Developing a Comprehensive Community-Based Bispecific Antibody Operations Program for Safe Step-Up Dosing and Ongoing Management

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Background

Bispecific antibodies have expanded treatment options for patients with relapsed or refractory hematologic malignancies. Despite their clinical benefits, implementation in community oncology settings is often challenged by the risks of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), infection, cytopenias, and intensive monitoring requirements. Historically, many patients required referral to academic centers for treatment initiation and step-up dosing. Maryland Oncology Hematology developed a standardized community-based operations program to provide safe, accessible care closer to home.

Objective

Describe the key operational, clinical, educational, and multidisciplinary components of a community-based bispecific antibody program that support safe step-up dosing, toxicity monitoring, caregiver engagement, adverse event management, and implementation across oncology practice settings.

References

Methods

A comprehensive operational framework was developed using a multidisciplinary approach involving physicians, advanced practice providers, pharmacists, nurses, clinical educators, and practice leadership.

Key elements included:

- Standardized patient selection criteria
- Caregiver education and readiness assessments
- REMS and pharmacy coordination processes
- Step-up dosing and monitoring workflows
- CRS and ICANS management pathways
- Long-term follow-up strategies



Discussion

Key Success Factors

- Dedicated Bispecific Champion
- Standardized workflows
- Multidisciplinary collaboration
- Structured caregiver involvement
- Community hospital partnerships
- Comprehensive staff competency training

Challenges

- Resource-intensive startup process
- Ongoing staff education requirements
- Coordination across multiple sites
- Continuous toxicity surveillance

Lessons Learned

- Standardized tools improve consistency.
- Early caregiver engagement improves preparedness.
- Community implementation is feasible with robust operational support.

Conclusion

Community oncology practices can safely implement bispecific antibody therapy through multidisciplinary planning, standardized operational processes, caregiver involvement, and comprehensive toxicity management. This framework provides a scalable and reproducible model for expanding access to innovative therapies while maintaining high standards of patient safety.

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