to any patient<br>**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.<br>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]<br>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]<br>**E0781** Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient[22]<br>**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<br>**A4222** Infusion supplies for external drug infusion pump, per cassette or bag<br>**Modifiers for EIP**<br>**-KD** Drug or biologic infused through DME<br>**-RR** Rental<br>**-KH** DMEPOS item, initial claim or first rental month<br>**-KI** DMEPOS item, second or third rental months<br>**-KJ** DMEPOS item, fourth to 15th rental months | Report the appropriate EIP code and appropriate modifier(s) as documented in the medical record.<br>Modifiers may be used to provide additional detail when billing for the EIP to the DME MAC.[8]<br>Note: Drug administration codes may get billed to the MAC and the E-codes may get billed separately to the DME MAC.<br>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]<br>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.

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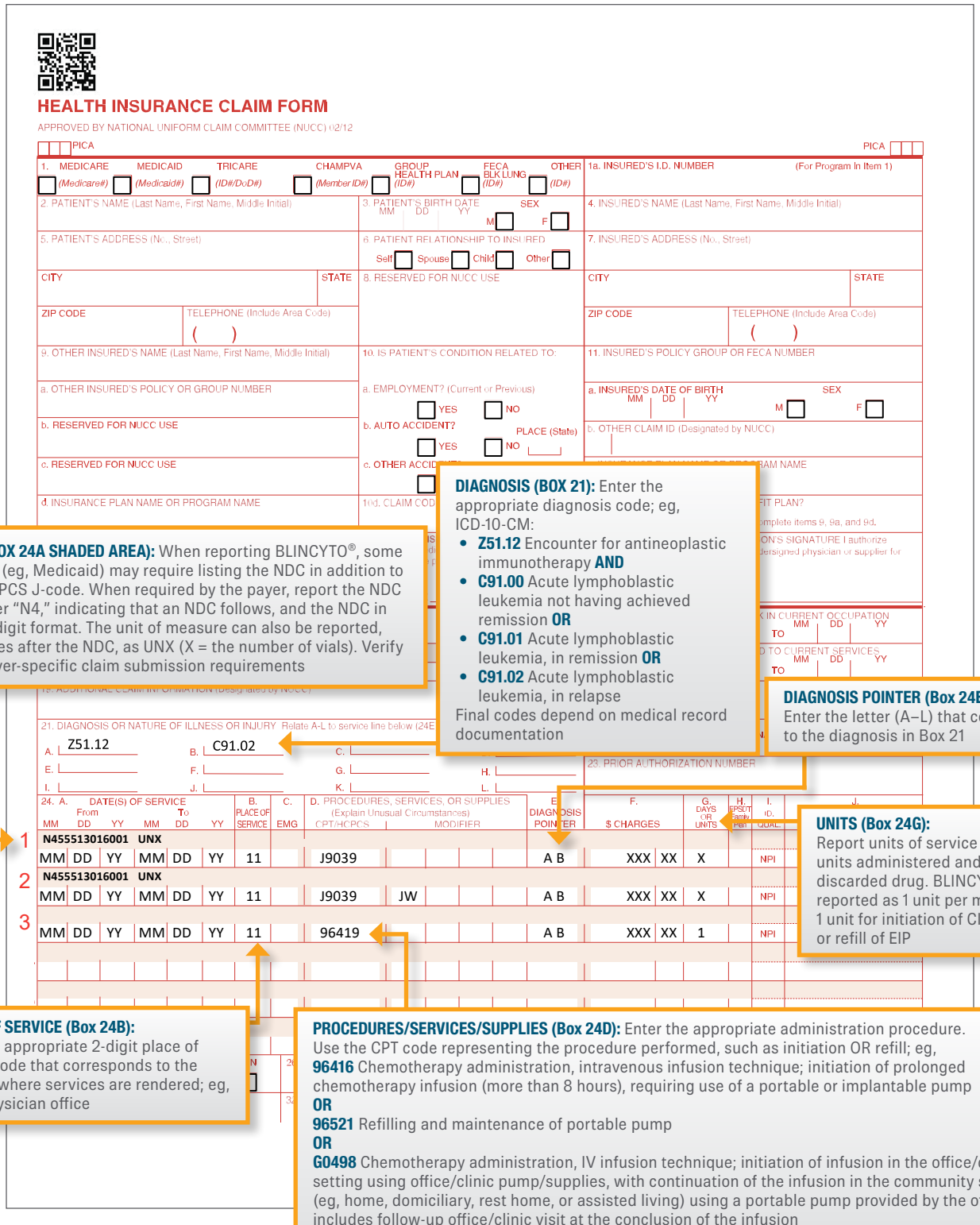
## Sample CMS-1500 Form: Physician Office Administration



HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program In Item 1)

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. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

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:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCID

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM COD

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)

A. Z51.12 B. C91.02 C. D. E. F. G. H. I. J. K. L.

22. PRIOR AUTHORIZATION NUMBER

| 24. A. DATE(S) OF SERVICE From MM DD YY | To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 N455513016001 UNX | | | | | | | | | | | |
| MM DD YY | MM DD YY | 11 | | J9039 | | A B | XXX | XX X | | NPI | |
| 2 N455513016001 UNX | | | | | | | | | | | |
| MM DD YY | MM DD YY | 11 | | J9039 | JW | A B | XXX | XX X | | NPI | |
| 3 MM DD YY | MM DD YY | 11 | | 96419 | | A B | XXX | XX 1 | | NPI | |

**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

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## 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**<br>**C91.00** Acute lymphoblastic leukemia not having achieved remission **OR**<br>**C91.01** Acute lymphoblastic leukemia, in remission **OR**<br>**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]<br>**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]<br>**99601** Home infusion/specialty drug administration, per visit (up to 2 hours)<br>**99602** Each additional hour<br>**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<br>**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<br>**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<br>**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.<br>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.<br>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]<br>These services may be covered by Medicaid, commercial plans, or Medicare Advantage plans.[20]<br>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.<br>Please note that FFS Medicare does not recognize S-codes, although other payers might.[20] |
| **Drug: BLINCYTO®** | **J9039** Injection, blinatumomab, 1 mcg<br>**JW** Discarded drug/not administered to any patient<br>**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]<br>Medicare sets maximum utilization at 875 units of service (UOS), which is equivalent to 25 vials per month in this site of care.[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]<br>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]<br>**E0781** Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient[22]<br>**A4222** Infusion supplies for external drug infusion pump, per cassette or bag<br>**Modifiers for EIP**<br>**-KD** Drug or biologic infused through DME<br>**-RR** Rental<br>**-KH** DMEPOS item, initial claim or first rental month<br>**-KI** DMEPOS item, second or third rental months<br>**-KJ** DMEPOS item, fourth to 15th rental months | Report the appropriate EIP code and appropriate modifier(s) as documented in the medical record.<br>Modifiers may be used to provide additional detail when billing for the EIP to the DME MAC.[8]<br>Report any supplies as necessary. |

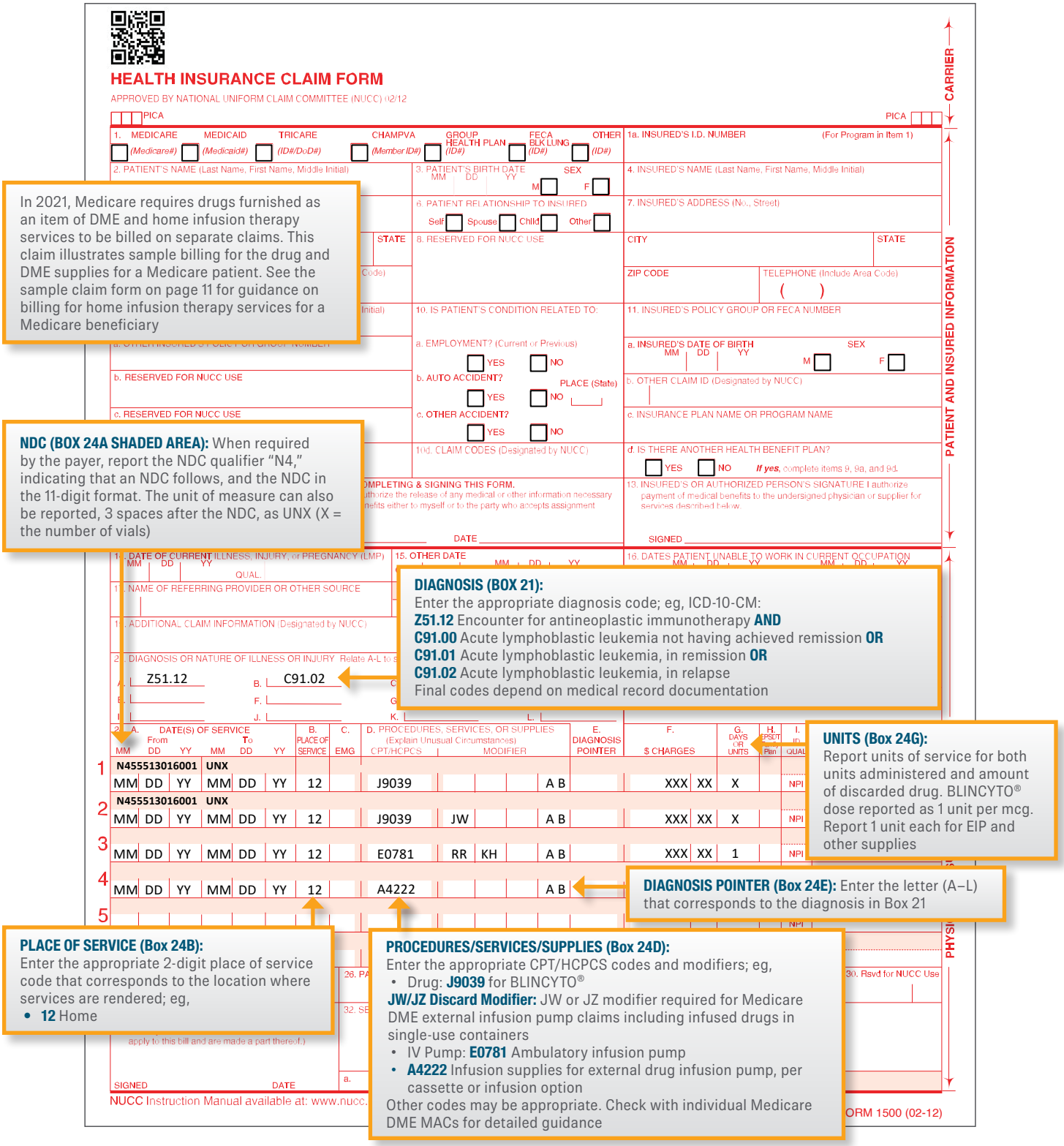
*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

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

# BLINCYTO®
# Billing Information Sheet

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

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




In 2021, Medicare requires drugs furnished as an item of DME and home infusion therapy services to be billed on separate claims. This claim illustrates sample billing for the drug and DME supplies for a Medicare patient. See the sample claim form on page 11 for guidance on billing for home infusion therapy services for a Medicare beneficiary

**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)

**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

**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 EIP and other supplies

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

**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/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

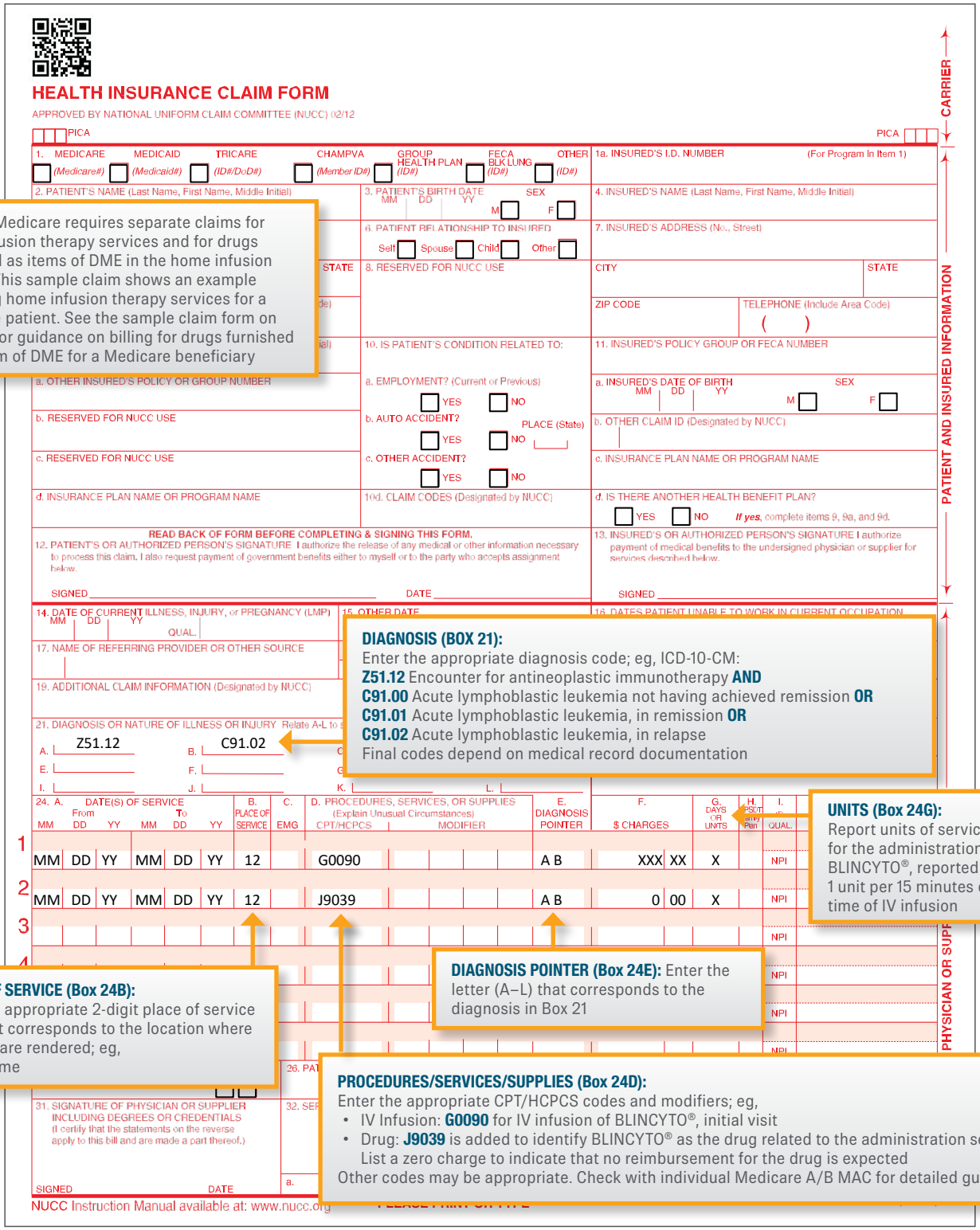
This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding 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

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

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




In 2021, Medicare requires separate claims for home infusion therapy services and for drugs furnished as items of DME in the home infusion setting. This sample claim shows an example for billing home infusion therapy services for a Medicare patient. See the sample claim form on page 10 for guidance on billing for drugs furnished as an item of DME for a Medicare beneficiary

**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

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

**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

**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

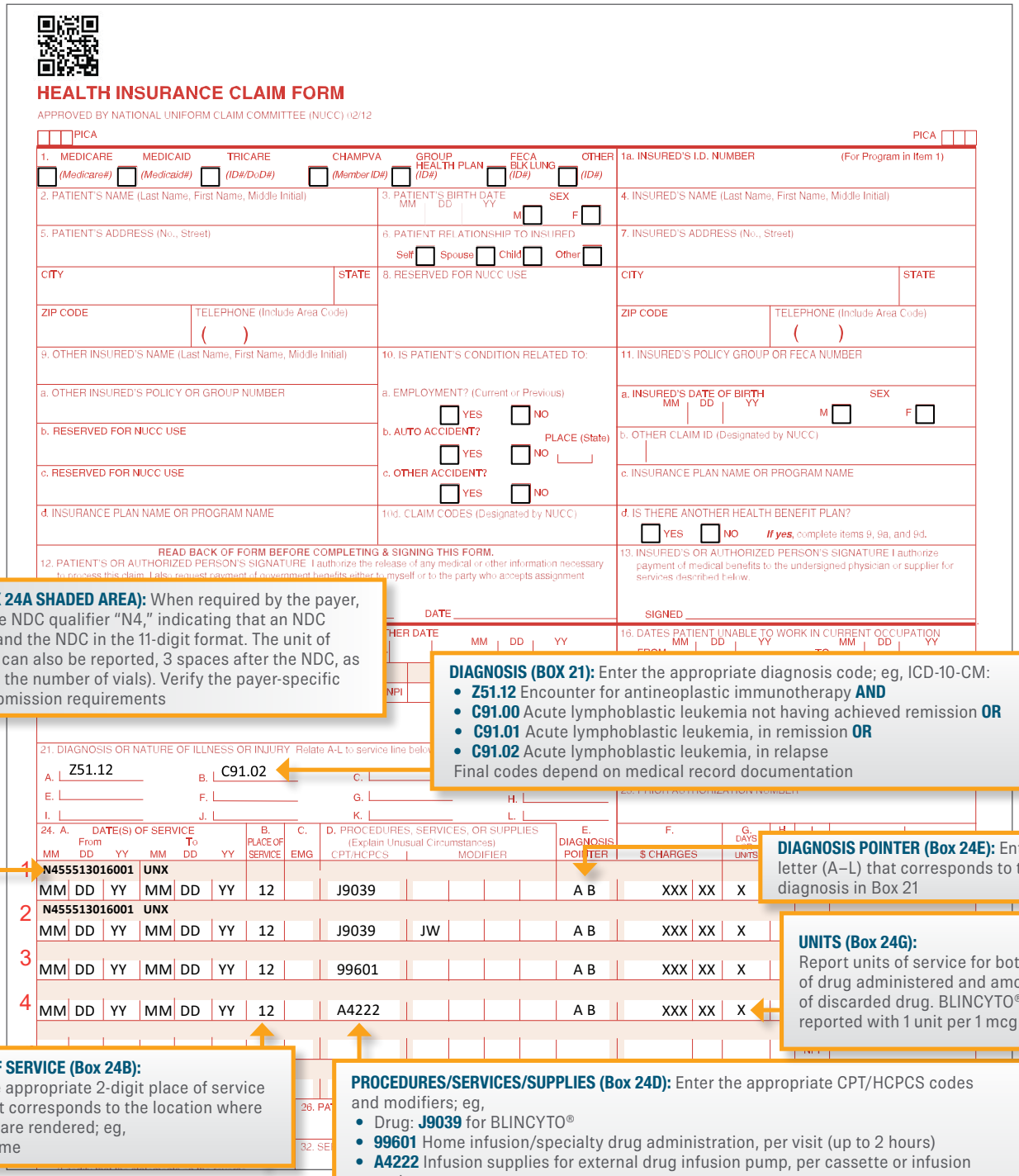
This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding 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

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

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




**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/HCPCS 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.

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

# BLINCYTO®
# Billing Information Sheet

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

**BLINCYTO® Dosing Options[11]**

| 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** |
| **7-day** | 35 mcg X 4-6 vials | **140-210** |

*Number of SDVs depends on dose, infusion duration, and patient's weight.[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 less than 45 kg, 4 to 5 vials are required. The safety of the administration of BLINCYTO® at a BSA of less than 0.4 $m^2$ 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.

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

# UNDERSTANDING EXAMPLES OF

BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial

# 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**

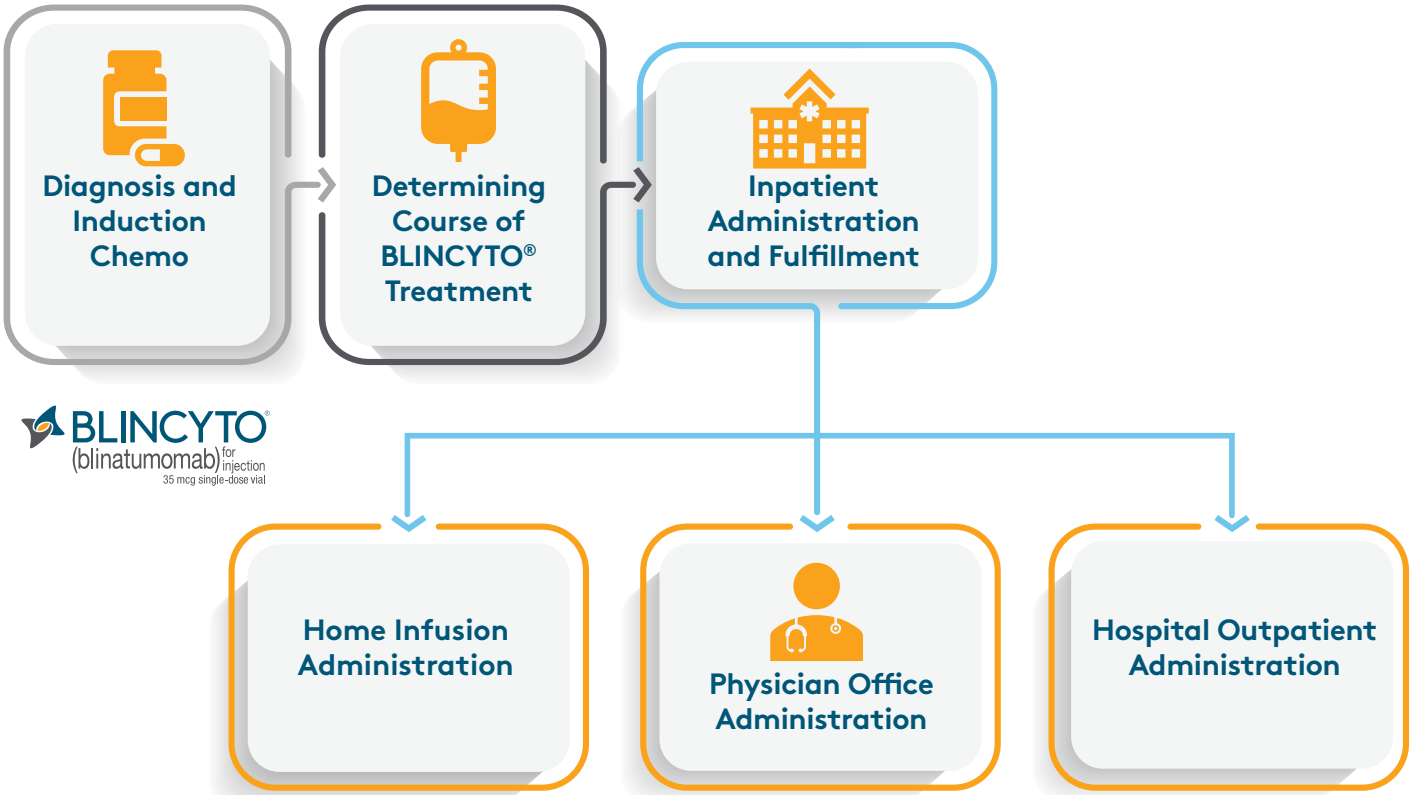
- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) 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®**<br>  | MS-DRG-based or global payment; typically includes BLINCYTO®[23]<br>Reimbursement varies by contracts between providers and payers<br>Some hospitals, in their contracts with managed care organizations, may negotiate a "carve out" benefit for drugs such as BLINCYTO®<br>• May allow separate payment of such drugs outside of the bundled payment for inpatient services | MS-DRG payment includes BLINCYTO®[24]<br>Covered under Medicare Part A benefit[25]<br>Hospital may be eligible for outlier payments if cost of admission exceeds certain threshold<br>Reimbursement varies for the 11 IPPS-Exempt Cancer Hospitals[26] | APR-DRG-based payment; typically includes BLINCYTO®[27]<br>Reimbursement varies by state; may follow Medicare allowable amounts |
| **Pump and Supplies**<br>  | | | |
| **Hospitalization**<br>  | | | |
| **Professional Services**<br>  | 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®**<br>  | Reimbursed based on contracted rates; methodology varies<br>Examples:[28]<br>• ASP + X%<br>• WAC + X%<br>• AWP – X%<br>May need prior authorization | Covered under Medicare Part B benefit<br>Typically reimbursed based on ASP + 6% when administered in a 340B hospital setting (with 2% sequestration reduction)[29,30]<br>MUE cap of 210 units (approx. 6 vials) per date of service applies[31,8] | Reimbursement may be similar to Medicare<br>OR<br>State-defined limit (eg, California uses a federal upper limit)[32]<br>May need prior authorization |
| **Pump and Supplies**<br>  | Reimbursement is bundled into the payment for the infusion service | Covered under Medicare Part B benefit<br>Reimbursement is bundled into the payment for the infusion service | Reimbursed based on fee schedule or bundled into the payment for the infusion service<br>Rates vary by state |
| **Professional Services**<br>  | Reimbursed based on contracted rate | Reimbursed based on the Medicare OPPS | |

Key: ASP – average sales price; AWP – average wholesale price; FFS – fee-for-service; MUE – medically unlikely edit; OPPS – 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<br>Examples:[28]<br>• ASP + X%<br>• WAC + X%<br>• AWP – X%<br>May need prior authorization | Covered under Medicare Part B benefit<br>Typically reimbursed based on ASP + 6% (with 2% sequestration reduction)[30,33]<br>MUE cap of 210 units (approx. 6 vials) per date of service applies[8,19] | Reimbursement may be similar to Medicare<br>OR<br>State-defined limit (eg, California uses a federal upper limit)[32]<br>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<br>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<br>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<br>Examples:[28]<br>• ASP + X%<br>• WAC + X%<br>• AWP – X%<br>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]<br>Typically reimbursed based on ASP + 6% (with 2% sequestration reduction)[30,33]<br>Billing cap of 25 vials per month applies[21] | Reimbursement may be similar to Medicare<br>OR<br>State-defined limit (eg, California uses a federal upper limit)[37]<br>May need prior authorization |
| **Pump and Supplies** | Reimbursed based on contracted rate | Covered under Medicare Part B benefit<br>Reimbursed as part of the Medicare DMEPOS Fee Schedule[35] | Typically reimbursed based on fee schedule<br>Rates vary by state |
| **Professional Services** | Reimbursed based on contracted rate | Covered under Part B<br>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

BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial

## 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 (≥ 10%) manifestations of neurological 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 over the age of 10 years may have a higher risk of seizures with BLINCYTO® therapy.

  Monitor patients for signs and symptoms of neurological toxicities, including ICANS, and interrupt or discontinue BLINCYTO® 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 cytoreduction 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 in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than

## IMPORTANT SAFETY INFORMATION *(continued)*

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® 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 BLINCYTO® full Prescribing Information, including BOXED WARNINGS.**

# SUPPORT SERVICES

AMGEN Support+

**CALL 866-264-2778**

Monday to Friday, 9:00 am to 8:00 pm ET,
or visit **www.AmgenSupportPlus.com**.

## 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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BLINCYTO® (blinatumomab) for injection
35 mcg single-use vial