

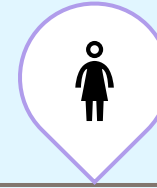
Navigating Bispecific Antibody Therapies in Multiple Myeloma: Roadmap for Onboarding and Operationalization

The recommendations and considerations presented in this asset are informed by a publication in which a panel of academic and community-based pharmacists with experience using BsAb was convened to review available evidence and provide expert perspectives on operationalizing and managing BsAb therapy.



Institutional integration & operationalization

- P&T workflow
- EHR & REMS
- Financial considerations



Patient selection

- Patient selection



Key stakeholders¹

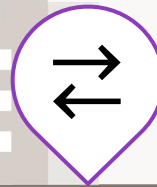
- Physicians
- Advanced practice providers
- Pharmacists
- Nursing
- Social work
- Critical care staff
- Emergency department staff
- Administrators

Additional considerations



Administration

- Drug admin/monitoring
- Care partner considerations



Transitions

- Patient transitions



Management

- CRS/Neurotoxicity/Infection ARs

AR, adverse reaction; BsAb, bispecific antibody; CRS, cytokine release syndrome; EHR, electronic health record; ICANS, Immune effector cell-associated neurotoxicity syndrome; P&T, Pharmacy & Therapeutics; REMS, Risk Evaluation and Mitigation Strategy.

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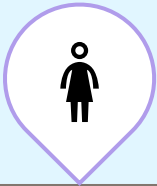
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Additional considerations²⁻⁴

- Operational Champion
- REMS coordinator
- Coordinators: REMS training; stakeholder notifications
- Order managers
- Care team member

REMS, Risk Evaluation and Mitigation Strategy.
1. Mahmoudjafari Z, Ali A, Davis J, Sandahl T, Nachar V, Mancini R. Seamless navigation of bispecific therapies: optimizing management and outpatient access with a focus on coordination. *J Adv Pract Oncol*. September 11, 2024. Accessed July 16, 2026. <https://doi.org/10.6004/jadpro.2024.15.8.15>.
2. ACCC. Bispecific Antibodies Checklist for Community Providers. Accessed July 15, 2026. <https://www.acco-cancer.org/docs/projects/bispecific-antibodies/checklist-for-bispecific-antibodies-jan-2022.pdf?sfvrsn=ad2f3ee4.2>.
3. Santos WJ, Graham ID, Lalonde M, Varin MD, Squires JE. The effectiveness of champions in implementing innovations in health care: a systematic review. *Implement Sci Commun*. 2022;3(80).
4. Peters B. *Annual Indiv Hematology Review™*. March 17, 2023. Accessed July 15, 2026. <https://www.indivhematologyreview.com/wp-content/uploads/2023/03/Peters.Brooke-Operational-Protocol-and-Standard-Operating-Procedures.pdf>.



Administration

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P&T workflow



Key considerations for implementation of BsAb therapy



Clinical
(efficacy, safety, dosing)



Financial



Site of care
(inpatient bed utilization, drug stocking)



Administrative
(insurance approval)



Training



Temporary approval process
(eg, protocols, order set)



Key stakeholders¹

- Physicians
- Advanced practice providers
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Additional considerations



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Patient transitions



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CRS/Neurotoxicity/Infection ARs

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Electronic health record (EHR)

- Promotes consistent practices, mitigates errors, and encourages timely referrals
- Key components
 - Definitions and grading of adverse reactions
 - Hold parameters
 - Rescue medications
 - Safety alerts (eg, REMS)



Risk Evaluation and Mitigation Strategy (REMS)

- Proactive approach to mitigate drug safety risks
- Key components
 - Authorized representative
 - Training and certification
 - Patient wallet cards/bracelets



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Transitions

Patient transitions



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Additional considerations

Financial considerations

It is important to understand the nuances of inpatient vs outpatient medication reimbursement to ensure optimal access to essential medications.

Resources

- **Guides:** coding; billing; reimbursement
- **Reimbursement codes:**
 - ICD-10; NDC; J-code

Inpatient considerations

- **Length of stay** (acute care)
- **Reimbursement considerations:**
 - IPPS
 - DRG payment
 - Medicare Two-Midnight rule
 - NTAP program, if applicable

Outpatient considerations

- **Precertification**
- **Reimbursement considerations:**
 - 340B pricing,
 - Medicare Part B (certain outpatient medications)
- **Payment model:** Fee-for-service; bundled; capitation (depending on contracts)

DRG, diagnosis-related group; ICD-10, International Statistical Classification of Diseases, 10th Revision; IPPS, Inpatient Prospective Payment System; NDC, national drug code; NTAP, New Technology Add-On Payment.

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Patient selection



Patient selection

Patient selection should be conducted in accordance with the individual product's Prescribing Information. Due to the risk of CRS and neurologic toxicity, including ICANS, follow hospitalization recommendations during step-up dosing according to the individual product's Prescribing Information.



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Additional considerations



Drug admin/monitoring

Care partner considerations



Transitions

Patient transitions



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Administration

Must ensure adequate monitoring capabilities and protocols for rapid escalation of care are in place. Consider partnering with larger treatment centers or those with inpatient services for the initiation of therapy.

Administration should be conducted in accordance with the individual product's Prescribing Information. Due to the risk of CRS and neurologic toxicity, including ICANS, follow hospitalization recommendations during step-up dosing according to the individual product's Prescribing Information.



Care partner considerations

- Education on monitoring parameters
- Ability to provide direct, in-home care and transportation
- Assist with monitoring equipment and neurologic assessment

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

Transitions

 Patient transitions

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Drug preparation & administration

- Pharmacy considerations: drug preparation and delivery
- Workflows for patient evaluations
- Post-injection monitoring (based on onset timing for CRS and neurologic toxicity, including ICANS)



Monitoring

- Patient vitals, lab values, and assessments for signs and symptoms of toxicity
- Designated contact line for patient questions and triaging alerts
- Daily check-ins: in-person or virtual

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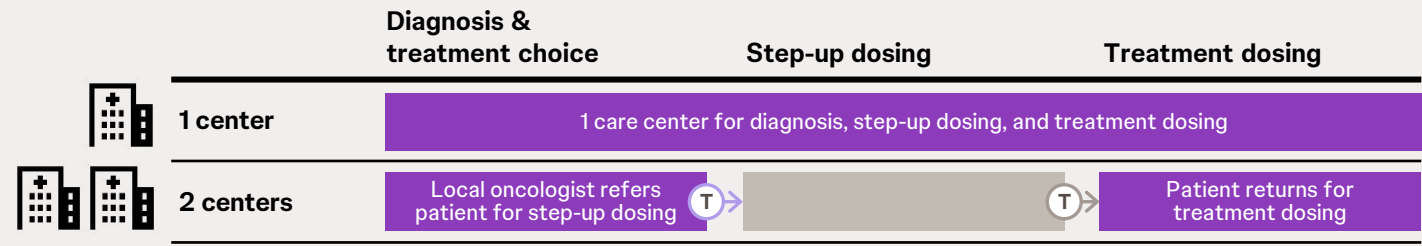
Patient transitions



Key considerations¹:

- Secure insurance authorization (for both centers prior to therapy initiation)
- Medication access and education for staff
- Handoff and documentation (eg, dates and doses, toxicity notations, REMS verification)
- Adverse event considerations (eg, if CRS neurotoxicity, including ICANS occurs, follow the individual product's Prescribing Information for recommendations for management based on severity of toxicity)

Variability can exist in the site of care models due to multi-phase treatment journey. Choice of model depends on individual organizations' current infrastructure and patient support ability.²



^aThis is the responsibility of each center; however, drug manufacturers can assist in these areas.

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2. ACCC. Best Practices in Expanding Access to Bispecific Antibodies and Adverse Event Management. Accessed July 16, 2026. <https://www.accc-cancer.org/docs/projects/bispecific-antibodies/bispecific-antibodies-brief.pdf>

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Management

For management of CRS, neurologic toxicities, including ICANS, and infections, follow hospitalization, pretreatment, monitoring, and management guidelines in the individual product's Prescribing Information.



CRS and neurologic toxicities, including ICANS

- Additional guidelines for grading and management of CRS and neurologic toxicities including ICANS include:
 - [ASTCT CRS & ICANS grading guidelines](#)
 - [IMWG guidelines on optimal BsAb use](#)
 - [NCODA Immunotherapy Hub](#)



Infections

- **Patient-specific factors:** age, performance status, comorbidities
- **Disease severity:** tumor burden, refractory status
- **History of prior treatments:** steroid use, previous infection profiles
- **Anticipated length of BsAb treatment**

J&J does not endorse or promote use of any specific guidelines. These are provided for information purposes only.

AR, adverse reaction; ASTCT, American Society for Transplantation and Cellular Therapy; BsAb, bispecific antibody; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IMWG, International Myeloma Working Group; NCODA, Network for Collaborative Oncology Development & Advancement