

# BLINCYTO®

## Billing Information Sheet



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

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

## Billing Information Sheet



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

Item	Revenue Code <sup>5,6,*</sup>	Coding Information (ICD-10-CM <sup>7</sup> /CPT <sup>9</sup> /HCPCS <sup>8</sup> /NDC <sup>11</sup> )	Notes
<b>Diagnosis: Encounter for drug therapy and ALL</b>	N/A	<b>Z51.12</b> Encounter for antineoplastic immunotherapy <b>AND</b> <b>C91.00</b> Acute lymphoblastic leukemia not having achieved remission <b>OR</b> <b>C91.01</b> Acute lymphoblastic leukemia, in remission <b>OR</b> <b>C91.02</b> Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition.
<b>Procedure: Administration via CIVI using an EIP</b>	Report the appropriate revenue code for the cost center in which the service is performed; eg, <ul style="list-style-type: none"> <li>• <b>0261</b> IV therapy: Infusion pump</li> <li>• <b>026x</b> IV therapy</li> </ul>	<b>96416</b> Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump <b>OR</b> <b>96521</b> Refilling and maintenance of portable pump <b>OR</b> <b>G0498</b> 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. <sup>8,9,12</sup> 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. <sup>13</sup>
<b>Drug: BLINCYTO®</b>	Report the appropriate revenue code for the cost center in which the service is performed; eg, <ul style="list-style-type: none"> <li>• <b>Medicare: 0636</b> Drug requiring detailed coding</li> <li>• <b>Other payers: 0250 or 0636</b> General pharmacy (if required by a given payer)</li> </ul>	<b>J9039</b> Injection, blinatumomab, 1 mcg <b>JW</b> Discarded drug/not administered to any patient <b>JZ</b> Zero drug amount discarded/not administered to any patient <b>JG</b> Drug or biological acquired with 340B Drug Pricing Program discount <b>TB</b> 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). <sup>14</sup> 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). <sup>15</sup> 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. <sup>†</sup> 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. <sup>16</sup>
	N/A	<b>NDC: 55513016001</b> 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. <sup>17</sup> 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.



# BLINCYTO®

## Billing Information Sheet



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

Item	Revenue Code <sup>5,6,*</sup>	Coding Information (HCPCS <sup>2</sup> )	Notes
<b>DME: EIP and supplies</b>	Report the appropriate revenue code for the cost center in which the service is performed; eg, <b>0290</b> DME	<p><b>E0779</b> Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater <b>OR</b></p> <p><b>E0781</b> Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient <b>OR</b></p> <p><b>A4222</b> Infusion supplies for external drug infusion pump, per cassette or bag</p> <p><b>Modifiers for use with E-codes for IV pump</b></p> <p><b>-KD</b> Drug or biologic infused through DME</p> <p><b>-RR</b> Rental</p> <p><b>-KH</b> DMEPOS item, initial claim, purchase or first rental month</p> <p><b>-KI</b> DMEPOS item, second or third rental months</p> <p><b>-KJ</b> 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.<sup>8</sup></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.



# BLINCYTO®

## 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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679		680		681		682	
683		684		685		686	
687		688		689		690	
691		692		693		694	
695		696		697		698	
699		700		701		702	
703		704		705		706	
707		708		709		710	
711		712		713		714	
715		716		717		718	
719		720		721		722	
723		724		725		726	
727		728		729		730	
731		732		733		734	
735		736		737		738	
739		740		741		742	
743		744		745		746	
747		748		749		750	
751		752		753		754	
755		756		757		758	
759		760		761		762	
763		764		765		766	
767		768		769		770	
771		772		773		774	
775		776		777		778	
779		780		781		782	
783		784		785		786	
787		788		789		790	
791		792		793		794	
795		796		797		798	
799		800		801		802	
803		804		805		806	
807		808		809		810	
811		812		813		814	
815		816		817		818	
819		820		821		822	
823		824		825		826	
827		828		829		830	
831		832		833		834	
835		836		837		838	
839		840		841		842	
843		844		845		846	
847		848		849		850	
851		852		853		854	
855		856		857		858	
859		860		861		862	
863		864		865		866	
867		868		869		870	
871		872		873		874	
875		876		877		878	
879		880		881		882	
883		884		885		886	
887		88					



# BLINCYTO®

## Billing Information Sheet



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

Item	Coding Information (ICD-10-CM <sup>7</sup> /CPT <sup>9</sup> /HCPCS <sup>8</sup> /NDC <sup>11</sup> )	Notes
<b>Diagnosis:</b> Encounter for drug therapy and ALL	<b>Z51.12</b> Encounter for antineoplastic immunotherapy <b>AND</b> <b>C91.00</b> Acute lymphoblastic leukemia not having achieved remission <b>OR</b> <b>C91.01</b> Acute lymphoblastic leukemia, in remission <b>OR</b> <b>C91.02</b> Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM code(s) to describe the patient's condition.
<b>Procedure:</b> Administration via CIVI using an EIP	<b>96416</b> Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump <b>OR</b> <b>96521</b> Refilling and maintenance of portable pump <b>OR</b> <b>G0498</b> 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. <sup>8,9,12</sup>  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®.
<b>Drug:</b> BLINCYTO®	<b>J9039</b> Injection, blinatumomab, 1 mcg <b>JW</b> Discarded drug/not administered to any patient <b>JZ</b> Zero drug amount discarded/not administered to any patient	Medicare requires use of the HCPCS code in the physician office setting <sup>18</sup> and has a maximum utilization of 210 units per date of service (based on prescribing information). <sup>19</sup> 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. <sup>15</sup>  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.*
	<b>NDC: 55513016001</b> 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. <sup>17</sup> 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.
<b>DME:</b> EIP and supplies	<b>E0779</b> Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater <sup>22</sup> <b>E0781</b> Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient <sup>22</sup> <b>G0498</b> 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 <b>A4222</b> Infusion supplies for external drug infusion pump, per cassette or bag <b>Modifiers for EIP</b> <b>-KD</b> Drug or biologic infused through DME <b>-RR</b> Rental <b>-KH</b> DMEPOS item, initial claim or first rental month <b>-KI</b> DMEPOS item, second or third rental months <b>-KJ</b> 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. <sup>8</sup>  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. <sup>13</sup>  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	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED	
CITY	STATE	7. INSURED'S ADDRESS (No., Street)	
ZIP CODE	TELEPHONE (Include Area Code)	8. RESERVED FOR NUCC USE	
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		b. AUTO ACCIDENT? YES NO	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME		11. INSURED'S POLICY GROUP OR FECA NUMBER	

**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 <sup>7</sup> /CPT <sup>9</sup> /HCPCS <sup>8</sup> /NDC <sup>11</sup> )	Notes
<b>Diagnosis:</b> Encounter for drug therapy and ALL	<b>Z51.12</b> Encounter for antineoplastic immunotherapy <b>AND</b> <b>C91.00</b> Acute lymphoblastic leukemia not having achieved remission <b>OR</b> <b>C91.01</b> Acute lymphoblastic leukemia, in remission <b>OR</b> <b>C91.02</b> Acute lymphoblastic leukemia, in relapse	Report the appropriate ICD-10-CM code(s) to describe the patient's condition.
<b>Procedure:</b> Administration via CIVI using an EIP	<b>G0090</b> 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 <sup>1</sup> <b>G0070</b> 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 <sup>1</sup> <b>99601</b> Home infusion/specialty drug administration, per visit (up to 2 hours) <b>99602</b> Each additional hour <b>S9329</b> 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 <b>S9330</b> 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 <b>S9338</b> 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 <b>S9379</b> 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. <sup>1</sup> These services may be covered by Medicaid, commercial plans, or Medicare Advantage plans. <sup>20</sup> 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. <sup>20</sup>
<b>Drug:</b> BLINCYTO®	<b>J9039</b> Injection, blinatumomab, 1 mcg <b>JW</b> Discarded drug/not administered to any patient <b>JZ</b> 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. <sup>1</sup> <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> <sup>21</sup> 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. <sup>15</sup> 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.*
	<b>NDC: 55513016001</b> 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. <sup>17</sup> 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.
<b>DME:</b> EIP and supplies	<b>E0779</b> Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater <sup>22</sup> <b>E0781</b> Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient <sup>22</sup> <b>A4222</b> Infusion supplies for external drug infusion pump, per cassette or bag <b>Modifiers for EIP</b> <b>-KD</b> Drug or biologic infused through DME <b>-RR</b> Rental <b>-KH</b> DMEPOS item, initial claim or first rental month <b>-KI</b> DMEPOS item, second or third rental months <b>-KJ</b> 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. <sup>8</sup> 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 d. CLAIM CODES (Designated by NUCC)

**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** **22. PROCEDURES, SERVICES, OR SUPPLIES** (Explain Unusual Circumstances) **23. DIAGNOSIS POINTER** **24. \$ CHARGES** **25. DAYS OR UNITS** **26. PSCT** **27. ID** **28. QUAL**

**29. NDC** **30. RESERVED FOR NUCC USE**

**31. SIGNED** **DATE**

**32. NUCC Instruction Manual available at: www.nucc.org**

**33. FORM 1500 (02-12)**

**34. PHYSICIAN**

**35. CARRIER**

**36. PATIENT AND INSURED INFORMATION**

**37. 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)

**38. 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

**39. 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 applies<sup>21</sup>

**40. 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

**41. 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

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

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 ☐ PICA

1. MEDICARE ☐ MEDICAID ☐ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☐ FECA BLK (LUNG) ☐ OTHER ☐

(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#) (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)

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

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

8. RESERVED FOR NUCC USE

CITY STATE ZIP CODE TELEPHONE (Include Area Code)

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? YES ☐ NO ☐ PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES ☐ NO ☐

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

11d. CLAIM CODES (Designated by NUCC)

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.

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

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

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 21

A. Z51.12 B. C91.02

24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS (or UNITS) H. PSCT I. J. QUAL.

1 MM DD YY MM DD YY 12 G0090 A B XXX XX X NPI

2 MM DD YY MM DD YY 12 J9039 A B 0 00 X NPI

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

**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

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

**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

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.)

32. SIGNATURE OF PATIENT OR AUTHORIZED REPRESENTATIVE

SIGNED DATE

a.

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#)
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		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE	
DATE		SIGNED	
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION	

**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 Options<sup>11</sup>**

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

\*Number of SDVs depends on dose, infusion duration, and patient's weight.<sup>11</sup>

<sup>†</sup>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.<sup>11</sup>

<sup>‡</sup>Prepared with Bacteriostatic 0.9% Sodium Chloride Injection (containing 0.9% benzyl alcohol).<sup>11</sup>

## 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.<sup>20</sup>



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 m<sup>2</sup> has not been established.<sup>11</sup> 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.<sup>20</sup>



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.<sup>20</sup>



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:<sup>20</sup>

- 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.

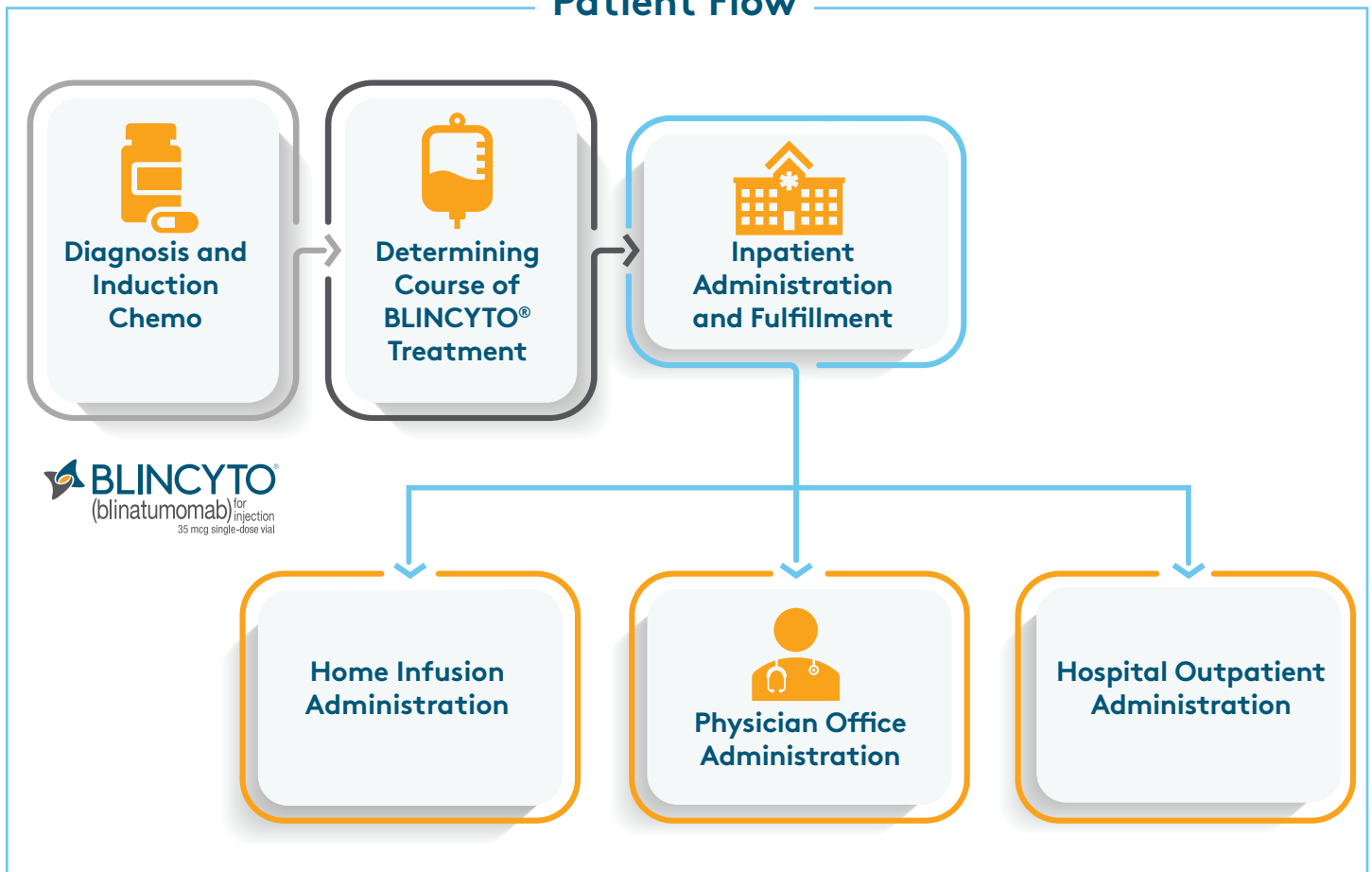
Please see additional Important Safety Information for BLINCYTO® on pages 18-19.



# 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
<b>BLINCYTO®</b> 	MS-DRG-based or global payment; typically includes BLINCYTO® <sup>23</sup>  Reimbursement varies by contracts between providers and payers	MS-DRG payment includes BLINCYTO® <sup>24</sup>  Covered under Medicare Part A benefit <sup>25</sup>  Hospital may be eligible for outlier payments if cost of admission exceeds certain threshold  Reimbursement varies for the 11 IPPS-Exempt Cancer Hospitals <sup>26</sup>	APR-DRG-based payment; typically includes BLINCYTO® <sup>27</sup>  Reimbursement varies by state; may follow Medicare allowable amounts
<b>Pump and Supplies</b> 	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"> <li>May allow separate payment of such drugs outside of the bundled payment for inpatient services</li> </ul>		
<b>Hospitalization</b> 			
<b>Professional Services</b> 	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
<b>BLINCYTO®</b> 	Reimbursed based on contracted rates; methodology varies Examples: <sup>28</sup> <ul style="list-style-type: none"> <li>ASP + X%</li> <li>WAC + X%</li> <li>AWP – X%</li> </ul> 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) <sup>29,30</sup>  MUE cap of 210 units (approx. 6 vials) per date of service applies <sup>31,8</sup>	Reimbursement may be similar to Medicare  OR State-defined limit (eg, California uses a federal upper limit) <sup>32</sup>  May need prior authorization
<b>Pump and Supplies</b> 	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
<b>Professional Services</b> 	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
<b>BLINCYTO®</b> 	Reimbursed based on contracted rates; methodology varies Examples: <sup>28</sup> <ul style="list-style-type: none"> <li>• ASP + X%</li> <li>• WAC + X%</li> <li>• AWP – X%</li> </ul> May need prior authorization	Covered under Medicare Part B benefit Typically reimbursed based on ASP + 6% (with 2% sequestration reduction) <sup>30,33</sup> MUE cap of 210 units (approx. 6 vials) per date of service applies <sup>8,19</sup>	Reimbursement may be similar to Medicare OR State-defined limit (eg, California uses a federal upper limit) <sup>32</sup> May need prior authorization
<b>Pump and Supplies</b> 	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
<b>Professional Services</b> 	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
<b>BLINCYTO®</b> 	Reimbursed based on contracted rates; methodology varies Examples: <sup>28</sup> <ul style="list-style-type: none"> <li>• ASP + X%</li> <li>• WAC + X%</li> <li>• AWP – X%</li> </ul> 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 <sup>34</sup> Typically reimbursed based on ASP + 6% (with 2% sequestration reduction) <sup>30,33</sup> Billing cap of 25 vials per month applies <sup>21</sup>	Reimbursement may be similar to Medicare OR State-defined limit (eg, California uses a federal upper limit) <sup>37</sup> May need prior authorization
<b>Pump and Supplies</b> 	Reimbursed based on contracted rate	Covered under Medicare Part B benefit Reimbursed as part of the Medicare DMEPOS Fee Schedule <sup>35</sup>	Typically reimbursed based on fee schedule Rates vary by state
<b>Professional Services</b> 	Reimbursed based on contracted rate	Covered under Part B Reimbursed under the home infusion therapy services benefit in 15-minute increments for applicable providers <sup>36</sup>	

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.  
  
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 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<sup>®</sup> treatment. BLINCYTO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- **Preparation and administration** errors have occurred with BLINCYTO<sup>®</sup> 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<sup>®</sup> treatment, during treatment, and until immune recovery following last cycle of BLINCYTO<sup>®</sup>.
- **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<sup>®</sup> where possible in neonates. When prescribing BLINCYTO<sup>®</sup> (with preservative) for neonatal patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO<sup>®</sup> (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<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and for 48 hours after the last dose.

## Adverse Reactions

- The safety of BLINCYTO<sup>®</sup> 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<sup>®</sup> in this pooled population were pyrexia, infusion-related reactions, headache, infection, musculoskeletal pain, neutropenia, nausea, anemia, thrombocytopenia, and diarrhea.

## Dosage and Administration Guidelines

- BLINCYTO<sup>®</sup> 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<sup>®</sup> [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<sup>®</sup>**

Visit **AmgenTherapyLocator.com** to locate alternative sites where BLINCYTO<sup>®</sup> 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<sup>+</sup>**

1234 5678 9100 0123

ROUTINE: XXXXXX MEMBER ID: XXXXXXXXXX  
PCN: XX GROUP: XXXXXXXXXX

Questions? Call (866) 264-2778

**AMGEN® Support<sup>+</sup> | 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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