BISPECIFIC ANTIBODIES CHECKLIST
FOR COMMUNITY PROVIDERS

The Association of Community Cancer Centers (ACCC) developed this checklist to help cancer practices and programs adopt the use of bispecific antibodies (BsAbs) to treat cancer. Community cancer providers may use this checklist whether their program is referring patients to academic centers or treating patients in-house. Users should refer to the section of the checklist that is pertinent to their situation.

For Community Cancer Centers Referring to Academic Centers

STEPS FOR ADMINISTRATION

☐ When applicable, review the Risk Evaluation and Mitigation Strategy (REMS) program for BsAbs.

☐ Provide quarterly education on administration, toxicities, and clinical pearls of the specific BsAb medication to staff, including those who may see patients on an urgent basis (e.g., emergency room staff).

♦ Educate staff about the expected side effects of the specific medication.
  ✔ For example, for blinatumomab, review the spectrum of cytokine release syndrome (CRS) symptoms across all organs (e.g., flu-like symptoms, hypotension, DIC, cytopenias, arrhythmias, multi-organ failure, etc.) and how to manage them.

♦ Create a detailed algorithm for the management of toxicities while considering the following:
  ✔ Who should patients call at different times of the day (including after hours) to report symptoms?
  ✔ Will the physician or advanced practice provider decide how to treat patients and determine if they should be admitted?
  ✔ What medications will patients need?
  ✔ Which hospitals will patients be admitted to if they require hospitalization?
For Community Cancer Centers Referring to Academic Centers

STEPS FOR ADMINISTRATION (CONTINUED)

- Ensure there is communication among all relevant healthcare providers and that the medical plan is communicated to patients and caregivers.
- Educate staff about who to contact for medical emergencies.
- Educate staff about the specifics of an infusion, such as extended infusion times, pump use, and how to flush a line and disconnect an infusion pump based on methods specific to a given drug.
  - For example, blinatumomab should be removed from tubing before a line is flushed to avoid significant toxicity by rapid infusion of the drug.

- Decide which parts of the admission process (e.g., pre-admission testing, ordering of pre-medications, etc.)—if any—will be the responsibility of your cancer center, or will be managed by the academic center.

- After patients receive a BsAb at an academic center, decide in collaboration with them what follow up will be conducted at your practice or program.
  - Consider which parts of the follow-up will be done at the academic center versus the community center (e.g., Where will the pump disconnect take place?).
  - Consider whether patients should be seen daily in the clinic during the first week after discharge.
  - If patients cannot be seen in the clinic daily, discuss instructions for patients to contact the clinic with temperature and symptom checks.
  - Consider how often patients should be monitored after the first seven days.
  - Consider using additional patient materials (such as wallet cards or bracelets) and monitoring tools (such as spot check devices or smart devices).
  - Consider how rehospitalizations will be handled following successful discharge from the academic center.
Decide what information your community cancer center needs to forward to the academic center and what information you need to keep patients informed.

- Develop a process to ensure that all institutions involved in patient care have access to patients’ medical information, whether it is through the same electronic medical record system (if the institutions are affiliated) or through external record-sharing (if not affiliated).

Discuss management of adverse events.

- Determine whether toxicities will be managed by your community cancer providers or the academic center providers.
  - Consider where patients should be hospitalized if the need arises.
  - Determine which situations would require patients to be admitted to the academic center.
  - Develop drug accountability processes to deal with potential events.
    - For example, with blinatumomab, prepare for a situation in which continuous infusion is started at one institution and is stopped/disconnected at another.

- Review appropriate management of toxicities per package insert, guidelines, and primary literature.

- Draft treatment algorithms as needed.

- Discuss what to do in the event of a pump malfunction for continuous infusions.
  - Consider potential partnerships with home healthcare systems.
  - Refer patient back to the academic center for re-dispensing of medication as needed.
  - Evaluate patients for potential toxicities if they receive an overdose.
  - For blinatumomab, re-dose steroids if an infusion was interrupted for four hours.
For Community Cancer Centers Referring to Academic Centers

STEPs FOR PATIENT CARE

- Review with patients the care plan from pre-testing to 100-day post-initiation before they have consultations with providers at an academic center.

- Establish that patients have adequate support during treatment (e.g., home medical services, attentive caregivers, easy access to transportation, psychological support).
  - Identify patients’ primary caregivers (e.g., family member, nurse).
  - Determine whether patients need visiting nurse services.
  - Consider social work consultations for additional support.

- Provide guidance to family members and caregivers.
  - Ensure caregivers understand the potential toxicities and complications of BsAb treatment.
  - Determine whether caregivers can provide transportation to and from clinics/hospitals as needed.
  - Ensure caregivers have contact information for providers in the clinic.
  - Ensure patients and caregivers have clear instructions on what to do in the case of an emergency and/or whom to call in different scenarios.

- Provide resources for financial assistance from drug companies, charitable foundations, etc.
  - The ACCC Patient Assistance & Reimbursement Guide is an excellent resource: accc-cancer.org/PAG.
  - See also manufacturer financial assistance specifically for blinatumomab: amgenassist360.com/hcp/blincyto-financial-assistance

- Establish follow-up schedule with patients.
  - Consider whether patients will go to the clinic for multiple visits throughout the week or use virtual methods for follow-up care.

- Counsel patients on the potential toxicities of BsAbs and assess for toxicities at each visit.
  - Educate patients and caregivers on monitoring for adverse events at home using digital technology as needed.

- Incorporate social work support during and after treatment and follow up with patients to monitor their well-being.
For Community Cancer Centers Administering BsAbs In-house

STEPS FOR ADMINISTRATION

☐ When applicable, review the Risk Evaluation and Mitigation Strategy (REMS) for BsAb.

☐ Consider designating nurse navigators or clinician leaders to serve as point persons for onboarding new BsAbs treatments.

☐ Discuss with pharmacy and financial departments how to add a new drug to a formulary.
  ☐ Establish payer contracts.
  ☐ Review billing and coding information sheets for specific products.
  ☐ Review pharmacy preparation instructions and acquire appropriate equipment (e.g., ambulatory infusion pumps).
  ☐ Determine how providers will order the medication.
    ◇ If electronically, develop an electronic treatment plan.
    ◇ If via paper, create a paper order form.
  ☐ Implement any other procedures as needed per individual clinic policies for onboarding new medications.

☐ Provide quarterly education on administration, toxicities, and clinical pearls of the specific BsAb medication to staff, including those who may see patients on an urgent basis (e.g., emergency room staff).
  ☐ Educate staff about the expected side effects of the specific medication.
    ◇ For example, for blinatumomab, review the spectrum of cytokine release syndrome (CRS) symptoms across all organs (e.g., flu-like symptoms, hypotension, DIC, cytopenias, arrhythmias, multi-organ failure, etc.) and how to manage them.
  ☐ Create a detailed algorithm for the management of toxicities while considering the following:
    ◇ Who should patients call at different times of the day (including after hours) to report symptoms?
    ◇ Will the physician or advanced practice provider decide how to treat patients and determine if they should be admitted?
    ◇ What medications will patients need?
    ◇ Which hospitals will patients be admitted to if they require hospitalization?
  ☐ Ensure there is communication among all relevant providers and that the medical plan is communicated to patients and caregivers.
  ☐ Educate staff about what to do for medical emergencies.
  ☐ Educate staff about the specifics of an infusion, such as extended infusion times, pump use, and how to flush a line and disconnect an infusion pump based on methods specific to a given drug.
    ◇ For example, blinatumomab should be removed from tubing before a line is flushed to avoid significant toxicity by rapid infusion of the drug.
For Community Cancer Centers Administering BsAbs In-house

STEPS FOR PATIENT CARE

- Confirm patient coverage for the drug (i.e., call payor or submit benefit verification).
  - Check and complete requirements for prior authorization.
  - If needed, confirm patient coverage for durable medical equipment, home infusion services, home healthcare services, etc.
  - Provide resources for financial assistance from drug companies, charitable foundations, etc.
    - The ACCC Patient Assistance & Reimbursement Guide is an excellent resource: accc-cancer.org/PAG.
    - See also manufacturer financial assistance specifically for blinatumomab: amgenassist360.com/hcp/blincyto-financial-assistance

- Review with patients the care plan from pre-testing to 100-day post-initiation.

- Ensure patients understand the potential toxicities and complications of BsAb treatment.

- Establish that patients have adequate support during treatment (e.g., home medical services, attentive caregivers, easy access to transportation, psychological support).
  - Determine whether patients need visiting nurse services.
  - Consider social work consultations for additional support.

- Provide guidance to family members and caregivers.
  - Ensure caregivers understand the potential toxicities and complications of BsAb treatment.
  - Determine whether caregivers can provide transportation to and from clinics/hospitals as needed.
  - Ensure caregivers have contact information for providers in the clinic.
  - Ensure that patients and caregivers have clear instructions on what to do in the case of an emergency and/or who to call in different scenarios.
- Coordinate infusion appointments.
  - Order pre-medications as indicated.
  - Set up continuous infusions as needed.
  - Ensure that tocilizumab is on hand to manage cytokine release syndrome (CRS).
  - Ensure that a hospital bed is reserved in an inpatient unit (step-down or intensive care unit) in case of an adverse event requiring extended onsite monitoring and management.

- Establish follow-up schedules with patients.
  - Consider whether patients will go to the clinic for multiple visits throughout the week or use virtual methods for follow-up care.

- Counsel patients on the potential toxicities of BsAbs and assess for toxicities at each visit.
  - Educate patients and caregivers about how to monitor for adverse events at home using digital technology, as needed.

- Incorporate social work support during and after treatment and follow up with patients to monitor their well-being.
A publication from the ACCC education program, “Preparing Community Providers for Bispecific Antibodies.” Learn more at accc-cancer.org/bispecific-antibodies.

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org. Follow us on social media; read our blog, ACCCBuzz; tune in to our podcast, CANCER BUZZ, and view our vodcast channel, CANCER BUZZ TV.

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