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

Supporting your patients' BLINCYTO® treatment journey

Considerations for your healthcare team while discharging patients on BLINCYTO®, from treatment initiation through continuation of care

INDICATION

- BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive 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 adult and pediatric patients.
- BLINCYTO® is indicated for the treatment of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients.

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.**

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Coming together to help guide patients through their BLINCYTO® treatment journey

Discharge planning early on can be an important factor in a patient's smooth transition to outpatient treatment.

Considerations for your Discharge Planning Team

Treatment Initiation

- Prepare for BLINCYTO® treatment, including hospitalization preparation
- Conduct benefits verification and ensure coverage
- Consider discussing coverage options with your patient to determine the feasibility of home health care

Before Discharge

- Evaluate patient benefit coverage
- Confirm patient has an outside advocate or caregiver (eg, a family member or social worker)
- Connect the patient and caregiver with the multidisciplinary team

Continued Care After Discharge

- Prepare for hospital discharge and continuation of care with multidisciplinary team
  - **Outpatient site of care considerations:**
    - Patient has educational resources and contact numbers for support
    - Arrangements are in place for outpatient site of care
    - Proximity to site of care, or lodging and potential transportation needs
  - **Home health considerations:**
    - Medication needs to be stored correctly
    - Location of ambulatory infusion services being provided
    - Hospital introductions and first home visits by home health care provider are scheduled
- Provide patient with home health contact information

AMGEN® Support+

Resources that can help support your patient's needs

Patient benefit verification* and provider resources

Submit, store, and retrieve benefit verifications electronically for all patients currently on Amgen Oncology medications with ease from our secure Amgen® SupportPlus Customer Portal

- Visit myAmgenPortal.com to register and submit forms online
- Submit a benefit verification request by calling Amgen® SupportPlus at (866) 264-2778, or faxing a completed Benefit Verification Form to 1-888-407-9787
  - Access form at www.amgensupportplus.com/hcp/blincyto
  - Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.
- AmgenTherapyLocator.com is a searchable database of locations and home infusion agencies where BLINCYTO® can be administered, if needed†

Ongoing patient support and provider resources

- Can process benefit verifications and provide Summaries of Benefits for:
  - Outpatient clinic nurse for patient intake

  OR
  - Home health care agency for patient intake
- Call an Amgen® SupportPlus Representative directly for your benefit verification needs by calling (866) 264-2778, or schedule a remote or live appointment with an Amgen® Access Specialist by visiting www.amgensupportplus.com/hcp/blincyto.
  - An Amgen Access Specialist can provide coverage and access resources to support your patients.
- The BLINCYTO® Home Infusion Treatment Referral Form is available to assist with referral to home infusion agency

Additional Patient Support Resources

- Dedicated Amgen Nurse Partners† can offer supplemental support and provide information about resources to help patients access their prescribed medication.
- The Amgen SupportPlus Co-Pay Program may help eligible commercially insured patients pay for their out-of-pocket prescription costs.
- 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.‡

▲ **Please review a sample BLINCYTO® Home Infusion Treatment Referral Form, included with this guide.**
You can download these forms at AmgenTherapyLocator.com or obtain them from your Amgen representative.

*Benefits information is provided as a courtesy only and is not comprehensive or instructive. Coding and coverage policies can change without warning. The HCP is solely responsible for determining coverage, coding, and reimbursement. Amgen does not guarantee coverage or reimbursement.

†Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

‡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.

IMPORTANT SAFETY INFORMATION

Contraindications

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Warnings and Precautions

- Cytokine Release Syndrome (CRS): CRS, which may be life-threatening or fatal, occurred in 15% of patients with R/R ALL and in 7% of patients with MRD-positive ALL. 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 (TBILI), and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO® overlap with those of infusion reactions, capillary leak syndrome, and hemophagocytic histiocytosis/ macrophage activation syndrome. If severe CRS occurs, interrupt BLINCYTO® until CRS resolves. Discontinue BLINCYTO® permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.
- Neurological Toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome: BLINCYTO can cause serious or life-threatening neurologic toxicity, including ICANS. The incidence of neurologic toxicities in clinical trials was approximately 65%. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment. The most common (≥ 10%) manifestations of neurological toxicity were headache and tremor. Grade 3 or higher neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. The majority of neurologic toxicities resolved following interruption of BLINCYTO, but some resulted in treatment discontinuation.

  The incidence of signs and symptoms consistent with ICANS in clinical trials was 7.5%. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Monitor patients for signs or symptoms of neurological toxicities, including ICANS, and interrupt or discontinue BLINCYTO® as outlined in the PI.
- 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 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and TBILI prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBILI rises to > 3 times ULN.
- Pancreatitis: Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.
- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- Preparation and administration errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).
- Immunization: Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.
- Benzyl Alcohol Toxicity in Neonates: Serious adverse reactions, including fatal reactions and the "gasping syndrome," have been reported in very low birth weight (VLBW) neonates born weighing less than 1500 g, and early preterm neonates (infants born less than 34 weeks gestational age) who received intravenous drugs containing benzyl alcohol as a preservative. Early preterm VLBW neonates may be more likely to develop these reactions, because they may be less able to metabolize benzyl alcohol.

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

  Monitor neonatal patients receiving BLINCYTO® (with preservative) for new or worsening metabolic acidosis. The minimum amount of benzyl alcohol at which serious adverse reactions may occur in neonates is not known. The BLINCYTO® 7-Day bag (with preservative) contains 7.4 mg of benzyl alcohol per mL
- Embryo-Fetal Toxicity: Based on its mechanism of action, BLINCYTO® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with BLINCYTO® and for 48 hours after the last dose.

Adverse Reactions

- The most common adverse reactions (≥ 20%) are pyrexia, infusion-related reactions, infections (pathogen unspecified), headache, neutropenia, anemia, and thrombocytopenia.

Dosage and Administration Guidelines

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

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Home infusion treatment referral form

❑ Please submit this completed form with a patient face sheet and supplemental relevant clinical notes.
Fax completed form and additional documentation to Home Infusion Agency.

Referring Physician Information

Ordering Physician Name: _____ NPI #: _____

Address: _____

Phone: _____ Fax: _____

Hospital/Clinic: _____

Case Manager Name: _____ Phone: _____

Servicing Provider Information

Infusion Service Provider: _____

Branch Location Address: _____

Patient Information

Fill out entirely OR ❑ **attach Face/Demographic Information Sheet**

Patient Name: _____ Date of Birth: _____

Address: _____

Address where patient is receiving Home Infusion (if different from address on patient face sheet) Phone: _____

Primary Caregiver (if applicable): _____ Phone: _____

Insurance Information

Fill out primary insurance plan name and member insured AND attach face sheet with insurance information OR ❑ **fax a copy of insurance card, front and back**

Primary Insurance: _____

Insured: _____

Phone: _____ Policy #: _____ BIN #: _____ RX #: _____
(if patient face sheet does not include insurance information)

Physician, please provide a clear/readable copy of the front and back of the insurance card including pharmacy benefit information.

Important information for Medicare Fee-for-Service (FFS) patients:

Blinatumomab (J9039) via an external infusion pump is only covered for:

- Up to nine (9) cycles for adult and pediatric beneficiaries with relapsed or refractory (R/R) CD19-positive B-Cell precursor acute lymphoblastic leukemia (ALL)

OR

- Up to four (4) cycles for adult and pediatric beneficiaries with CD19-positive B-Cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%

If the patient does not meet this criteria, then coverage [shifts] to Medicare Part D.

Patient Medical Information

Primary Diagnosis Code: ❑ C91.00 ALL not having achieved remission (possible MRD) ❑ C91.01 ALL in remission (possible MRD) ❑ C91.02 ALL in relapse ❑ Other: _____
If other, additional documentation may be needed.

Philadelphia Chromosome Status: ❑ + or ❑ - CD19 20 22 Status: ❑ + or ❑ - ❑ ECOG Score: _____ CNS Involvement: ❑ yes or ❑ no

MRD+: _____ Height: _____ Weight: _____ Planned Discharge Date: _____

BLINCYTO® is medically necessary for (Patient's Name): _____ as documented by: _____

_____

Line of therapy requested: ❑ 1st _____ ❑ 2nd _____ ❑ 3rd _____

Prior Therapy (if any and include dates if known): _____

Reason for discontinuing previous acute therapy(ies): _____

Contraindications (if any): _____

Patient is currently taking the following supplemental agents: _____

Other Relevant Information (Psychosocial factors to note or that will affect discharge planning): _____

_____

Indications and Important Safety Information

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