

Sharing Operational Insights for the Delivery of Bispecific Antibodies in Solid Tumors

Spotlight on West Virginia University Cancer Institute



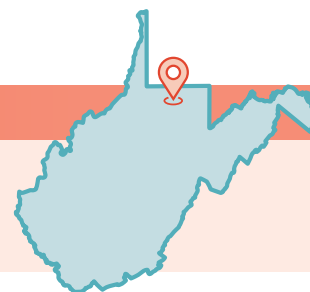
Remarkable progress in cancer immunotherapy has been made over the past decade. Bispecific antibodies, a relatively recent development in cancer therapeutics, show promise in enhancing the precision and efficacy of cancer treatment. Unlike traditional monoclonal antibodies that target a single antigen, bispecific antibodies engage 2 distinct targets simultaneously. Bispecific antibody drugs have proven clinically effective, and several are FDA-approved for the treatment of hematologic malignancies. However, clinical data and research indicate that these agents have significant

immunotherapeutic potential, and they may soon be available to treat such solid tumors as small cell lung cancer, prostate cancer, and gastrointestinal cancers.

In this spotlight, Association of Cancer Care Centers (ACCC) shares West Virginia University (WVU) Cancer Institute's approach to implementing bispecific antibodies in traditional hematologic cancers and lessons learned from clinical trials in the newer solid tumor space.

West Virginia University (WVU) Cancer Institute

LOCATION: Morgantown, West Virginia
CENTER TYPE: Academic Medical Center



WVU Cancer Institute is a regional network of care centers. Its flagship location is the Mary Babb Randolph Cancer Center in Morgantown, West Virginia, which is home to the state's largest group of specialized programs. At this facility, patients and families receive comprehensive cancer care along with a wealth of support from a multidisciplinary team of nurses, dietitians, social workers, and financial counselors to ensure access to the latest oncologic advancements and innovations.

The Mary Babb Randolph Cancer Center is the Institute's largest, most comprehensive cancer care facility with healthcare professionals who offer the full spectrum of cancer care and expertise. WVU Cancer Institute is nationally recognized and accredited by several organizations, including the American College of Surgeons Commission on Cancer, the National Accreditation Program for Breast Centers, and the Foundation for the Accreditation of Cellular Therapy.

There are 15 centers across the WVU Cancer Institute network with sites in West Virginia, Maryland, and Pennsylvania. The Mary Babb Randolph Cancer Center includes a multidisciplinary team of 5 hematologists, 55 infusion nurses, 5 nurse navigators, 1 transplant coordinator, and 3 nurse coordinators dedicated to transplant and cellular therapy coordination for eligible patients. Four pharmacists are specifically assigned to transplant and cellular therapy or hematologic malignancies.

Five social workers handle logistics and other issues, including 2 social workers for patients undergoing transplant and cellular therapy; the remaining 3 social workers provide general patient support. The team also includes 7 advanced practice providers (APPs) assigned to individual physicians and floating roles; they facilitate care coordination between inpatient and ambulatory settings. Despite the rural landscape, the academic center ensures accessibility to the latest advancements in cancer treatment, particularly bispecific therapies.

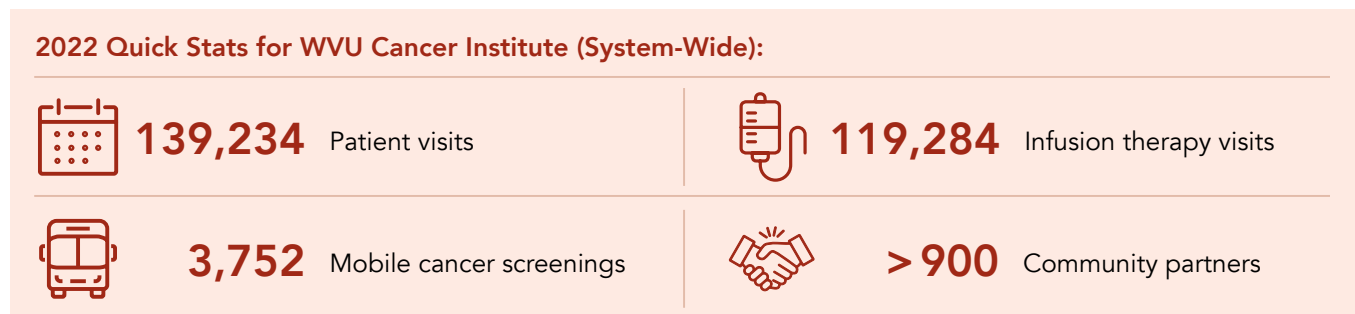


Table 1. Mary Babb Randolph Cancer Center: Transplant and Cellular Therapy Facts and Figures

Patient Volumes	
Patients (total) who received or are currently receiving bispecific antibodies as therapy.	36
Patients monitored who are not currently receiving treatment.	4
Patients in active treatment/therapy.	7
Patients in remission (with treatment completed).	2
Patients with blood cancers who received bispecific antibodies as therapy.	35
Patients with solid tumor cancers who received bispecific antibodies as therapy.	1
Patient Profiles	
Patient demographics (gender, age, race)	Male, 61% Average age, 50 years Race, mostly White
Patients from rural areas	Almost 100%
Patients using telehealth for at least some visits	Approximately 25%
Language(s) spoken	English
Payer mix	Government-based health plans, approximately 66% Commercial insurance, approximately 33%

Initiating Treatment Conversations with Patients

The first step when considering the use of bispecific antibodies is to engage with patients and review eligibility requirements to determine whether a patient is a candidate for treatment. Konstantinos Sdrimas, MD, assistant professor at West Virginia University School of Medicine, advocated for the use of bispecific antibodies and noted that he actively pursues their integration. However, he noted that the first critical step is the initial conversation with patients about their treatment options.

Dr. Sdrimas emphasized the crucial role of patient education, data-driven discussions, and discussions on cost of care. In West Virginia, where patients often place significant trust in their physicians, these conversations are critical to building trust with the patient and allowing them to feel more at ease when following their doctors' advice.

Beyond diagnosis, the eligibility criteria for bispecific therapy at WVU Cancer Institute includes factors such as patient caregiver support, socioeconomic factors, and insurance barriers. The logistical challenges faced by patients is a subject confronted by Aaron Cumpston, PharmD, BCOP, a pharmacy clinical specialist in hematologic malignancy, transplant, and cellular therapy. These challenges include travel constraints, lack of social or home support, limited patient understanding, and financial issues. Acknowledging these hurdles, Dr. Cumpston stated, "We have patients [who] come [from] 4 to 5 hours away for their visits.... There are a lot of hurdles we have to talk through." The requirement for a full-time caregiver presents additional challenges in rural areas where such support may be limited. Addressing the needs of a rural population necessitates a nuanced understanding and tailored strategies for effective cancer care delivery.

Criteria for support at WVU Cancer Institute include:

- diagnosis
- fit indication
- travel
- patient support (beyond transportation, requiring a caregiver 24 hours per day, 7 days per week)
- insurance and financial considerations.

The final decision to pursue bispecific therapy is a collaborative effort agreed upon by all involved physicians. The inclusion of bispecific therapy discussions in tumor boards underscores the center's commitment to evidence-based decision-making. "We have a weekly [tumor board] meeting [where we discuss] our patients who are in transplant and cellular therapy," explained Dr. Sdrimas. These boards are broken down by provider, with attending physicians participating along with the entire care team. This allows the team to discuss each patient's progress, therapeutic options, and treatment goals and to make adjustments if a patient is better suited for a different therapy. Eligibility questions and potential barriers are thoroughly discussed during these meetings. More informally, providers interact on a more frequent basis, even in the break room. "I mean, we're a small group—there [are] only 5 of us. So, we talk a lot," added Dr. Sdrimas.

Once a patient has been identified and deemed eligible for treatment, a series of subsequent steps occur, usually on the same day. The drug onboarding process involves close collaboration between pharmacists, nurse clinicians, and insurance providers. The team works seamlessly to:

- enter the treatment order into the system
- identify dates for treatment
- obtain necessary authorizations from the patient's insurance
- interact with drug company representatives and explore drug acquisition programs to navigate any insurance hurdles while awaiting approval
- collaborate with the satellite pharmacy to order the product
- meet with the patient to provide counseling from a pharmacist's perspective, ensuring that they are well-informed and supported on the first day of treatment (if not the same day).

The process becomes more complex when coordinating bispecific treatment with staff at other sites or institutions.

At the Institute's smaller sister sites, where patients may have initiated bispecific antibody treatment at outside facilities, care teams must investigate pharmacy benefits to obtain those specific antibodies. This additional hurdle involves navigating different insurance approval processes, white bagging the medication into the cancer center, and ensuring its delivery to the patient.



What is "White Bagging"?

"White bagging" refers to the distribution of patient-specific medication from a pharmacy to the physician's office, hospital, or clinic for administration.

Care Coordination and Administration of Bispecific Antibodies

The complex delivery of bispecific antibodies requires effective care coordination and a balance between inpatient and outpatient teams. At WVU Cancer Institute, patient care teams operate with clear distinction between inpatient and outpatient care and minimal personnel crossover. Stacy Forst, PA, in the division of hematology/oncology plays a crucial role in managing communication between these teams. When preparing to admit a patient, communication is vital; it flows in both directions and involves consent before admission, insurance authorization, communication with the inpatient team to convey the plan, and establishment of post-discharge plans as the patient emerges from treatment.

Treatment may be given in an outpatient setting, or it may involve patient admission for observation due to potential adverse effects. In particular, cytokine release syndrome and neurotoxicity are major concerns. Typically, patients in the outpatient setting are monitored at the Institute, but some patients are admitted for observation immediately after outpatient administration. Presently, 66% to 75% of patients have full, outpatient administration and monitoring; 25% to 33% of patients are admitted for inpatient monitoring following step-up dosing. However, as care teams become more comfortable with bispecifics, this strategy may change, with continual evaluation of patient experiences guiding the eventual transition to outpatient administration as aligned with the Risk Evaluation and Mitigation Strategy.

The impact of social drivers of health on care coordination, especially as it relates to a patient's support system, becomes evident during therapy. Leaders at the Institute recognize challenges faced by patients in terms of caregivers and transportation and actively provide robust support through housing and transportation assistance, financial assistance resources, and drug therapy programs. Members of the Institute found that the easiest way to accomplish this was

to leverage the infrastructure of their successful outpatient support programs (including transplant and chimeric antigen receptor (CAR) T-cell therapy) and to extend similar services for bispecific therapies to ensure that patients have necessary support during their treatment.

Home health referrals that offer services such as bag exchanges and laboratory care are used based on therapy type. These referrals benefit patients who face challenges with caregiver support and transportation. However, eligibility varies, with geographic limitations and insurance constraints affecting some patients. The program is actively working to optimize its policies for home health services, recognizing the need for education and collaboration with institutions to expand service availability.

Partnerships with other facilities in local health systems also have been explored as a solution. The collaboration between WVU Cancer Institute and other sites demonstrates a willingness to assist and learn about patients, providing a unique opportunity within the growing healthcare system.

Drawing lessons from CAR T-cell therapy, Dr. Cumpston highlights similarities in the learning curve for bispecific therapies. Whereas the former poses significant financial challenges, the latter offer more financial feasibility. The lower occurrence of severe adverse effects with bispecific therapies also introduces the possibility of outpatient administration, mirroring the models established for CAR T-cell therapy. "As these CAR T [patient] volumes have grown, it's financially becoming almost a requirement that people can do them outpatient... CAR T has kind of shown us that we can do these things outpatient," he stated, emphasizing the need to adapt and model the process after other successful therapy procedures in facilitating outpatient treatment.

“We’re navigating challenges that many other centers are also facing, particularly in terms of inpatient and outpatient considerations, and the unique aspects of systemizing medications, especially given the variations in step-up dosing protocols.”

—Aaron Cumpston, PharmD, BCOP

Reflecting on Lessons Learned

Determining the highest risk of cytokine release syndrome concerning specific step-up doses, the recommended duration for close monitoring around each relative step-up dose, and the first treatment dose is an ongoing endeavor. “Once you get through the early phase, they’re very doable at smaller centers with less infrastructure,” notes Dr. Cumpston. However, the care team at WVU Cancer Institute emphasizes that it is imperative to stay involved in care as patients transition to outside facilities and especially smaller centers that may be less acquainted with these therapies to assist in managing potential toxicities.

Institute leadership advocates for collaboration between community cancer centers and larger organizations or

academic centers; patients would begin bispecific antibody treatment at larger centers, complete the initial cycles, and continue treatment at a local or community setting. This approach offers local oncologists support, ensuring a seamless transition for patients requiring admission to the larger institution. The key lies in meticulous documentation and exchange of information to provide comprehensive patient care.

Leaders at the Institute also emphasized the critical importance of care coordination in navigating the complexities of emerging therapies. Whether handled by 1 staff member or multiple individuals, dedicated care coordination is vital in managing the growing volume of therapies and patients.

Managing adverse events:

- Leverage available data (eg, from approval studies)
- Understand low-grade toxicity risks
- Develop educational resources for nurses and conduct team reviews of treatment plans
- Educate patients on recognizing potential issues
- Create more detailed and drug-specific protocols

Application of Bispecifics in Solid Tumor

In 2021, staff at WVU Cancer Institute designed and managed a clinical trial for tebentafusp, a bispecific T-cell engager (BiTE) administered by intravenous infusion and used to treat uveal melanoma (eye cancer). At the Institute, this project was managed by the solid tumor care team and primarily was considered an inpatient clinical trial.

In a recent CANCER BUZZ video podcast ([Episode 148](#)), Dr. Cumpston underscored the profound impact of bispecific antibodies on cancer treatment, emphasizing their effectiveness and durability, particularly in refractory patients. “These drugs are having a really big impact on the landscape of many disease states,” he stated, highlighting the high response rates observed across various malignancies.

With recent FDA approvals and expanding target options, bispecific antibodies are poised to revolutionize cancer therapy and signal a paradigm shift in treatment approaches.

Christine Barrett, PharmD, BCOP, a medical oncology clinical pharmacy specialist at WVU Cancer Institute who also joined the podcast, discussed the challenges of delivering bispecific antibodies in solid tumors for which experience with these therapies is relatively new. She highlighted the need for detailed protocols and collaboration among healthcare teams to effectively manage and monitor patients receiving BiTE therapies.

In addressing the concerns of community practices, Dr. Barrett advised healthcare professionals at community practices

to reach out to staff at larger institutions for guidance and support as they navigate the complexities of bispecific antibody administration. She stressed the value of seeking assistance from experienced institutions with staff who successfully implemented bispecific antibodies therapies; this underscored the importance of knowledge-sharing and collaboration within the healthcare community.

The transformative potential of bispecific antibodies in cancer treatment continues to reshape the care landscape. This change demands the leveraging of expertise from larger institutions, improvement in care coordination, and implementation of standards and best practices to optimize patient outcomes, particularly in community settings where resources may be more limited.

“Implementing these BiTE therapies can seem very overwhelming for institutions that maybe are not as familiar...[however], there is a network of institutions out there that have...taken on administering these BiTE therapies and have a lot of experience that can be very helpful.”

— Christine Barrett, PharmD, BCOP

Summary

The leadership of WVU Cancer Institute has made significant progress in leveraging bispecific antibodies to provide innovative and effective treatments. With a dedicated and diverse care team, the Institute staff members address the unique challenges posed by West Virginia’s population, ensuring that patients receive advanced therapies as they navigate logistical and socioeconomic barriers. Through continuous collaboration, education, and patient-centric approaches, WVU Cancer Institute and its leadership remain at the forefront of cancer treatment as they offer hope and improved outcomes for individuals facing this challenging journey.

In 2020 and 2022, the Association of Cancer Care Centers (ACCC) produced a series of hematologic malignancy-focused programs, including **Preparing Community Providers for Bispecific Antibodies** and **Best Practices in Expanding**

Access to Bispecific Antibodies and Adverse Event Management. These programs were intended to identify and address barriers to informing healthcare professionals about bispecific antibodies and to prepare these providers to use this treatment.

In 2023, ACCC expanded upon this work with the new educational program **Sharing Operational Insights for the Delivery of Bispecific Antibodies in Solid Tumor** with support by Amgen. This program explores the potential of bispecific antibodies for treating patients with solid tumors and highlights the latest findings in solid tumor applications. By showcasing current best practices and guidelines, this program assists care teams in preparing to administer bispecific antibody therapies for solid tumors, particularly in community care and rural cancer program settings.

Acknowledgments

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Access additional educational resources for the use of bispecific therapies at acc-cancer.org/bispecifics-solid-tumors.

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