NYOH Development and Implementation of Outpatient Bispecific Antibody Therapy Program

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Background

Outpatient bispecific antibody programs address an important gap in care by allowing the safe administration and monitoring of therapies associated with cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Outpatient administration of these treatments offers the potential for improved patient access, reduced travel burden, optimize inpatient bed utilization and the ability to safely deliver care in the community setting.

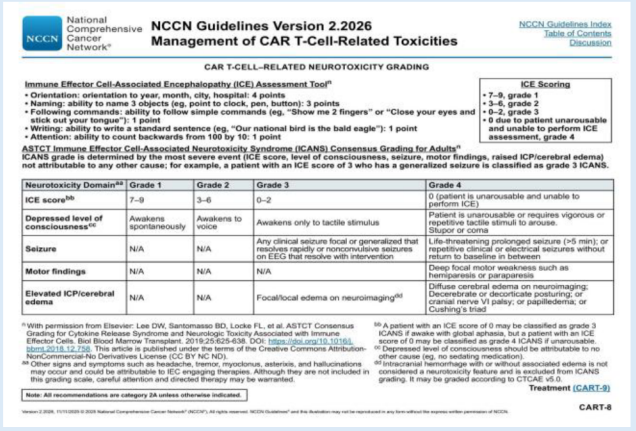
Objective(s)

- Identify the key components required to implement a **safe outpatient bispecific antibody program** in the community setting.
- Identify the **multidisciplinary team members** and their roles in implementing an outpatient bispecific program
- Describe the **impact** of outpatient bispecific antibody programs on patient access and travel burden
- Compare inpatient and outpatient bispecific treatment models with respect to healthcare resource utilization and patient access
- Design an outpatient bispecific antibody **implementation framework that incorporates patient selection, monitoring, and multidisciplinary care coordination**

Methods

A multidisciplinary Bispecific Outpatient Treatment Committee at New York Oncology Hematology (NYOH) designed and executed a program to transition ramp-up dosing to the community outpatient setting. Four foundational pillars were developed to ensure patient safety and operational continuity:

- ❖ Specialized Standard Operating Procedures (SOPs)
- ❖ Dedicated MD/RN On-Call management pathway
- ❖ Formal evening/night nursing compensation structure for continuous remote monitoring
- ❖ Rigorous clinical checkpoint checklist



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NCCN Guidelines Version 2.2026
Management of CAR T-Cell-Related Toxicities

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CAR T-CELL–RELATED NEUROTOXICITY GRADING

Immune Effector Cell-Associated Encephalopathy (ICE) Assessment Tool[a]
- Orientation: orientation to year, month, city, hospital: 4 points
- Naming: ability to name 3 objects (eg, point to clock, pen, button): 3 points
- Following commands: ability to follow simple commands (eg, "Show me 2 fingers" or "Close your eyes and stick out your tongue"): 1 point
- Writing: ability to write a standard sentence (eg, "Our national bird is the bald eagle"): 1 point
- Attention: ability to count backwards from 100 by 10: 1 point

ICE Scoring
- 7–9, grade 1
- 3–6, grade 2
- 0–2, grade 3
- 0 due to patient unarousable and unable to perform ICE assessment, grade 4

ASTCT Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) Consensus Grading for Adults[a]
ICANS grade is determined by the most severe event (ICE score, level of consciousness, seizure, motor findings, raised ICP/cerebral edema) not attributable to any other cause; for example, a patient with an ICE score of 3 who has a generalized seizure is classified as grade 3 ICANS.

Neurotoxicity Domain[a,b]	Grade 1	Grade 2	Grade 3	Grade 4
ICE score[b,b]	7–9	3–6	0–2	0 (patient is unarousable and unable to perform ICE)
Depressed level of consciousness[c,d]	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse. Stupor or coma
Seizure	N/A	N/A	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (>5 min); or repetitive clinical or electrical seizures without return to baseline in between
Motor findings	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Elevated ICP/cerebral edema	N/A	N/A	Focal/local edema on neuroimaging[d,d]	Diffuse cerebral edema on neuroimaging; Decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad

[a] With permission from Elsevier: Lee DW, Santomasso BD, Locke FL, et al. ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant. 2019;25:625-638. DOI: https://doi.org/10.1016/j.bbmt.2018.12.758. This article is published under the terms of the Creative Commons Attribution-NonCommercial-No Derivatives License (CC BY NC ND).

[b] Other signs and symptoms such as headache, tremor, myoclonus, asterixis, and hallucinations may occur and could be attributable to IEC engaging therapies. Although they are not included in this grading scale, careful attention and directed therapy may be warranted.

[b] A patient with an ICE score of 0 may be classified as grade 3 ICANS if awake with global aphasia, but a patient with an ICE score of 0 may be classified as grade 4 ICANS if unarousable.

[c] Depressed level of consciousness should be attributable to no other cause (eg, no sedating medication).

[d] Intracranial hemorrhage with or without associated edema is not considered a neurotoxicity feature and is excluded from ICANS grading. It may be graded according to CTCAE v5.0.

Note: All recommendations are category 2A unless otherwise indicated.

Treatment (CART-9)

CART-8

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Figure 3: ASTCT Grading for CRS[5]

CRS parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever*	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C
		with		
Hypotension	None	Not requiring vasopressors	Requiring vasopressors with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
		And/or†		
Hypoxia	None	Requiring low-flow nasal cannula‡ or blow-by	Requiring high-flow nasal cannula‡ nonrebreather mask, or Venturi mask	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)

Organ toxicities associated with CRS may be graded according to Common Terminology Criteria for Adverse Events (CTCAE) v5.0 but they do not influence CRS grading.
*Fever is defined as temperature >38°C not attributable to any other cause. In patients who have CRS then receive antipyretic or anticytokine therapy such as tocilizumab or steroids, fever is no longer required to grade subsequent CRS severity. In this case, CRS grading is driven by hypotension and/or hypoxia. † CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause. For example, a patient with temperature of 39.5° C, hypotension requiring 1 vasopressor, and hypoxia requiring low-flow nasal cannula is classified as grade 3 CRS. ‡ Low-flow nasal cannula is defined as oxygen delivered at <6 L/minute. Low flow also includes blow-by oxygen delivery, sometimes used in pediatrics. High-flow nasal cannula is defined as oxygen delivered at >6 L/minute.

Discussion

With this program we were able to treat **four patients** completely outpatient with zero admissions to the hospital, or the need to bring patients into the hospital overnight in 2025. To date in 2026 we have successfully treated twenty-one patients completely outpatient with zero admissions to the hospital or need to bring patients into the office overnight.

Results / Conclusion

Implementing a structured community oncology outpatient framework for bispecific ramp-up dosing is safe, highly effective, and scalable. This center-of-excellence model eliminates the need for travel to distant tertiary centers, significantly mitigates the financial burden on the healthcare economy, and optimizes inpatient bed utilization while maintaining uncompromised patient safety

Reference(s)

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