



Please submit this completed form with a patient face sheet and supplemental relevant clinical notes.
Fax completed form and additional documentation to treating site.

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 patient face sheet

Patient Name: _____ Date of Birth: _____
Address: _____
 For Home Infusion, address of home where patient is taking 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 patient face sheet with insurance information OR fax a copy of insurance card, front and back

Primary Insurance: _____
Insured: _____
Insurance Phone: _____ Policy #: _____ BIN #: _____ RX #: _____

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): _____

It is the responsibility of the healthcare provider to determine the appropriate code(s) for products or services provided to their patients. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently; we cannot guarantee coverage or reimbursement for any product or service. Further, Amgen does not suggest or endorse the use of any particular home health/infusion provider. This is not intended to be a source of medical advice or treatment and does not replace in any way independent medical advice regarding a patient's diagnosis or treatment.

Please see Indications and Important Safety Information on Page 2, and full Prescribing Information, including **Boxed WARNINGS**, and Medication Guide for BLINCYTO®.

BLINCYTO® (blinatumomab) 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 neurologic 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 neurologic toxicity included cranial nerve disorders. The majority of neurologic toxicities resolved following interruption of BLINCYTO®, but some resulted in treatment discontinuation.

The incidence of signs and symptoms consistent with ICANS in clinical trials was 7.5%. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. There is limited experience with BLINCYTO® in patients with active ALL in the central nervous system (CNS) or a history of neurologic events. Patients with a history or presence of clinically relevant CNS pathology were excluded from clinical studies. Patients with Down Syndrome over the age of 10 years may have a higher risk of seizures with BLINCYTO® therapy.

Monitor patients for signs and symptoms of neurologic toxicities, including ICANS, and interrupt or discontinue BLINCYTO® as outlined in the PI. Advise outpatients to contact their healthcare professional if they develop signs or symptoms of neurologic 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 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and total blood bilirubin prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if total bilirubin rises to > 3 times ULN.

- **Pancreatitis:** Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.

- **Leukoencephalopathy:** Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.

- **Preparation and administration** errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).

- **Immunization:** Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.

- **Benzyl Alcohol Toxicity in Neonates:** Serious adverse reactions, including fatal reactions and the “gaspings syndrome,” have been reported in very low birth weight (VLBW) neonates born weighing less than 1500 g, and early preterm neonates (infants born less than 34 weeks gestational age) who received intravenous drugs containing benzyl alcohol as a preservative. Early preterm VLBW neonates may be more likely to develop these reactions because they may be less able to metabolize benzyl alcohol.

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

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

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

Adverse Reactions

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

Dosage and Administration Guidelines

- BLINCYTO® is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.

- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see full [Prescribing Information](#), including **Boxed WARNINGS**, and [Medication Guide](#) for BLINCYTO®.

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