Implementation of a Bispecific T-Cell Engager Therapy Program at a Community Cancer Center



ispecific T-cell engager therapy was introduced in 2014 with the accelerated approval of blinatumomab for acute lymphoblastic leukemia.¹ Ten years later, multiple bispecifics are now on the market with accelerated approvals for relapsed and refractory multiple myeloma, non-Hodgkin lymphomas, and select solid tumors.1-7 Bispecific therapies have demonstrated competitive and durable overall response rates (ORRs) in the treatment-refractory setting (myeloma ORR, 61%-74%; lymphomas ORR, 56%-80%).1-7 The current landscape of both refractory myeloma and lymphoma typically includes addressing the decision to pursue chimeric antigen receptor (CAR) T-cell therapy as a patient's second or subsequent line of treatment. Historically, CAR T-cell therapy has delivered the most competitive outcomes of any current refractory treatment option in these 2 disease states, but at a cost to the patient.^{8,9} In the community setting, these include prolonged hospitalization, a severe toxicity profile, and a considerable delay to treatment due to manufacturer limitations. Bispecific therapy exemplifies a more feasible cellular therapy to administer in the community setting.¹⁰ Bispecifics offer patients readily available, off-the-shelf alternatives associated with a more modest toxicity profile and deliver competitive ORRs. Administration of bispecific therapies in the community setting would allow clinicians to aggressively treat refractory diseases while keeping patients closer to their respective homes and support systems, leading to both time and cost savings.

Operationalizing and administering bispecifics in the community setting requires significant planning, education, and open communication within the local medical community. Each bispecific product has unique characteristics regarding Risk Evaluation and Management Strategy (REMS) programs, inpatient-vs-outpatient initiation, pretreatment cytoreduction, ramp-up dosing, and on-target off-tumor adverse events (AEs). The pharmacist's role in the implementation of a bispecifics program in the community setting has proved critical to safely using novel T cell–redirecting therapies and managing their unique AEs, including cytokine release syndrome (CRS) and neurotoxicity. In this article, we describe our pharmacy-led process of operationalizing a program in which a community health system can initiate and maintain bispecific therapies for patients. Our adverse event management strategy began with the creation of an electronic order set designated for the management of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome.

Methods and Process

At Munson Healthcare, Cowell Family Cancer Center, in Traverse City, Michigan, the feasibility of administering bispecifics in the community setting was initially presented to our interprofessional oncology Quality and Safety Committee. Upon physician approval to pursue this process, the pharmacy formed a bispecifics committee. Key personnel in this group included oncology pharmacists, clinical informatics, oncology and critical care nursing staff, and a physician champion. Initial objectives included the following:

- · Creating standardized work via policies and procedures
- · Developing toxicity monitoring and management protocols
- Offering ongoing staff education
- Understanding transitions of care
- Conducting pharmacoeconomic analysis.

Following the creation and implementation of the bispecific program, provider and nursing readiness were measured.

Policy Development and REMS Program Enrollment

The operationalization of bispecifics at our institution began with comprehensive standardized protocols. Using guidelines from the National Comprehensive Cancer Network (NCCN), the American Society for Transplantation and Cellular Therapy (ASTCT), the *(Continued on page 9.)*

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Society for Immunotherapy of Cancer (SITC), and existing frameworks from institutions already administering bispecifics, our oncology pharmacy team developed procedures for ordering, administering, and managing toxicities of bispecifics. Logistics addressed in policy development included the following:

- Adding bispecifics to our hospital formulary
- Outlining our institutional process for ordering bispecifics in the inpatient setting
- Developing inpatient toxicity monitoring and documentation practices.

If required for administration, the infusion pharmacy and ordering provider were enrolled in the appropriate REMS program. Compliance with program requirements is necessary for continued eligibility to administer bispecifics.

AE Education and Management Strategies

Our adverse event management strategy began with the creation of an electronic order set designated for the management of CRS and immune effector cell-associated neurotoxicity (ICANS). The pharmacy team worked closely with clinical informatics staff to build a comprehensive order set including medical management of toxicity, monitoring parameters (vital signs, neurotoxicity assessments), daily laboratory tests, and any imaging or consults recommended by ASTCT, NCCN, or SITC. Pharmacists drafted an educational document embedded in the order set for nursing staff that contained detailed grading criteria and instructions for when to escalate attention to developing toxicity to physicians.

As part of the toxicity monitoring strategy, we created a scoring tool for nurses to use for evaluating ICANS directly in our electronic health record (EHR). Our goal was for nursing staff to have a readily accessible, standardized evaluation to reduce the burden of frequent monitoring required during initiation. The tool incorporated an immune effector cell–associated encephalopathy (ICE) score and drop-down menus with options correlating to other grading criteria for ICANS. Other elements of toxicity assessment are outlined in the reference text. The goal was for nursing to use the reference text, vital signs, ICE score, and other neurotoxicity assessments in tandem to assign a grade that would then be relayed to the provider as outlined by our policy.

Staff Education

Once the electronic order set, EHR scoring tools, and institutional policies were complete, all staff members involved in the care of patients receiving bispecifics were educated on these new resources. Target groups for education included intensive care unit (ICU) staff, oncology nurses and physicians, emergency department (ED) personnel, hospitalists, neurologists, and pharmacists. Education was provided virtually and in person and was conducted by Cowell Family Cancer Center pharmacists, physicians from outside institutions with experience prescribing bispecifics, and medical science liaisons. The focus of education was primarily on the management of CRS and ICANS during ramp-up and after hospital discharge, as these present some of the biggest barriers to implementation in the community

If toxicities are identified, the closing message on the portal will prompt patients to call their medical oncologist's primary nurse for further direction.

setting. Of note, REMS programs often require documentation that nursing staff administering bispecifics have received education on these toxicities.

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For the inpatient nursing team, we provided a virtual module containing information on bispecifics and toxicity management. This module is readily accessible via our online library and can be assigned to nursing staff at any time. The intent was to have educational material ready on demand for nursing staff who have not received recent education on bispecific therapy but will be responsible for these patients' care. We will also be using this document to augment orientation of new nurses and midlevel providers to bispecific therapy.

Transitions of Care

Pharmacists played a pivotal role in creating a process to monitor patients at home for CRS and ICANS. Although the risk is low, it is possible for these toxicities to occur outside the ramp-up period, usually within the first few cycles.^{2-7,11} To address this barrier, we designed an outpatient monitoring questionnaire to assist with the transition of care from the first treatment dose to the outpatient infusion clinic regardless of ramp-up setting (outpatient vs inpatient). This outpatient questionnaire is sent to patients' smart devices once daily to assess them for CRS, ICANS, general health concerns, and adherence to oral infectious prophylaxis medications (**Table 1**).

Patients who initiate bispecific therapy are also discharged with a vitals kit including an oral thermometer, an automated blood pressure cuff, and a pulse oximeter. Pharmacy or nursing staff educate patients on each item prior to discharge. Patients document their daily results in the questionnaire on their patient portal. Using these results, the portal can alert patients if they are experiencing grade 1 CRS, grade 2 or higher CRS, or any grade of ICANS. If toxicities are identified, the closing message on the portal will prompt patients to call their medical oncologist's primary nurse for further direction. The questionnaire encourages a safe transition to the outpatient setting with continued daily monitoring until the patient's follow-up appointment.

Financial Navigation

Like CRS and ICANS management, reimbursement models represent a big barrier for community cancer centers developing bispecific programs. At Cowell Family Cancer Center, the pharmacy purchasing team worked closely with the bispecific committee and financial navigators to assess the sustainability of our program. Although we concluded that inpatient reimbursement will likely not result in a net profit for the institution, subsequent outpatient

Table 1. Outpatient Toxicity Screening Questionnaire						
CRS SCREENING QUESTION	15					
Blood pressure	≥90/60 mmHg or < 90/60 mmHg					
Oral temperature	≥100.4ºF or <100.4ºF					
Oxygen saturation	>90% or ≤90%					
IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME WORKSHEET QUESTIONS						
Were you able to identify all the of the week, year, and city you l	Yes or no					
Were you able to identify and na	Yes or no					
Were you able to show 2 fingers	Yes or no					
Were you able to handwrite the "Our national bird is the bald eag	Yes or no					
Were you able to count backwa	Yes or no					
GENERAL HEALTH						
Have you experienced any new	Yes or no					
Any new symptoms/possible adv	Yes or no					
ADHERENCE						
Have you missed any doses of y prophylaxis?	Yes or no					
Do you need any refills sent for	Yes or no					
Have you missed any doses of a prophylaxis?	Yes or no					
Do you need any refills sent for prophylaxis?	Yes or no					

PJP, Pneumocystis jirovecii pneumonia; TMP/SMX, trimethoprim/sulfamethoxazole.

infusions tend to offset the inpatient financial burden. Billing codes, modifiers, and major payer reimbursement models should all be assessed prior to initiating patients on bispecific therapy to ensure sustainability. Medical liaisons for bispecific therapy also served as valuable resources for the purchasing and billing teams at Munson Healthcare.

Assessment of Staff Preparedness

Following bispecific program development, we conducted a single-center, retrospective analysis, approved by the Institutional Review Board at Munson Healthcare, to measure medical oncologists' and the inpatient oncology nursing team's readiness to initiate patients on bispecific therapy. Surveys were given to staff members before (presurvey) and after (postsurvey) appropriate education by pharmacists, medical liaisons, and/or physicians. Both surveys consisted of 5 questions and were graded on a 5-point Likert scale (1 being least amenable, 5 being most amenable). The analysis included inpatient oncology nursing staff and medical oncologists at Cowell Family Cancer Center who attended at least 1 educational presentation. Providers outside oncology and outpatient oncology nursing staff were excluded. The primary end point was the difference in provider and nursing readiness scores before and after education.

The presurvey for physicians (Table 2) was administered prior to any educational presentations. The postsurvey for physicians was administered following education by 2 guest medical oncologists who initiate and manage bispecific therapy for patients. These presentations focused on logistics surrounding bispecific therapies and toxicity management. The presurvey for nursing (Table 3) was conducted immediately following education on the new EHR tools and bispecific toxicity management presentations. The postsurvey was planned to be administered following the first patient to initiate bispecific therapy inpatient. Only a presurvey was conducted with nursing staff due to the lack of eligible patients to receive bispecifics within the designated study period. The single nursing survey was assessed using descriptive statistics, and provider responses were analyzed using descriptive statistics and Kruskal-Wallis equality-of-populations rank test.

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Table 2. Provider Survey (Readiness)					
Q1	I am confident that I could successfully order the new bispecific "Power Plan" in Powerchart.				
Q1	I am confident that I could successfully order the new bispecific "Power Plan" in Powerchart.				
Q2	I am confident that I can manage patients who experience ICANS while inpatient.				
Q3	I am confident that I can manage patients who experience CRS while inpatient.				
Q4	I am confident responding to "on-call" questions pertaining to patients receiving bispecific therapy.				
Q5	The existing bispecific protocol and supporting documents are sufficient for me to initiate a patient on bispecific therapy at Munson Medical Center.				

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

Table 3. Nursing Survey (Readiness)					
Qı	I am confident I can use the new "neurotoxicity assessment" category in "interactive view" on Powerchart.				
Q2	The reference text gave me the guidance needed to successfully grade my patients for CRS.				
Q3	The reference text gave me the guidance needed to successfully grade my patients for ICANS.				
Q4	I understand the basic mechanism behind the toxicities associated with bispecific therapy.				
Q5	I understand when I need to page the medical oncologist to receive a toxicity management plan to treat a patient experiencing either ICANS or CRS.				

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

Figure 1. Nursing Survey Results (N=5)



Figure 2. Pre-Provider Survey Results (N=7)



Figure 3. Post-Provider Survey Results (N=7)



Table 4. Results of Kruskal-Wallis Equality-of-Populations Rank Test on Provider Surveys

PROVIDER SURVEY (READINESS) (N=7)							
Questions	Q1	Q2	Q3	Q4	Q5		
Pre-education (median ± IQR)	4 ± 0	3 ± 1	4 ± 1	3 ± 2	3 ± 2		
Post education (median ± IQR)	4 ± 0	3 ± 2	3 ± 2	3 ± 2	3 ± 2		
<i>P</i> value	.936	.728	.115	.734	.122		

Abbreviation: Interquartile range (IQR)

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Study Results

Five inpatient oncology nurses and 7 medical oncologists participated in the staff readiness surveys. The inpatient oncology nursing team (N=5) completed the 5-question survey with median scores and ranges for each question as follows: Q1 was 5 points (IQR, 0; range, 3-5), Q2 was 5 points (range, 4-5), Q3 was 5 points (range, 4-5), Q4 was 4 points (range, 4-5), and Q5 was 5 points (range, 4-5). The medical oncologists (N=7) completed an identical provider survey before and after an educational session. The median scores with IQRs for the pre- vs postsurveys were as follows: Q1 was 4 ± 0 vs 4 ± 0 points (P = .9361), Q2 was 3 ± 1 vs 3 ± 2 points (P = .7284), Q3 was 4 ± 1 vs 3 ± 2 points (P = .1152), Q4 was 3 ± 2 vs 3 ± 2 points (P = .7349), and Q5 was 3 ± 2 vs 3 ± 2 points (P = .1221). There were no statistically significant differences observed among any of the 5 questions on the medical oncologists' surveys following at least 1 observed bispecific educational session.

Discussion

The pursuit of bispecific therapies in the relapsed and refractory setting across various tumor types presents as a feasible opportunity for community cancer centers. One of the biggest barriers in using bispecific therapies in the community setting is the unique prescribing information requirements surrounding inpatient vs outpatient initiation for each product.¹⁻⁷ Community cancer centers must assess their site's readiness and ability to potentially admit and manage these patients for their first ramp-up dose(s). We measured our medical oncologists' readiness using a 5-question survey to determine whether the educational sessions the pharmacy team conducted or helped organize significantly affected their feelings of readiness toward prescribing bispecific therapies. The Kruskal-Wallis rank test revealed no statistically significant difference in provider opinion on their readiness to use bispecifics at our institution.

However, the inpatient nursing staff had high median scores for all 5 of their survey questions following an educational session by pharmaceutical representatives who spoke on toxicity profile and management. These high scores may suggest the inpatient oncology nursing team feels confident they could care for a patient being admitted for initiation of bispecific therapy. The numerical difference Patient-specific factors should help drive the decision to pursue CAR T-cell or bispecific therapy.

in median readiness scores between the nursing and provider surveys could also be attributed to the daily toxicities both groups consistently manage. The medical oncologists do not manage acute hypotension, fever, and hypoxia in the outpatient setting, whereas inpatient nurses routinely care for patients who exhibit these similar symptoms. The inpatient oncology unit at Munson Healthcare is not strictly comprised of patients with cancer; nurses who staff this unit regularly care for terminally or acutely ill patients who do not have cancer. Managing the acute toxicity profile associated with the initiation of bispecific therapies presents another barrier for community cancer centers. Engaging inpatient provider groups (eg, ED, ICU, hospitalists) to support these patients' care was a key component in the bispecific therapy program at Munson Healthcare.

The strengths of our study included being one of the first studies to address specific logistics regarding how to implement bispecifics in the community setting and highlighting the need to educate and coordinate care for these patients as they transition from initiation to maintenance phases. The limitations of our study included small sample sizes and the lack of a comparator survey for nursing staff. As stated previously, although we planned to administer a follow-up survey to nursing staff after our first patient initiated bispecific therapy, the postsurvey was not administered to nursing staff due to a lack of eligible patients receiving bispecific therapy within the study's time frame.

Historically, patients with relapsed/refractory myeloma and lymphoma had limited treatment options with poor response rates. Bispecific and CAR T-cell therapies exemplify efficacious alternatives for this population.^{9,12-15} Prior to bispecifics, CAR T-cell therapy

Implementing bispecific T-cell engager therapies in the community setting will promote continuity of care, provide a local environment for cellular therapies in more rural communities, and optimize patient outcomes.

provided one of the most effective and durable responses in this setting. However, the complexity of pursuing CAR T-cell therapy at a large academic medical center often limits its availability to patients in rural communities.9,10 The influx of patients who now qualify to receive CAR T-cell therapy has also led to significant treatment delays for patients due to a limited number of manufacturers being able to produce patient-specific modified CAR T cells. Patient-specific factors should help drive the decision to pursue CAR T-cell or bispecific therapy. For older or frail patients, bispecific products tend to be associated with a more modest AE profile than that of CAR T-cell therapy, and they can be paused or stopped in response to AEs. Bispecific products may not result in the efficacy seen with CAR T- cell therapy for treatment-refractory patients, but they offer quick availability, modest toxicities, comparable ORRs, and durable responses for patients who cannot pursue CAR T-cell therapy.

Two AEs of particular interest in the community setting are CRS and neurotoxicity due to the hospitalization requirements for grade 2 or higher CRS or any-grade neurotoxicity. Data on multiple myeloma bispecifics report 58.0% to 79.0% of patients experienced all-grade CRS, but only 0.6% to 2.0% of patients experienced grade 3.2-4 Additionally, researchers observed a low incidence of immune effector cell-associated neurotoxicity syndrome or neurotoxicity with the myeloma bispecifics (all-grade range, 3%-14%).²⁻⁴ The International Myeloma Working Group immunotherapy committee recently published consensus guidelines and recommendations for how to optimally use myeloma bispecifics and will aid community cancer centers in developing safe and effective protocols to manage patient cases.¹⁶ Similarly, the American Society of Hematology recently published consensus recommendations for the management of CD3xCD20 bispecific therapies.¹⁷ The relapsed and refractory lymphoma bispecifics also have demonstrated predominately low-grade CRS and neurotoxicity.5-7 On average, the lymphoma bispecifics showed all-grade CRS rates of 44.0% to 70.2% (grade \geq 3 incidence, 2.5%-4.2%), and the incidence of all-grade immune effector cell-associated neurotoxicity syndrome ranged from 5.0% to 8.0%.5-7 These modest toxicity profiles showcase why bispecifics are appropriate candidates to be considered for initiation and administration in the community setting.

Conclusion

Bispecific therapies show high clinical efficacy in myeloma, lymphoma, and select solid tumors. Competitive and durable responses have been replicated in heavily pretreated patients, which has resulted in ongoing clinical trials assessing bispecifics in frontline settings. These treatments, however, are associated with unique toxicities that require significant interprofessional collaboration to optimize patient care at community cancer centers. Although we did not see statistically significant improvement in overall provider readiness, we anticipate that as bispecifics use increases nationally and outcomes data mature, our medical oncology group will successfully use the bispecific program at their discretion. As bispecifics become more widely used, the community setting represents a feasible environment for initiation and maintenance of these agents. Implementing bispecific T-cell engager therapies in the community setting will promote continuity of care, provide a local environment for cellular therapies in more rural communities, and optimize patient outcomes.

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Disclosures

The authors have declared no potential conflicts of interest.

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Our Program at a Glance

Munson Medical Center is the main hospital of Munson Healthcare, a regional network of 8 community hospitals located in northern Michigan. Munson Medical Center is a 442-bed Level II Trauma Center, which includes a 24-bed inpatient oncology department. Munson Medical Center serves as the main hub for our hub-and-spoke health-system model.

Cowell Family Cancer Center operates under a similar hub-and-spoke model to provide oncology services to the greater northern Michigan region. There are 6 regional infusion centers that act as the spokes, and Cowell Family Cancer Center acts as the main hub. Cowell Family Cancer Center provides patients a fully integrated cancer services building comprising 5 radiation oncologists, laboratory services, 8 medical oncologists, 1 gynecology oncologist, a 50-chair infusion suite, an infusion pharmacy with 8 clinical pharmacists, and a multitude of ancillary services (eg, geneticist, dietitian, physical therapy, speech therapy, occupational therapy). The infusion pharmacy's clinical pharmacists are based out of Cowell Family Cancer Center, but they also oversee and dispense any oncolytic that is administered inpatient at Munson Medical Center.

Cowell Family Cancer Center is a stand-alone outpatient facility. However, it is located on the grounds of Munson Medical Center, and there is direct access to the hospital. Incorporation of bispecific therapy was implemented at only Cowell Family Cancer Center and Munson Medical Center, the main hubs of Munson Healthcare.