Putting Bispecific T-Cell Engagers into Action

This is a playbook for how to operationalize bispecific T-cell engagers.

Step 1: 🤝 Build the Interprofessional Team

Step 2. 📚 Provide Education and Training

Step 3. 🗂️ Coordinate Care

Step 4. 🚪 Address Access Issues

Step 5. 📑 Create Protocols

Step 1: 🤝 Build the Interprofessional Team

Unite a dynamic healthcare team to operationalize bispecific T-cell engagers.

Why it matters: The effective use of bispecific T-cell engagers requires an interprofessional team that combines expertise from various disciplines. Creating a diverse interprofessional team ensures coordinated care across various settings, whether inpatient or outpatient.

Essential members of the interprofessional team include:

- **Oncologists and hematologists**: Provide clinical oversight and treatment planning.
- **Advanced practice providers (APPs)**: Collaborate with the interprofessional team to provide comprehensive care.
- **Pharmacists**: Ensure accurate medication management, monitor drug interactions, and educate other healthcare staff about therapies.
- **Nursing staff**: Provide hands-on care, like giving systemic therapy, managing your care, answering questions, and helping patients cope with side effects.
- **Social workers**: Address patient needs related to care transitions and logistical support (transportation, financial counseling, etc.)
- **Other key stakeholders**: electronic medical record (EMR)/information technology (IT) support, care partners, scheduling staff, medical assistants, billing staff, patient navigators, and administrative personnel.

Who's leading the charge? It's important to identify a **practice champion**— a key leader who advocates for and facilitates the implementation of bispecific T-cell engagers.

- They educate and train staff on treatment protocols, enhance communication among team members, and oversee the implementation processes.
- Typically, practice champions are physicians, pharmacists, APPs, or quality improvement specialists.

Streamlined success. Establish structured approval workflows that ensure quick access to bispecific T-cell engagers while adhering to organizational standards.

- Engage the interprofessional team to assess treatment requests and gather essential data for Pharmacy & Therapeutics (P&T) committee evaluation
    - **Note**: Not all institutions will have a P&T committee.
- Create **pre-formulary order sets** designed to minimize errors in dosage and administration, enhancing patient safety.

Step 2. 📚 Provide Education and Training

Comprehensive education and training for the care team, patients, and care partners are essential for successfully implementing bispecific T-cell engager therapies.

Why it matters: Effective education and training are vital—they empower the care team, patients, and care partners to navigate the complexities of bispecific T-cell engager therapies, ensuring preparedness, patient safety, and optimal treatment outcomes.

Educating and training the care team. The care team must be well-informed and skilled in managing bispecific T-cell engager therapies. Institutions should develop a centralized database or resource center with access to management protocols, patient scenarios, and support materials for healthcare providers.

- **Protocols:** Detailed instructions on patient eligibility, administration procedures, monitoring, and toxicity management specific to bispecific T-cell engagers, including graded responses for cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS).
- **Clinical Updates:** Regular educational sessions on the latest developments in bispecific T-cell engagers and emerging research findings.
- **Simulation Training:** Role-playing scenarios for nurses and pharmacists to practice emergency responses to anticipated adverse reactions.

Effective training for the care team not only enhances their confidence but also directly impacts patient safety and treatment efficacy, leading to improved overall outcomes.

Educating and training patients and care partners. Patients and their care partners require education to navigate their treatment journey successfully. Patient education materials (booklets, wallet cards, digital applications) enhance awareness and facilitate self-monitoring and reporting.

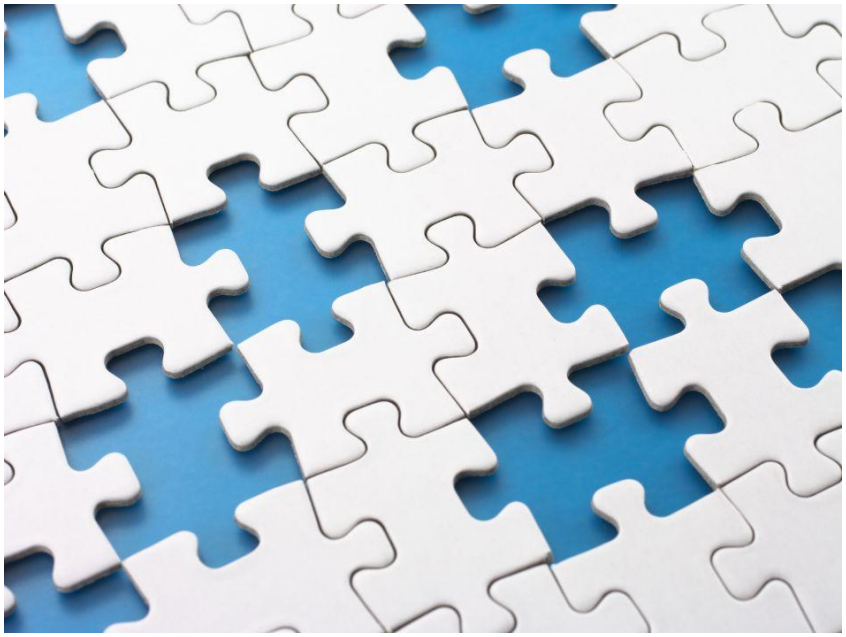
- **Educational materials**: Overview of the treatment process, potential side effects, and precautions.
- **Toxicity awareness**: Training on identifying signs (e.g., CRS, ICANS), what symptoms to monitor, and when to seek help.
- **REMS requirements** (if applicable): In-depth education regarding enrollment, wallet cards, and ongoing monitoring obligations.

Unique considerations. Care partners are vital for patients receiving bispecific T-cell engager therapy.

- The interprofessional team should establish guidelines to select effective care partners and provide them with training on coping strategies.

By equipping both patients and care partners with the necessary knowledge and skills, clinics can enhance the treatment experience and ensure a safer and better quality of care.

Step 3. 🗂️ Coordinate Care



Efficient coordination and communication among the care team are essential for seamless transitions and optimal management of patients receiving bispecific T-cell engager therapies.

Why It matters: Effective transitions ensure continuity and safety during treatment. Clearly defined team roles and open communication facilitate swift responses to complications and enhance patient management.

Can all patients be treated outpatient? Outpatient administration should be considered only after evaluating patient-specific risk factors, such as disease burden and prior treatment responses.

Coordinate outpatient care by**:**

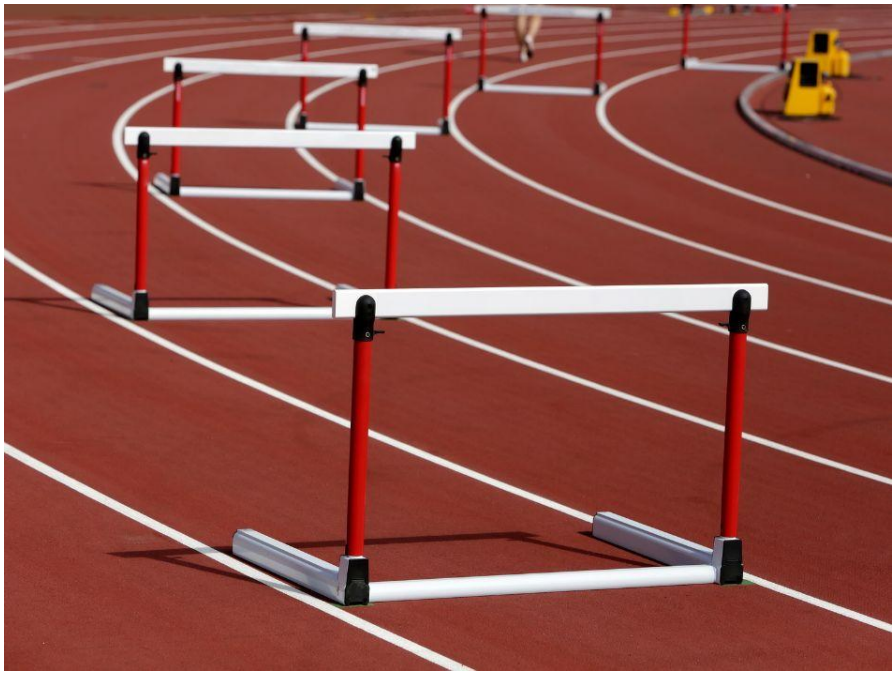
- **Regular check-ins**: Schedule daily virtual or in-person consultations during step-up dosing to assess vital signs and symptoms.
- **Monitoring tools**: Provide patients with essential equipment (e.g., pulse oximeters, thermometers, blood pressure cuffs) and detailed usage instructions.
- **Staff and infrastructure**
    - Organize staffing to support post-therapy observation and manage any adverse reactions effectively.
    - Ensure a dedicated contact line for patients to reach clinical staff with questions or concerns.
- **Medication and laboratory preparedness**
    - Ensure all necessary medications, including pretreatment therapies and those for managing adverse reactions, are readily available.
    - Confirm lab results and vital signs meet appropriate thresholds before administering therapy.

Transitioning between centers. Smooth transitions between treatment centers, whether integrated or non-integrated, are essential for patients requiring coordinated care.

- **Comprehensive documentation:** Obtain and coordinate the transfer of patient medical records and transition plans.
- **Single-center management**: If feasible, have one center manage step-up doses in the initial cycle of treatment to minimize confusion and ensure consistency in care.
- **Consistent communication**
    - Encourage ongoing communication between referring and receiving centers to discuss any complications, ensuring smooth transitions.
    - Align transition timing with inpatient facilities to support care planning and ensure an adequate treatment supply.
- **Follow-up and coordination**
    - Schedule follow-up calls or appointments to monitor patient progress.
    - Maintain communication across the care team to coordinate appointments, infection prophylaxis, and monitoring efforts.

Sharing is caring. Share insights and strategies with local centers developing bispecific antibody programs to foster broader understanding and best practices.

Step 4. 🚧 Address Access Issues



Effective coordination with payers and streamlined clinical operations are crucial for ensuring access to bispecific T-cell engager therapies and facilitating smooth transitions in patient care.

Why it matters: Open communication with payers and efficient clinical practices are vital for timely access to therapies, facilitating authorization and reimbursement while overcoming financial and logistical barriers to patient treatment.

Financial considerations directly impact patient access to treatment, reimbursement processes, and the overall affordability of care.

- **Insurance coordination**
  - **Communication with payers**: Set up lines of communication with insurance payers to ensure all documentation, including prior authorization requirements, is accurate to support timely authorization and reimbursement.
  - **Non-formulary approval process**: Establish a non-formulary approval process to provide immediate access to new treatments while awaiting formal review.
- **Patient support services**: Provide resources to help patients navigate access and reimbursement processes, including coordinating care between hospitals and outpatient sites and verifying patient cost-sharing for ongoing treatment.
- **EMR structures**: Build EMR systems to streamline treatment plans and appointment scheduling. This includes implementing a non-formulary request process within the EMR to reduce administrative and billing errors.
- **Healthcare coverage finalization and coordination with institutions**: Work with both inpatient and outpatient facilities to finalize healthcare coverage, patient cost-sharing, and logistics, ensuring comprehensive treatment pathways.
- **Streamlining clinical operations:** Develop strategies to streamline clinical operations, aiming to reduce procedural delays, maximize efficiency, and improve patient care.

Is outpatient care appropriate? To ensure appropriate candidates for outpatient initiation of bispecific T-cell engager therapy, establish clear eligibility criteria.

- **Clinical indicators**: Assess clinical indicators, including inflammatory markers and performance status, through interprofessional reviews to gauge patient suitability.
- **Geographic and travel barriers**: Consider geographic challenges and patient transportation needs when planning transitions into care. Evaluate caregiver readiness to assist with transportation and follow-up care needs.
- **Care partner preparedness**: Offer educational materials and training for caregivers on how to monitor side effects and support patient needs effectively.

Additional considerations.

- **Language access**: Ensure that educational materials and communication methods are accessible to patients of diverse linguistic backgrounds.
- **Partnership with community resources**: Collaborate with local organizations to provide additional logistical support for patients facing access challenges.

By addressing these financial, logistical, and community-related barriers, healthcare teams can enhance patient access to bispecific therapies, ensuring comprehensive support throughout the treatment journey.

Step 5. 📑 Create Protocols

Clear protocols are vital for operationalizing bispecific T-cell engagers, focusing on patient eligibility, CRS and ICANS management, care team training, and nurse coordinator triage.

Why it matters: Clear protocols are necessary to ensure the safe and effective administration of bispecific T-cell engagers, as they guide the care team through the complexities of treatment and potential adverse reactions. These protocols help standardize practices and enhance communication.

Protocols are essential for **identifying and managing CRS and ICANS**, especially when the risk is highest during step-up doses.

- Implement protocols outlining REMS program requirements for prescribers, including online training, enrollment processes, and patient counseling, along with necessary enrollment materials.
- Equip care partners with the knowledge to recognize symptoms early and respond effectively.

Some bispecific T-cell engagers have REMS programs due to the risks of CRS and ICANS.

- **For prescribers**, REMS requirements may include online training, enrollment, and patient counseling, along with specific materials needed for enrollment.
- **For pharmacies and healthcare settings**, REMS requirements may involve designating an authorized representative, online training and enrollment, and staff training.

Additionally, protocols should be created for identifying and managing **other potential toxicities** associated with bispecific T-cell engagers.

- This includes developing guidelines for monitoring and intervention strategies based on the severity and type of toxicity.

Establishing **SOPs for nurse triage** of patients experiencing CRS and ICANS symptoms is crucial, as is outlining clear guidelines for **on-call coverage** by physicians or APPs to ensure timely management of complications.

It's important to **define the frequency of staff training** on bispecific T-cell engagers and their toxicities to ensure all team members are well-equipped to recognize and respond to toxicities.

- Ongoing education should be emphasized, reflecting the evolving understanding of these therapies.

Regular meetings of the interprofessional team should be scheduled to discuss bispecific T-cell engager therapies and make informed decisions.

- **Protocol review process**: Implement a systematic review process for protocols to adapt to new evidence and clinical experiences, ensuring that practices remain up-to-date and effective.
- **Feedback mechanisms**: Establish feedback loops where staff can report challenges or successes regarding the protocols, contributing to ongoing refinement and improvement of the management processes.

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