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 FDA-approved dosing options in inpatient and outpatient treatment settings.

Updates for 2018 include:

• Information on billing the 7-day infusion option (7-DIO) in addition to the shorter-duration 24-hour and 48-hour bags

<table>
<thead>
<tr>
<th>Dosing option</th>
<th>Dose per vial X number of single-dose vials (SDVs*)</th>
<th>Number of billing units</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour</td>
<td>35 mcg X 1 vial</td>
<td>35</td>
</tr>
<tr>
<td>48-hour</td>
<td>35 mcg X 1-2 vials</td>
<td>35-70</td>
</tr>
<tr>
<td>7-day</td>
<td>35 mcg X 4-6 vials</td>
<td>140-210</td>
</tr>
</tbody>
</table>

• New coding requirement for BLINCYTO® administered in the outpatient setting of 340B hospitals
  – The Centers for Medicare & Medicaid Services (CMS) requires use of new modifiers on Medicare claims for drugs acquired under the 340B Drug Discount Program

• Medicare patients receiving BLINCYTO® in the inpatient setting are no longer eligible for additional reimbursement
  – The new technology add-on payment (NTAP) designation has been retired; hospitals may still be eligible for outlier payments based on payer guidance and managed care contract provisions

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

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® is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children.

This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

BLINCYTO® is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.
### BLINCYTO® Billing Information Sheet

#### Hospital Inpatient (HIP) Site of Service

<table>
<thead>
<tr>
<th>Item</th>
<th>Revenue Code*</th>
<th>Coding Information (ICD-10-CM/HCPCS/NDC/CPT/ICD-10-PCS)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis:</strong> Encounter for drug therapy and ALL</td>
<td>N/A</td>
<td>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</td>
<td>Report the appropriate ICD-10-CM diagnosis code(s) to describe the patient’s condition. Basic diagnosis coding and billing for BLINCYTO® indication is consistent across all formulations.</td>
</tr>
<tr>
<td><strong>Drug:</strong> BLINCYTO® and external infusion pump (EIP)</td>
<td>J9039 Injection, blinatumomab, 1 mcg</td>
<td>NDC: 55513-0160-01 BLINCYTO® 35 mcg lyophilized powder, single-dose vial (SDV) intravenous (IV) solution stabilizer, 10 mL SDV</td>
<td>HCPCS codes are not required by Medicare in the HIP, but they may be used for itemization purposes with all payers. Some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. For most payers, the number of billing units per HCPCS code is reported using increments of the value as listed in the code description. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format. 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.</td>
</tr>
<tr>
<td></td>
<td>E0791 Parenteral infusion pump, stationary, single or multi-channel E0776 IV pole</td>
<td>Report the appropriate revenue code for the cost center in which the service is performed; eg, • 0250 General pharmacy • Other payers: 0250 (or 0636 for Drugs requiring detailed coding, if required by a given payer)</td>
<td>HCPCS codes are not required by Medicare in the HIP, but they may be used for itemization purposes with all payers. Report the appropriate HCPCS code for the EIP and supplies as documented in the medical record.</td>
</tr>
<tr>
<td><strong>Administration:</strong> Continuous intravenous infusion (CIVI) via EIP</td>
<td>96416 Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR 96521 Refilling and maintenance of a portable pump XW03351 Introduction of blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1 OR XW04351 Introduction of blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1</td>
<td>The Medicare NTAP designation has been retired. However, hospitals will still need to report the appropriate ICD-10-PCS code to account for the administration procedure. HCPCS codes are not required by Medicare in the HIP, but they may be used for itemization purposes with all payers. Report the appropriate HCPCS code for the infusion service provided as documented in the medical record.</td>
<td></td>
</tr>
</tbody>
</table>

**Coding Information Definitions:**
- ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification
- HCPCS – Healthcare Common Procedure Coding System
- NDC – National Drug Code
- 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.
BLINCYTO® Billing Information Sheet

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

**Sample UB-04 (CMS-1450) Form**

**Hospital Information:**
- Anytown Hospital
  - 100 Main Street
  - Anytown, Anystate 01010

**Patient Information:**
- Patient Name: Smith, Jane
  - Address: 123 Main Street, Anytown, Anystate 12345

**Completing the CMS-1450 for Hospital Inpatient Admission for Dates of Service on or After 01/01/2015**

**Z51.12**
- Encounter for antineoplastic immunotherapy

**C91.00**
- Acute lymphoblastic leukemia not having achieved remission

**C91.01**
- Acute lymphoblastic leukemia, in remission

**C91.02**
- Acute lymphoblastic leukemia, in relapse

**Total Codes:**
- Final codes depend on medical record documentation and payer requirements

**SERVICE UNITS (Field 46):**
- Report units of service for both units administered and amount of discarded drug.
- BLINCYTO® dose reported as 1 unit per mcg

**TOTAL CHARGES (Field 47):**
- Report appropriate charges for product used and related procedures

**PRODUCT AND PROCEDURE CODES (Field 44):**
- HCPCS and CPT codes are not required by Medicare in the HIP, but they may be used for itemization purposes with all payers

**Product**
- Medicare: Enter the HCPCS code representing BLINCYTO® administered through EIP; eg, J9039 (blinatumomab) per 1 mcg.
- Verify payer requirements for reporting discarded drug with modifier JW

**EIP:**
- Enter the HCPCS code representing the EIP and supplies used; eg,
  - E0791 Parenteral infusion pump, stationary, single or multi-channel
  - E0776 IV pole

**REVENUE CODES* (Field 42) and DESCRIPTIONS (Field 43):**
- Medicare: 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)

**DIAGNOSIS CODES* (Field 67 and 67A–Q):**
- Enter the appropriate diagnosis code; eg, ICD-10-CM:
  - Z51.12 Encounter for antineoplastic immunotherapy
  - C91.00 Acute lymphoblastic leukemia not having achieved remission
  - C91.01 Acute lymphoblastic leukemia, in remission
  - C91.02 Acute lymphoblastic leukemia, in relapse

**Final Codes:**
- Final codes depend on medical record documentation and payer requirements

**REMARKS (Field 80):**
- 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 in the 11-digit format. Verify the payer-specific claim submission requirements

**PRINCIPAL PROCEDURE (Field 74):**
- Enter principal ICD-10-PCS procedure code
  - XW03351 Introduction of blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1
  - XW04351 Introduction of blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1

*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.
<table>
<thead>
<tr>
<th>Item</th>
<th>Revenue Code*</th>
<th>Coding Information (ICD-10-CM/CPT/HCPCS/NDC)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis: Encounter for drug therapy and ALL</td>
<td></td>
<td>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</td>
<td>Report the appropriate ICD-10-CM diagnosis code(s) to describe the patient’s condition. Basic diagnosis coding and billing for BLINCYTO® indication is consistent across all formulations.</td>
</tr>
<tr>
<td>Procedure: Administration via CIVI using an EIP</td>
<td></td>
<td>96416 Chemotherapy administration, IV infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR 96521 Refilling and maintenance of portable pump OR G0498 Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion</td>
<td>CPT codes may be used to report the CIVI procedures associated with BLINCYTO® to the Part A/B Medicare Administrative Contractor (MAC) and non-Medicare payer. For Medicare patients, HCPCS code G0498 will replace CPT 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 (HI). The healthcare provider should consult the payer or MAC to determine which code is most appropriate for administration of BLINCYTO®. There are no differences in how to code for the infusion administration procedure among the different formulations of BLINCYTO®.</td>
</tr>
<tr>
<td>Drug: BLINCYTO®</td>
<td></td>
<td>J9039 Injection, blinatumomab, 1 mcg JW* Discarded drug JG* Drug or biological acquired with 340B Drug Pricing Program discount TB* Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes</td>
<td>Medicare policies reflect the code for BLINCYTO® (J9039 per 1 mcg). However, coding requirements may vary by payer. Like many payers, Medicare requires the use of the modifier JW, 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. Effective on and after dates of service starting January 1, 2018, Medicare providers who are not exempt from the 340B payment adjustment will report modifier &quot;JG&quot; to identify if a drug was acquired under the 340B program. Exempt facilities that include children’s hospitals, certain cancer centers, and rural sole community hospitals will need to report modifier &quot;TB&quot; on Medicare claims if the drug was acquired under 340B. The TB modifier is for informational purposes only and will not impact reimbursement. 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. 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.</td>
</tr>
</tbody>
</table>

*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

Hospital Outpatient Department (HOPD) (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Revenue Code*</th>
<th>Coding Information (HCPCS&lt;sup&gt;6&lt;/sup&gt;)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME: EIP and supplies</td>
<td></td>
<td>E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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</td>
<td>Note: Drug administration codes may get billed to the MAC and the E-codes may get billed separately to the DME MAC. 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 using the E-codes. Report any supplies as necessary. Basic coding and billing for a BLINCYTO®-related EIP is consistent across all formulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A4222 Infusion supplies for external drug infusion pump, per cassette or bag</td>
<td></td>
</tr>
</tbody>
</table>

*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

**Anytown Hospital**
100 Main Street
Anytown, Anystate 01010

**Patient Name:** Smith, Jane
**Address:** 123 Main Street, Anytown, Anystate 12345

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**SERVICE UNITS (Field 46):**
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.

**TOTAL CHARGES (Field 47):**
Report appropriate charges for product used and related procedures.

**REVENUE CODES* (Field 42) and DESCRIPTIONS (Field 43):**
Use most appropriate revenue code for cost center for services (eg, 0261 for CIVI therapy [initiation or refill] via EIP).

**PRODUCT AND PROCEDURE CODES (Field 44):**
Administration procedure:
Use the CPT code representing the procedure performed, such as initiation or refill; eg, J9039 — Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump.

**REMARKS (Field 80):**
Identify the drug being administered as BLINCYTO® and provide a concise description of the services provided. Some payers (eg, Medicaid) may require listing the NDC in addition to the HCPCS J-code. When required by the payer, report the NDC in the 11-digit format. Verify the payer-specific claim submission requirements.

**DIAGNOSIS CODES (Field 67 and 67A–Q):**
Enter the appropriate diagnosis code, eg, ICD-10-CM:
- Z51.12 Encounter for antineoplastic immunotherapy
- C91.00 Acute lymphoblastic leukemia not having achieved remission
- C91.01 Acute lymphoblastic leukemia, in remission
- C91.02 Acute lymphoblastic leukemia, in relapse

Final codes depend on medical record documentation.

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*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.*
## BLINCYTO® Billing Information Sheet

### Physician Office

<table>
<thead>
<tr>
<th>Item</th>
<th>Coding Information (ICD-10-CM/CPT/HCPCS/NDC)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis: Encounter for drug therapy and ALL</td>
<td><strong>Z51.12</strong> Encounter for antineoplastic immunotherapy</td>
<td>Report the appropriate ICD-10-CM code(s) to describe the patient’s condition. Basic diagnosis coding and billing for BLINCYTO® indication is consistent across all formulations.</td>
</tr>
<tr>
<td>AND <strong>C91.00</strong> Acute lymphoblastic leukemia not having achieved remission OR <strong>C91.01</strong> Acute lymphoblastic leukemia, in remission OR <strong>C91.02</strong> Acute lymphoblastic leukemia, in relapse</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Procedure: Administration via CIVI using an EIP | **96416** Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours) requiring use of a portable or implantable pump OR **96521** Refilling and maintenance of portable pump OR **G0498** Chemotherapy administration, IV infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (eg, home, domiciliary, rest home, or assisted living) using a portable pump provided by the office/clinic; includes follow-up office/clinic visit at the conclusion of the infusion | CPT codes may be used to report the CIVI procedures associated with BLINCYTO® to the Part A/B MAC and non-Medicare payers. For Medicare patients, HCPCS code G0498 will replace CPT codes (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 HI.  
6,9,11 The healthcare provider should consult the payer or MAC to determine which code is most appropriate for administration of BLINCYTO®.  
There are no differences in how to code for the infusion administration procedure among the different formulations of BLINCYTO®. |
| | **J9039** Injection, blinatumomab, 1 mcg | Medicare requires use of the HCPCS code in the physician office setting. However, coding requirements may vary by payer.7  
Like many payers, Medicare requires the use of the modifier JW, 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.12 |
| JW** Discarded drug | | 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.8 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. |
| **NDC: 55513-0160-01** BLINCYTO® 35 mcg lyophilized powder, SDV IV solution stabilizer, 10 mL SDV | | Report any supplies as necessary. Basic coding and billing for a BLINCYTO®-related EIP is consistent across all formulations. |
| DME: EIP and supplies | **E0779** Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater **E0781** Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient **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 **Modifiers for EIP** - **KD** Drug or biologic infused through DME - **RR** Rental - **KH** DMEPOS item, initial claim or first rental month - **KI** DMEPOS item, second or third rental months - **KJ** DMEPOS item, fourth to 15th rental months **A4222** Infusion supplies for external drug infusion pump, per cassette or bag | 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.6  
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 using the E-codes.13  
Report any supplies as necessary. Basic coding and billing for a BLINCYTO®-related EIP is consistent across all formulations. |
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.
### Home Infusion - Multiple Payers (Medicare and non-Medicare)

<table>
<thead>
<tr>
<th>Item</th>
<th>Coding Information (ICD-10-CM/CPT/HCPCS/NDC*)</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td><strong>Diagnosis:</strong> Encount er for drug therapy and ALL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>Report the appropriate ICD-10-CM code(s) to describe the patient’s condition. Basic diagnosis coding and billing for BLINCYTO® indication is consistent across all formulations.</td>
</tr>
<tr>
<td><strong>Procedure:</strong> Administration via CIVI using an EIP</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>99601 Home infusion/specialty drug administration, per visit (up to 2 hours) 99602 Each additional hour S9329 HI therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9330 HI therapy, continuous (24 hours or more) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9338 HI therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem S9379 HI 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</td>
<td>Providers may report HI services, routine and non-routine medical supplies, and home health aide and medical social services for the treatment of illness or injury. For the service to be covered under fee-for-service (FFS) Medicare, patients must be certified “homebound” (eg, homebound certification form CMS-485) and under a physician’s plan of care. Nursing services are not covered by Medicare if the patient, who is not certified as “homebound,” has only FFS Medicare or FFS Medicare with a Medicare supplement. These services may be covered by Medicaid, commercial plans, or Medicare Advantage plans. Please note that FFS Medicare does not recognize S-codes, although other payers might. The healthcare provider should consult the payer to determine which code is most appropriate for administration of BLINCYTO®. There are no differences in how to code for the infusion administration procedure among the different formulations of BLINCYTO®.</td>
</tr>
<tr>
<td><strong>Drug:</strong> BLINCYTO®</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>J9039 Injection, blinatumomab, 1 mcg JW Discarded drug</td>
<td>Many payers require the use of the modifier JW, 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. 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. 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.</td>
</tr>
<tr>
<td><strong>NDC:</strong> 55513-0160-01 BLINCYTO® 35 mcg lyophilized powder, SDV IV solution stabilizer, 10 mL SDV</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DME:</strong> EIP and supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient</td>
<td>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 MAC. Report any supplies as necessary. Basic coding and billing for a BLINCYTO®-related EIP is consistent across all formulations.</td>
</tr>
</tbody>
</table>
Sample CMS-1500 Form: Non-Medicare Payer by Home Infusion Provider

**HEALTH INSURANCE CLAIM FORM**

**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. 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.

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

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

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.
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.15

The 7-DIO requires 6 vials of BLINCYTO® and 1 vial of IV Solution Stabilizer for patients ≥ 45kg. For patients weighing 22 to 44kg, 4 to 5 vials are required.1 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.15

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.15

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:15
- The entities that can bill for DME and the associated supplies
- The number of units billed for BLINCYTO® J9039
- 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)
Indications

BLINCYTO® is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children.

This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

BLINCYTO® is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

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.

Please click here to access the full Prescribing Information, including Boxed WARNINGS and Medication Guide, for BLINCYTO®.