
From Questions to Confidence:
Bispecific T-cell Engagers in the Community
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SPRING FORUM

1


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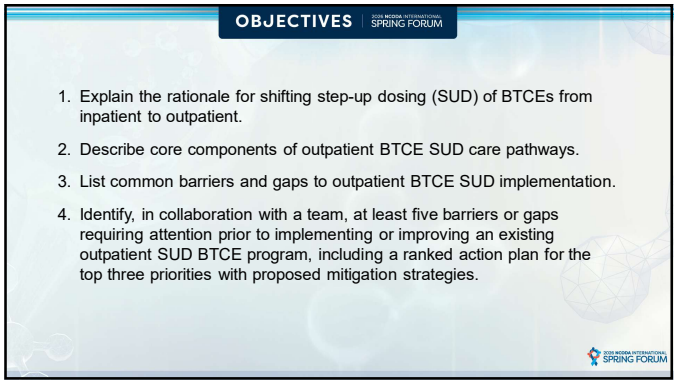
2


OBJECTIVES
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1. Explain the rationale for shifting step-up dosing (SUD) of BTCEs from inpatient to outpatient.
2. Describe core components of outpatient BTCE SUD care pathways.
3. List common barriers and gaps to outpatient BTCE SUD implementation.
4. Identify, in collaboration with a team, at least five barriers or gaps requiring attention prior to implementing or improving an existing outpatient SUD BTCE program, including a ranked action plan for the top three priorities with proposed mitigation strategies.
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3

Bispecific T-cell engagers (BTCE) are designed to bind two different targets: T-cells and cancer cells.

Why it matters

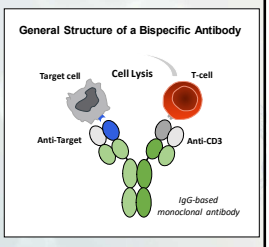
BTCEs physically bind T-cells to cancer cells, triggering T-cell activation and release of cytotoxic molecules that kill the cancer cells

As of April 2026, **10 BTCEs are FDA approved**.

- Disease States: B-Cell ALL, Non-Hodgkin Lymphoma, Multiple Myeloma, Small Cell Lung Cancer, and Uveal Melanoma

Combination regimens are here!

Reminder: Not all "bispecifics" target T-cells!
- Non-T-cell-engaging bispecifics do NOT cause the same adverse reactions or require the same operational considerations as BTCEs.



Einsele H, et al. Cancer. 2020;126(14):3192-3201.
Dean D, et al. Pharm Times. 2025;714.
Zhou S, et al. Biomark Res. 2021;9(1):38.

4

All commercially available BTCEs require step-up dosing to mitigate the risk of cytokine release syndrome (CRS) and neurologic problems.

Why it matters

Practices face significant challenges in managing patients during step-up dosing period, necessitating:

- Excellent patient monitoring and caregiver support
- Coordinated scheduling, often between different hospitals and clinics
- Consistent follow-up by interprofessional teams

1. NCODA. Immunotherapy Hub. 2026.

5

To implement an effective BTCE program, you will need to:

- Build an Interprofessional Team
- Provide Education and Training
- Coordinate Care
- Address Access Issues
- Create Protocols

1. NCODA. Immunotherapy Hub. 2026.

6

There is no single best site of care for Step-Up Dosing (SUD).

- Historically performed inpatient; some sites now safely offer outpatient SUD.
- Outpatient SUD requires risk stratification, monitoring plans, emergency transfer pathways, and trained staff/equipment.
- Not all patients are candidates for outpatient care.
- Some sites may still prefer inpatient SUD.

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7

Why Are Sites Moving BTCE SUD Outpatient?

- Reduces inpatient days, time toxicity, and system costs demonstrated across real-world cohorts
- Most CRS/ICANS cluster around early SUD; predominantly grade 1–2
- Outpatient models achieved safe SUD with acceptable admission rates
- Subcutaneous formulations and step-up/accelerated schedules lower peak exposure and risk
- Preserves scarce inpatient beds and expands geographic access beyond tertiary centers

- Rahbari KJ, et al. *JCO Oncol Pract*. Published online December 4, 2025.
- Pelland AA, et al. *Curr Oncol*. 2025;32(4):238.
- Sandahl TB, et al. *JCO Oncol Pract*. 2025;21(5):702-709.
- Mehmoudjafari Z, et al. *J Adv Pract Oncol*. Published online September 11, 2024.
- DOVE. Immune effector cell associated neurotoxicity syndrome.

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8

How Are Sites Moving BTCE SUD Outpatient?

- Patient selection: reliable 24/7 caregiver, ≤30–90 min travel, ECOG PS ≤2, controlled comorbidities, no uncontrolled infection, moderate tumor burden or low inflammatory markers
- Premedications: acetaminophen + antihistamine per label; dexamethasone preferred for prophylaxis/pulse for many agents
- Consider prophylactic biologics selectively (tocilizumab or anakinra) where evidence supports agent-specific benefit
- Use validated/accelerated step-up schedules only per published safety data
- Early home interventions: pocket dexamethasone plan, home vitals (BP, SpO_2, temp), structured symptom reporting (hotline/portal)
- Objective escalation triggers: ASTCT CRS grading, ICE score changes, fever/hypotension/hypoxia thresholds

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- ASTCT, American Society of Transplantation and Cellular Therapies; BP, blood pressure; ECOG, Eastern Cooperative Oncology Group; ICE, immune effector cell encephalopathy; PS, performance status; SpO_2, peripheral capillary oxygen saturation

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9

How Are Sites Moving BTCE SUD Outpatient?

- Multidisciplinary core: physicians, APPs, infusion nurses, pharmacists, nurse navigators, social workers, ED/ICU liaisons
- REMS/compliance and P&T: ensure REMS certification, pre-formulary order sets, EHR decision support with agent-specific order sets
- Remote monitoring: RPM platform or structured RN telephone/visit program + home devices; staffed triage hub (RN/APP) with decision trees
- Pharmacy & rescue meds: guaranteed on-site immediate access to tocilizumab, steroids, and anakinra (if used); standardized dispensing workflows
- Direct-admit pathway: reserved oncology bed or oncology urgent care to avoid ED delays; defined admit criteria (e.g., ≥ grade 2 CRS/ICANS)
- Metrics: track outpatient SUD completion, CRS/ICANS rates, hospital admissions/LOS, rescue-med use, patient satisfaction

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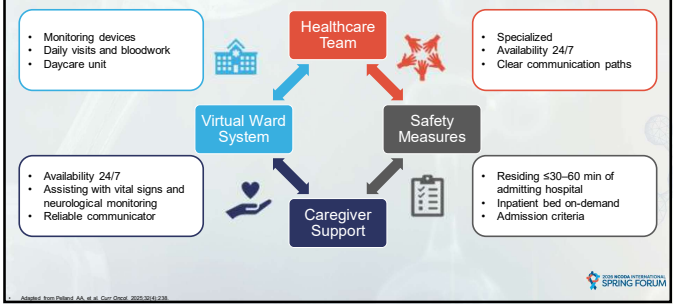
- ED, emergency department; EHR, electronic health record; ICU, intensive care unit; LOS, length of stay; P&T, pharmacy and therapeutics committee; RPM, remote patient monitoring

Key Considerations for Outpatient BTCE SUD



- Adapted from Pelland AA, et al. *Curr Oncol*. 2025;32(4):238.

Practical Takeaways for Outpatient BTCE SUD

- Pilot a small, well-selected cohort per agent (strict criteria, full SOPs, RPM/triage operational)
- Confirm REMS, P&T approvals, and stock rescue meds + educate pharmacy/infusion staff
- Create EHR order sets with embedded ASTCT/ICE guidance, prebuilt rescue orders, and REMS alerts
- Train ED/hospitalists and distribute patient wallet cards; provide home devices and clear caregiver education
- Define escalation rules & direct-admit workflow; allow outpatient management of selected grade 1 CRS per protocol
- Monitor outcomes (CRS/ICANS by agent, admissions/LOS, rescue med use, patient experience); iterate

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Team Exercise: Barriers → Ranked Action Plans

- Task (20 min): Identify 5 barriers/gaps to outpatient SUD implementation.
  - For top 3 barriers: provide ranked action plan — specific solution, resources, and one measurable metric.
  - Note: Focus on practical, implementable fixes (not vague statements).
- Deliverable: One completed group worksheet + concise top-3 action plan (one line each) for sharing.
- Presentation: 1 team rep, 2 minutes to present top-3 action plans at session end.

13

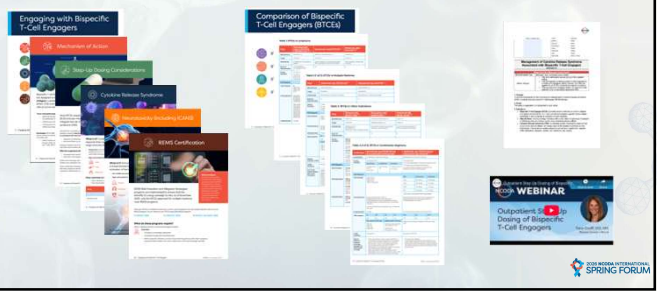
NCODA Resources

Immunotherapy Hub

Bispecific TSK

14

NCODA Resources: Immunotherapy Hub



15

NCODA Resources: Bispecific T-Cell Engager TSK

Kit Contents

- Treatment Booklet
- Treatment Calendar
- Patient Wallet Card
- Blood Pressure Monitor
- Pulse Oximeter
- Digital Thermometer

Complimentary for NCODA Members

16

SUMMARY

- Outpatient SUD for BTCEs can safely reduce inpatient time, cost, and patient burden when done for selected patients.
- Key requirements: clear selection criteria, caregiver/proximity plan, standardized clinical protocols, and rapid escalation pathways.
- Essential infrastructure: trained multidisciplinary team, pharmacy/rescue-med readiness, and monitoring/triage capability (RPM or staffed RN coverage).
- Common barriers: regulatory/REMS logistics, staffing and training, drug access/coding, remote monitoring capacity, and transitions/ED coordination.
- Priority actions: establish SOPs/EHR order sets, secure rescue-meds and pharmacy workflows, and create a staffed triage + direct-admit pathway.
- Next steps: pilot with strict criteria, collect core metrics, refine protocols, then broaden implementation.

17

QUESTION & ANSWER

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18

19