National Home Infusion Association

Infusion Practice Standard

Subject: Recommendations for Assessment of Risk: Blinatumomab Handling During Receiving, Compounding, Administration, and Disposal

Introduction

The practice standards of NHIA represent a consensus of professional judgment, expert opinion, and documented evidence. They provide guidance and direction to NHIA members and other audiences who affect the home infusion industry and the patients served. Using them may help comply with federal and state laws and regulations, meet accreditation requirements, and improve patient care. They establish reasonable goals that are progressive and challenging, yet attainable, as best practices in applicable home or alternate site settings. They should not be viewed as NHIA requirements. Members and other practitioners should assess and adapt the use of NHIA's practice standards based on independent judgment.

Purpose

Blinatumomab (BLINCYTO®) is a bispecific CD19-directed CD3 T-cell engager indicated for CD19-positive B-cell precursor acute lymphoblastic leukemia.[1] It appears in Table 2 of the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.[2] Amgen has established a manufacturer-derived occupational exposure limit of 80 µg/m³ as an 8-hour time-weighted average over a 40-hour work week and classifies blinatumomab as an Occupational Exposure Band (OEB) 3 compound (20–100 µg/m³).[3]

USP General Chapter <800> allows an entity to perform an Assessment of Risk (AOR) to establish alternative containment strategies and work practices for the final dosage forms of certain hazardous drugs, but not for antineoplastics that require manipulation.[4] Blinatumomab's placement in Table 2 means it meets NIOSH hazardous drug criteria but is not automatically subject to full <800> containment, and an AOR is an available pathway. The AOR determines containment strategy, personal protective equipment (PPE), and work practices; it does not modify the sterile compounding requirements of USP <797>, which remain fully applicable.[4,5]

This flexibility is necessary in practice to ensure patient access to home infusion services. Not every home infusion pharmacy has access to a negative-pressure compounding room, and manufacturer drug-device compatibility data for closed system transfer device (CSTD). Manufacturers have not established drug-device compatibility with blinatumomab. Organizations may therefore reasonably differ in the combination of engineering controls, PPE, and procedural safeguards selected. A documented AOR makes that combination transparent, defensible, and grounded in the pharmacy's actual process and in current regulatory guidance.

NHIA recommends that organizations achieve full compliance with USP <800> where pharmacy infrastructure supports it, including a negative-pressure compounding room either within a <800>-compliant cleanroom suite or within a containment segregated compounding area (C-SCA). Where that infrastructure is not present, NHIA recommends a documented, facility-specific AOR for blinatumomab informed by USP <800> principles. Under either pathway, each organization remains responsible for reviewing its policies, procedures, and pharmacy design to ensure its assessment is accurate and current.

Practice Standard Development Procedure

A need for standardized guidance was identified regarding AOR determinations for blinatumomab, given its NIOSH Table 2 designation and the resulting variability in how home infusion pharmacies approach containment, PPE selection, and CSTD use. The absence of

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established manufacturer drug-device compatibility data and inconsistent facility infrastructure across the industry reinforced the need for a risk-based framework, and the topic is highly relevant to a significant portion of NHIA's membership that compounds and administers hazardous biologic antineoplastic agents.

The NHIA Quality and Standards Committee, comprising experienced home infusion pharmacists and hazardous drug safety professionals, reviewed the NIOSH Hazardous Drug List, USP <797> and <800>, the blinatumomab package insert and safety data sheet, and current member practices and community feedback on engineering controls, PPE selection, and CSTD use.

Target Audience

The target audience includes clinicians, regulatory and accrediting agencies, reimbursement organizations, and industry stakeholders.

Practice Standard for Assessment of Risk – Blinatumomab

Each row states the action to be taken and the rationale supporting it. Steps follow the order in which blinatumomab moves through the organization.

	Action	Rationale
Assessment and documentation		
1.	Confirm blinatumomab's current placement on the NIOSH Hazardous Drug List when the AOR is created and at each review. Retain the relevant NIOSH list excerpt, the current safety data sheet, the package insert, and any subsequent labeling from the manufacturer as supporting documentation.	NIOSH periodically revises which drugs appear in Table 1 versus Table 2. Table 2 placement is the basis for a risk-based assessment rather than full USP <800> containment, so the classification in effect at the time of the assessment must be on file.[1,2,4]
2.	Evaluate and address exposure risk across four dimensions: personnel during compounding and handling; the compounding and administration environment; and waste from compounding byproducts and post-administration materials in the home.	Addressing each dimension separately establishes which controls are required and which the organization adopts voluntarily.[1,2]
3.	Obtain Designated Person review and approval of the AOR before implementation and at least every 12 months thereafter, or sooner if new safety information, a NIOSH list update, or a USP <800> revision is published.	Dated approval gives staff, surveyors, and regulators a single point of reference for why the selected controls were chosen.
Receiving and storage		
4.	Wear at least one pair of chemotherapy gloves meeting ASTM D6978 when unpacking blinatumomab and deactivate and decontaminate any container or bin used to move blinatumomab between the receiving, storage, and compounding areas. Wash hands with soap and water after glove removal.	External carton and vial surfaces may carry residual contamination. Reused transport containers are a direct route for moving that contamination into clean areas.

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	Action	Rationale
5.	Store vials in a dedicated, labeled HD refrigerator, positioned to prevent spillage or breakage (e.g., on a low shelf or on shelving with a raised front lip).	Breakage is the most likely uncontrolled release during storage, and blinatumomab requires refrigerated storage.[3]
Compounding		
6.	When compounding blinatumomab in a USP <797> environment without full <800> containment: (a) prepare in an ISO Class 5 primary engineering control (PEC) located within an ISO Class 7 buffer area; (b) don two pairs of ASTM D6978 chemotherapy gloves, and a gown demonstrated to resist hazardous drug permeation; (c) deactivate, decontaminate, clean, and disinfect the PEC after compounding; and (d) discard the outer glove and remaining garb as trace-contaminated waste.	USP <797> applies regardless of the AOR outcome. The manufacturer's labeling specifies only "appropriate protective clothing and gloves," so NHIA sets the conservative baseline that NIOSH and <800> apply to antineoplastic handling. This PPE set compensates for the absence of negative pressure.[1,2,3]
7.	Until documented drug-device compatibility is available, the manufacturer's package insert does not recommend using a CSTD for vial and bag manipulations during compounding. Do not add a CSTD at the point of administration.	USP <800> states that a CSTD should be used when compounding and must be used when administering antineoplastic hazardous drugs when the dosage form allows. Blinatumomab's labeled administration set-up does not allow an add-on device, and no manufacturer compatibility data exist.[1,3]
Administration		
8.	Administer through a central vascular access device using a dedicated lumen when a multi-lumen access device is used, with the tubing and in-line filter specified in the package insert. Do not flush the infusion line, including at bag changes and at the end of the infusion; aspirate residual drug from the vascular access device before any clinically required flush. Monitor the patient in accordance with the package insert.	A dedicated, unflushed vascular access device keeps the fluid path closed and limits exposure during bag changes. Flushing also delivers a bolus of drug and can result in excess dosage.[3]
9.	Nurses should wear two pairs of ASTM D6978 chemotherapy gloves for connecting, disconnecting, and bag changes; a chemotherapy-rated gown when spillage or splashing is possible; and eye protection when splashing is possible. Follow hand hygiene standards before and after glove removal.	Administration manipulations occur in a closed fluid path and carry lower exposure risk than compounding, so single gloving is appropriate, with the gown and eye protection addressing the residual risk at connections and bag changes.[1,2]
Spills, waste, and transport		

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	Action	Rationale
10.	Provide a spill kit that is immediately accessible wherever blinatumomab is handled, compounded, transported, or administered, and provide staff with a documented spill procedure.	The home has no engineering controls, so spill response depends entirely on supplies and instructions being on hand at the point of use.
13.	Transport blinatumomab and its finished preparations in containers that minimize the risk of breakage, leakage, or damage, consulting the safety data sheet for any product-specific transport conditions. Hold finished preparations awaiting delivery in a designated area dedicated to storing HDs in the refrigerator (if applicable) in an access-restricted area, and document that location and any compensating practices in the AOR.	Transport and holding occur outside the controls of the compounding area, so containment depends on packaging and on restricting access to the storage location.[4]
12.	Dispose of unused drug, vials, and compounding waste as hazardous waste in accordance with federal, state, and organizational requirements. Empty administration bags and tubing in the home, which contain only trace amounts, may generally be discarded as household waste unless state or local requirements specify otherwise.	Bulk and trace waste carry different regulatory obligations and treating trace home waste as bulk hazardous waste is neither required nor practical for patients.

PROPOSED

References:

1. Blincyto® (blinatumomab) [Package insert]. Amgen Inc. Thousand Oaks, California. April 2026.
2. NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings. By Hodson L, Ovesen J, Couch J, Hirst D, Lawson C, Lentz TJ, MacKenzie B, Mead K. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-130.
3. Amgen. BLINCYTO® Safety Data Sheet. Amgen Inc. Thousand Oaks, California. Revision no. 7, 18 Aug. 2025. https://www.msds.amgen.com/blincyto-safety-datasheet. (Accessed August 2026)
4. General Chapter: USP. Pharmaceutical Compounding – Hazardous Drugs – Handling in Healthcare Settings <800>. In USP-NF Rockville, MD: USP, July1, 2020.
5. General Chapter: USP. Pharmaceutical Compounding – Sterile Preparations <797>. In: USP-NF Rockville, MD: USP, May 1, 2024. DOI: https://doi.org/10.31003/USPNF_ M99925_08_01

Comments/Contact: NHIA welcomes feedback and suggestions for content to incorporate into future revisions and editions. Contact: info@nhia.org

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