



Expanding Access to Cellular and Bispecific Therapies

Considerations and Recommendations



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About SITC



Society for Immunotherapy of Cancer

The Society for Immunotherapy of Cancer (SITC) is the world’s leading member-driven organization specifically dedicated to professionals working in the field of cancer immunology and immunotherapy. Established in 1984, SITC is a 501(c)(3) not-for-profit medical professional society comprised of over 4650 influential research scientists, physician scientists, clinicians, patients, patient advocates, government representatives and industry leaders dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy.

Through emphasis on high-caliber scientific meetings; dedication to education and outreach activities; focus on initiatives of major importance in the field; and commitment to collaborations with like-minded domestic and international organizations, government and regulatory agencies, associations and patient advocacy groups, SITC brings together all aspects of the cancer immunology and immunotherapy community. SITC aims to make cancer immunotherapy a standard of care and the word “cure” a reality for cancer patients everywhere.

About ACCC



Association of Community Cancer Centers

The Association of Community Cancer Centers (ACCC) is a powerful community of more than 34,000 multidisciplinary practitioners and 1700 cancer programs and practices nationwide.

Founded in 1974, ACCC brings together healthcare professionals across all disciplines in oncology to promote quality cancer care. It is estimated that 65 percent of the nation's cancer patients are treated by a member of ACCC.

Members rely on ACCC for education and advocacy support in adapting and responding to complex changes and challenges in the delivery of quality cancer care. ACCC provides resources on operations and management for programs and practices, reimbursement issues, policy and regulatory changes at the state and national levels, trends in cancer care, integrating new technologies and therapies, and more.

Overview

The SITC ACCC Expanding Access to Cellular and Bispecific Therapies workshop, SITC and ACCC gathered experts tasked with providing recommendations for centers interested in opening cellular therapy and bispecific programs. Through group discussion, the workshop came to consensus on a number of recommendations that address three distinct categories. These recommendations are detailed as actions suggested to be taken prior/while opening a program.



- **STANDARDIZE** education programs
- **ENSURE** multidisciplinary education
- **EMPHASIZE** patient education
- **UNDERSTAND** REMS requirements
- **DEVELOP** a plan for employee turnover



- **STUDY** the academic center example
- **EMPHASIZE** adverse event management
- **CONSIDER** geographic barriers
- **ESTABLISH** an effective multidisciplinary team
- **STREAMLINE** Clinical Operations
- **ADVOCATE** for investment
- **ACCEPT** limitations and capacity



- **ESTABLISH** communication with payers
- **UNDERSTAND** financial ramifications
- **STAY INFORMED** about current research
- **SUPPORT** real-world data collection
- **UNDERSTAND** selection criteria
- **HELP** patients understand billing
- **UTILIZE** preexisting resources
- **ENSURE** proper coding to support long term-reimbursement calculations

Educate



Education across the entire care continuum serves as the foundation for any cellular therapy and/or bispecific program. Developing strategies for engaging appropriate stakeholders and keeping the care team informed about current practice is critical for initiating a sustainable and effective program.

STANDARDIZE education programs

Cellular therapies and bispecifics are considered “novel therapies” at many cancer centers across the country. As such, centers and stakeholders should prioritize comprehensive education to ensure optimized patient care. Certification programs are one effective strategy to address gaps in education concerning these therapies. However, certification programs differ across specialties, which can introduce confusion for stakeholders on which program to prioritize and which guidelines apply to their specific clinical scenarios. In addition, education programs must sufficiently meet regulatory requirements for respective therapies. To avoid potential pitfalls, workshop participants emphasize standardizing education and certification programs, then tailoring programs further to meet a center’s specific needs. These efforts will help relieve staff burden and ensure that each center is effectively trained for safe and efficient patient care. Oncology-focused societies such as SITC and ACCC can serve as excellent resources for education on cellular therapies and bispecifics that can be incorporated into training programs.

A few examples:

- One-page primer on chimeric antigen receptor (CAR) T-cell therapies that provides an overview of each team member’s responsibility
- Pocket guide that outlines how to diagnose and treat cytokine release syndrome (CRS) related to CAR T-cell therapy and CRS related to bispecific antibodies
- Videos that summarize the patient experience across different phases of the treatment journey
- Team preparation guidelines that may be required for treatment initiated in an inpatient vs. outpatient setting
- Patient cases or simulations on the identification and management of treatment-related toxicities at varying levels of severity.

Contextualize your education programs based on whether you currently offer, plan to offer, or will continue to refer patients to treatment centers for:

- CAR T-cell therapies
- Bispecific antibodies
- Tumor-infiltrating lymphocytes (TIL)

ENSURE multidisciplinary education

Cellular therapies and bispecifics are unique compared to many other immunotherapies and require multidisciplinary involvement from across the care team. Surgeons, oncologists, nurses, pharmacists, administrators, and other members of the care team each play an important role in administering therapy for a patient with cancer. In some care centers, education concerning therapies is limited to the direct care team. However, cellular therapies and bispecifics require expanded education programs that enable all members of the care team to be properly trained and equipped to handle various scenarios. Many different examples exist for optimized multidisciplinary educational approaches for cellular therapy and bispecific programs. Most commonly, established and accredited bone marrow transplant (BMT) centers serve as excellent examples for multidisciplinary educational programs, where strong infrastructure is already in place for all members of the care team. The American Society for Transplantation and Cellular Therapy (ASTCT) and the Foundation for the Accreditation of Cellular Therapy (FACT) can offer further information and guidance on multidisciplinary team education and infrastructure.

EMPHASIZE
patient education

Participants emphasized the importance of a “patient first” approach for any cellular therapy and bispecific program. These therapies often involve unique and differing treatment plans compared to other oncology treatments. Patient understanding and commitment is also vital to success. Patients often have unique perspectives and may ask questions about specifics such as treatment administration, safety, and the number of team members involved. Participants highly recommend that any potential care center considering cellular therapy and bispecific programs initiate collaborations with advocacy groups and societies such as SITC and ACCC to strengthen their patient education programs. Strong relationships between stakeholders will help ensure patients are comfortable with administration of their therapies and support optimal outcomes.

UNDERSTAND
REMS requirements

Cellular therapies in particular have associated Risk Evaluation and Mitigation Strategies (REMS) in place through regulatory requirements. REMS for each therapy are different and require specified education to ensure that appropriate patient metrics are collected during treatment. As such, it is especially critical that any prospective treatment center fully analyze REMS specific to any therapy of interest and ensure that proper education and staffing infrastructure is in place prior to treating any patient. Groups like ASTCT and FACT have established education on specific REMS for implementation that can be useful to cancer centers.

CAR T-cell Therapies:	Bispecific Antibodies:
Axicabtagene ciloleucel (Yescarta)*	Amivantamab-vmjw (Rybrevant)
Brexucabtagene autoleucel (Tecartus)*	Blinatumomab (Blincyto)**
Ciltacabtagene autoleucel (Carvykti)*	Epcoritamab (Epkiny)
Idecabtagene vicleucel (Abecma)*	Mosunetuzumab-axgb (Lunsumio)
Lisocabtagene maraleucel (Breyanzi)*	Tebentafusp-tebn (Kimmtrak)
Tisagenlecleucel (Kymriah)*	Teclistamab-cqyv (Tecvayli)*

* Risk Evaluation and Mitigation Strategy (REMS) program
 **REMS program was removed

DEVELOP
a plan for employee turnover

Employee turnover naturally occurs in workplaces around the world. However, one major concern for cellular therapy and bispecific programs is ensuring that all aspects of administration can be maintained during times of employee turnover. This can become problematic as care teams for these programs must undergo a significant level of education prior to treating any patients, and any gap in education and training can cause significant delays in patient care and reimbursement. As such, it is essential that all prospective care centers develop sustainable and comprehensive training plans to mitigate any possible issues caused by employee turnover.

Coordinate



Effective and efficient communication across the entire care team is achieved through planning and commitment. Formalized communication structures are critical for ensuring appropriate patient management within any cellular therapy and bispecific program.

STUDY

the academic center example

Prior to their recent clinical success, availability of cellular therapies and bispecifics has been primarily limited to academic centers due to the required infrastructure for collection, manufacturing, infusion, and patient monitoring. Participants noted that expansion into community settings is actively being discussed, but that there are concerns that such centers may not have a strong blueprint to follow. Participants agreed that lessons learned from the academic center and clinical trial experience should be heavily referenced and used as an example when considering establishment of a cellular therapy and bispecific program. For example, cancer centers that have established cellular therapy programs have identified the need for new team members such as a cellular therapy program manager and financial staff who can navigate the complex health insurance prior authorization process. Moreover, there is growing interest to initiate more cellular therapies and bispecifics in the outpatient setting for appropriate patients. SITC and ACCC are well equipped to facilitate connections between academic centers with prior therapeutic experience and community cancer centers that are interested in expanding their treatment offerings.

EMPHASIZE

adverse event management

A hallmark of cellular therapies and bispecifics is their relatively unique adverse event profile compared to other oncologic treatments, including alternative immunotherapies. Adverse events from these modalities include cytokine release syndrome and specific neurologic disorders that require close monitoring of patients during and after infusion, as well as rapid interventions if symptoms arise. If patients require hospitalization, they need to be directed to hospitals that are equipped to handle these unique types of adverse events. Many groups, including SITC, have developed guidelines and supporting materials that detail appropriate management of adverse events that may be observed in cellular therapy and bispecific programs. Participants emphasized that prospective centers should review and familiarize themselves with current adverse event management standards and ensure that the full care team is well informed prior to treating the first patient.

CONSIDER

geographic barriers

Catchment areas for both academic and community cancer centers can vary widely in relation to geographical reach. For certain centers, catchment reach may expand hundreds of miles and have geographic barriers that may impact timeliness of treatment from both patient and logistical perspectives. Transitions of care may be especially challenging to coordinate when patients need to travel great distances. Patients should have clear guidance on how their local oncologist will coordinate post-treatment care and monitor for long-term effects. Participants highlighted how each center should carefully analyze their overall reach and develop strategies to ensure rapid treatment of patients in any cellular therapy and bispecific program.

ESTABLISH

an effective multidisciplinary team

Treatment of patients with cellular therapies and bispecifics requires a multidisciplinary team consisting of oncologists, midlevel providers, nurses, pathologists, surgeons, and administrators. Participants stressed the importance of having each prospective center carefully study how to construct a multidisciplinary team, including who should be involved and how to enable strong communication and collaboration. Participants also highlighted that treatment of patients with cellular therapies and bispecifics requires 24-hour care that may not be standard for other available treatments. The on-call schedule should include an oncologist experienced with cellular therapies who is available on nights and weekends. Many societies including ASTCT and FACT have developed materials that detail multidisciplinary team construction and can assist any prospective center looking to initiate these programs.

STREAMLINE Clinical Operations

Participants detailed the various processes and steps involved with administering cellular therapies and bispecifics to cancer patients and noted challenges given that standard patients are often very sick and require immediate care. As such, it was recommended that prospective centers "identify ways to reduce procedural delays and batch certain processes together for maximum efficiency." Streamlining patient intake, ensuring rapid apheresis and cellular collection, and expediting manufacturing are all examples of processes that can be refined in order to expedite patient care.

ADVOCATE for investment

Participants highlighted the infrastructure requirements for safe and effective cellular therapy and bispecific administration and noted how successful centers provided commitment through current and future investment. Many cancer centers, especially those in community and rural settings, do not have established infrastructure for cellular therapy and bispecific administration and require building new facilities, training new staff, and strengthening pre-existing support systems. Advocacy for such investment is critical, and centers interested in cellular therapy and bispecific programs should only consider moving forward if commitment for such investments exists.

ACCEPT limitations and capacity

While many cancer centers will work to establish adequate infrastructure for administering cellular therapies and bispecifics, limitations on such care will always be present. For example, a center will have a limited number of beds and personnel, and these aspects will always limit the total number of patients that can be treated at a given time. Some centers may lack clinical experts, such as neurologists, who are experienced in treating patients who develop serious neurologic toxicities. Participants stressed the importance of prospective centers understanding their specific limitations and ensuring that they do not overextend. They also stressed how understanding limitations is critical for safe and effective patient care.

Facilitate



The required logistics for administration of novel cellular therapies and bispecifics can appear daunting to any center regardless of prior preparation. Learning from centers and stakeholders who have successfully navigated these challenges can provide a prospective center a blueprint for how to provide these therapies in a mutually efficient manner for both patients and providers.

ESTABLISH

communications with payers

Payers have been encouraged to reevaluate payment and reimbursement models due to the significant costs of cellular therapy and bispecific treatment. Efficient and accurate reimbursement models will significantly enhance patient access to these therapies. As such, it is critical that stakeholders develop strong communication strategies with payers to detail changes in treatment strategies and the associated costs in order to modify reimbursement models. Prospective centers should consider direct communications to payers on these issues, but should also work to become involved in field-wide consortium-level communications in order to create a uniform voice and opinion on appropriate reimbursement and economics of these therapies. As prior authorization for cellular therapy may take multiple weeks, explore ways to streamline internal and external communication to ensure that all the necessary documents are ready and complete.

UNDERSTAND

financial ramifications

The significant costs of cellular therapies and bispecifics directly affect both centers and patients. It is vital that prospective centers work to improve care processes that can ultimately shorten hospitalization and reduce costs for all involved parties. Center costs are reliant upon payer reimbursement, therefore subsequent improvement upon processes could help reduce burden. For example, centers could work to reduce administrative burden in order to make care more efficient. Centers could also evaluate outpatient vs inpatient care as a potential mechanism to help control costs. More centers are demonstrating safe ways to initiate cellular therapies and bispecifics in the outpatient setting. Concerning patients, real-world costs are associated with their care. Travel and time away from work are just a few of the real-world costs that patients must consider, and centers should think proactively about how to better support patients through these expenditures.

STAY

informed about current research

Cellular therapies and bispecifics serve as excellent examples on how rapidly the oncology treatment landscape can evolve. It is critical that centers that are considering adding these therapies also be prepared to remain current on active research. Stakeholders continue to work on novel clinical research that may alter treatment recommendations and/or allow for new therapeutics to enter the clinic. In addition, significant research is focused on manufacturing, administration, and toxicity management. As such, standards of care may quickly change, and centers should be ready to ensure that novel treatment considerations can be quickly incorporated into their care programs.

SUPPORT

real-world data collection

Long-term evaluations of cellular therapies and bispecifics are not yet available as these treatments only recently entered clinical practice. As such, collection of real-world data concerning treatment efficacy, toxicity management, and overall care coordination are critical for driving process improvements and economic viability. For example, data from collection efforts could serve to generate consensus procedural maps for prospective centers that detail how to build and expand administration capabilities and infrastructure. Additionally, real-world data can provide leverage for conversations with payers on how to strengthen reimbursement to ensure patient access and center viability. Professional societies such as SITC and ACCC could serve as excellent facilitators for data collection efforts in the future.

Facilitate

UNDERSTAND selection criteria

Cellular therapies and bispecifics are only viable for patients that fall into specific eligibility criteria. Reimbursement complications can readily arise if non-eligible patients receive treatment. It is important that prospective centers understand eligibility criteria for cellular therapies and bispecifics to implement protocols that ensure patients will qualify prior to treatment administration. These safeguards will result in streamlined billing and more positive patient/center experiences.

ENSURE proper coding to support long-term reimbursement calculations

Specific billing codes and parameters are used for cellular therapy and bispecifics. Long-term sustainability of cellular therapies and bispecifics will require centers to become familiar with and utilize these codes. Ensuring accurate coding ensures appropriate reimbursement from payers and helps build a substantial data set for payers to reevaluate reimbursement thresholds as therapy utilization increases.

HELP patients understand billing

While patient-provider discussions commonly include billing considerations and treatment costs, cellular therapy and bispecifics require additional consideration due to the real-world costs associated with treatment which can impact a patient's overall financial situation, treatment decisions, and health outcomes. As such, it is important that prospective centers enlist dedicated personnel and have adequate educational and supportive resources available to help patients and providers navigate billing considerations for prospective treatments to promote shared decision-making.

UTILIZE preexisting resources

Billing and coding for cellular therapies and bispecifics is complicated and often evolves as more data become available for reimbursement calculations. Due to these growing complexities, professional societies such as ASTCT have taken action and developed resources to educate stakeholders about the current landscape for billing and coding for these therapies. Reviewing pre-existing resources serves as an excellent first step for any prospective center working to comprehend and incorporate billing and coding for cellular therapies and bispecifics. Having these resources readily available for staff responsible for billing and coding can increase efficiency and improve reimbursement outcomes, which serve to improve the patient and center experience.

Workshop Details and Participants

Background

As immunotherapies continue to show efficacy and safety for the treatment of various cancers, it is of crucial importance that access to these therapies continues to expand. While academic medical centers often have infrastructure in place to adapt to the changing immunotherapeutic landscape, community cancer centers that serve the significant portion of cancer patients across the US face unique challenges that limit accessibility. In particular, novel cellular therapies and bispecific molecules for the treatment of patients with both solid and liquid tumors require sufficient infrastructure, specialized monitoring, dedicated administration protocols, and individualized training to facilitate safe and effective administration. To help promote rapid patient access to novel immunotherapeutics, the Society for Immunotherapy of Cancer (SITC) and the Association of Community Cancer Centers (ACCC) collaborated to host a joint workshop in Boston, Massachusetts, to discuss how to apply lessons learned from academic cancer centers in the community care setting. Workshop participants included leadership representatives from academia, community providers, industry, and hospital administrators.

Goals and Structure

The overarching goal of the SITC ACCC *Expanding Access to Cellular and Bispecific Therapies Workshop* was to identify primary hurdles and potential solutions for providing novel therapeutics in the community care setting and provide community cancer centers with recommendations to consider when exploring implementation of these novel therapies. Workshop participants were divided into five breakout groups, each dedicated to a specific topic area related to providing cellular therapies and bispecifics. The breakout group topics included:

1. Education
2. Coding and Billing
3. Continuity of Care
4. Team Management
5. Economics

Through in-depth small group discussion and reporting back to the larger group, participants came to a consensus on several actions that address the identified topics, and provided the following recommendations detailed throughout this report. These recommendations have been grouped into three key themes that can serve as a resource for any cancer center exploring the introduction of a cellular or bispecific therapy program.

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Workshop Details and Participants

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