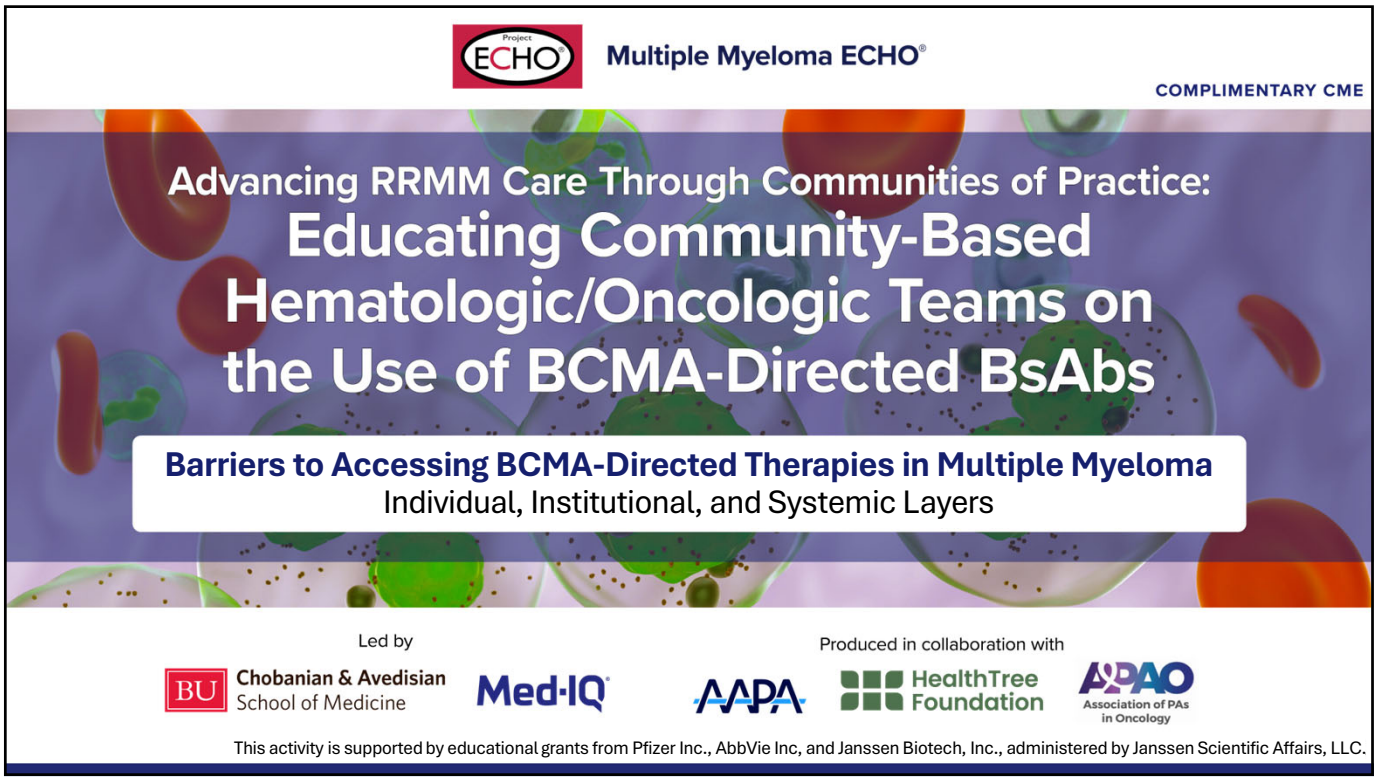

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Learning Objectives

Upon completion, participants should be able to:

1. Identify and categorize barriers to accessing BCMA-directed therapies for patients with multiple myeloma
2. Discuss the impact of these barriers on health outcomes in various contexts
3. Propose evidence-informed strategies and policy solutions to mitigate these barriers

3

The BCMA-Directed Therapy Landscape

CAR T-Cell Therapy	Bispecific Antibodies	Antibody-Drug Conjugate
73%–98% ORR	**61%–71%** ORR	**77%–82%** ORR
Idecabtagene vicleucel (ide-cel) Ciltacabtagene autoleucel (cilta-cel)	Teclistamab Elranatamab Linvoseltamab	Belantamab mafodotin (combination regimens)

FDA prescribing information; Berdeja JG, et al. *Lancet*. 2021;398:314-24; Munshi NC, et al. *N Engl J Med*. 2021;384:705-16; Moreau P, et al. *N Engl J Med*. 2022;387:495-505; Lesokhin AM, et al. *Nat Med*. 2023;29:2259-67; Bumma N, et al. *J Clin Oncol*. 2024;42:2702-12; Mateos MV, et al. *J Clin Oncol*. 2024;42:439572; Trudel S, et al. *J Clin Oncol*. 2024;42:LBA105.

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The Access Gap: By the Numbers

40% of referred patients actually receive CAR T-cell therapy

25% die while waiting for CAR T-cell therapy

17% of BCMA-directed CAR T-cell recipients are racial/ethnic minorities vs 34% in catchment area

77% of disparity studies cite insurance status as a barrier to MM treatment access

Multiple Myeloma Hub. https://multiplemyelomahub.com/medical-information/current-and-future-use-of-bcma-directed-car-t-cell-therapy-in-mm; Banerjee R, et al. *Blood Cancer J.* 2024;14:149; Paruzzo L, et al. *Blood Immunol Cell Ther.* 2025;1:100007; Gasoyan H, et al. *Clin Lymphoma Myeloma Leuk.* 2023;23:e420-7.

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A Three-Layer Framework for Understanding Barriers

INDIVIDUAL
Patient-Level Barriers

Age, race/ethnicity, sex, language, health literacy, insurance, geography, caregiver support, beliefs

INSTITUTIONAL
Provider and Health System

Referral bias, REMS certification, workforce shortages, community oncology gaps, implicit bias, clinical trials

SYSTEMIC
Policy and Structural

Medicaid/ACA policy, OBBBA, reimbursement, manufacturing, regulatory burden, work requirements

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Individual Barriers: Age and Sex

Age

- Median age at MM diagnosis is 69 years, yet elderly patients are underrepresented in clinical trials
- Reduced odds of receiving autoHCT with each yearly increment after age 67
- No mandated age cutoff exists, yet physician discretion often defaults to age-based exclusion
- Combination therapies improve outcomes even after adjusting for frailty in patients aged ≥ 75 years
- CAR T-cell trials historically enrolled younger, fitter patients, limiting real-world generalizability

Sex & Gender

- MM incidence: higher incidence in men (57%) vs women (43%); men generally have inferior outcomes
- Despite better prognosis, women have poorer access to treatment
- Gender differences in caregiver support availability affect treatment decisions
- Women are more likely to decline intensive therapy due to caregiving responsibilities

Banerjee R, et al. *Blood Cancer J.* 2024;14:149;
Shan X, et al. *Haematologica*. 2025;110:2839-43; Mateos MV, et al. *Blood Cancer J.* 2023;13:109.

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Individual Barriers: Race and Ethnicity

Progressive Exclusion of Racial/Ethnic Minorities From BCMA Therapy

33.9% Catchment Area

28.1% MM Cohort

26.1% CAR T-Cell Eligible

17.1% Received BCMA-Directed CAR T-Cell Therapy

Evidence-Based Findings

- Black patients represent 20% of MM diagnoses but are underrepresented in BCMA-directed therapy access
- Systemic distrust stemming from historical injustices reduces clinical trial participation
- Black patients receiving consistent metro care had the BEST outcomes; access, not biology, is the driver
- 76% of studies identify racial disparities in MM treatment; 60% identify ethnic disparities
- Hispanic/Latino patients face compounded barriers: language + insurance + geography
- Racial/ethnic minorities show comparable outcomes when they receive therapy; the gap is in the pathway to treatment

Paruzzo L, et al. *Blood Immunol Cell Ther*. 2025;1:100007; Bauer MA, et al. *Haematologica*. 2025;111:713-7.

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Individual Barriers: Language, Literacy, and Geography

Language and Literacy

- 43% of studies identify language as a barrier to MM treatment
- Only 34.8% of patients receiving English-only consent forms understood that MM treatment is not curative vs 60% receiving bilingual forms
- Machine translation contains meaning-changing errors in cancer consent documents
- Underuse of professional interpreters reduces informed decision making

Geography

- Rural patients face delayed referrals, less trial participation, and longer distance to transplant centers
- CAR T-cell therapy requires transplant-capable centers; vast rural areas have none
- Patients living 2 to 4 hours away are 40% less likely to receive CAR T-cell therapy
- Distance correlates with lower autoHCT utilization

Financial Toxicity

- CAR T-cell therapy costs > $400,000 per patient (base payment)
- BsAbs require treatment until progression (potentially years of cost)
- Medicare base payment: $314,176 FY2026, often below actual costs
- Medicaid reimbursement varies by state; many states offer suboptimal coverage

Hibbs S, et al. *Support Care Cancer*. 2026;34:317; Gasoyan H, et al. *Clin Lymphoma Myeloma Leuk*. 2023;23:e420-7; Ahmed N, et al. *Transplant Cell Ther*. 2024;30:714-25.

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Institutional Barriers: Referral Bias and REMS

Referral Patterns and Implicit Bias

- Most patients are referred to trials by their oncologist; clinician bias directly affects who is referred
- Providers perceive minoritized patients as less interested in trials, despite evidence to the contrary
- Inflexible organizational structures reinforce implicit assumptions in practice
- Lack of evidence-based referral guidelines means subjective decisions create opportunities for bias
- Age-based exclusion: no mandated cutoffs, but physician discretion often defaults to chronological age
- UC Davis study: Black patients are less likely to receive autoHCT even when clinically appropriate

REMS, CRS/ICANS, and Clinical Infrastructure

- REMS requires institutional AND individual provider certification
- Step-up dosing: 24- to 48-hour inpatient hospitalization per dose for BsAbs
- CRS in:
  - 72% of teclistamab-treated patients
  - 56% of elranatamab-treated patients
  - 46% of linvoseltamab-treated patients
  - But ≤ 1% grade ≥ 3
- Community oncologists report limited CRS/ICANS management experience
- Complex infection prophylaxis: antiviral, antibacterial, antifungal, IVIG
- Staffing requirements strain already-thin community oncology workforce

Beauchemin M, et al. www.medrxiv.org/content/medrxiv/early/2025/06/26/2025.06.25.25330296.full.pdf; Esteghamat NS, et al. *Clin Lymphoma Myeloma Leuk*. 2024;24:e119-29; Moureau P, et al. *N Engl J Med*. 2022;387:495-505; Lesokhin AM, et al. *Nat Med*. 2023;29:2259-67; Bumma N, et al. *J Clin Oncol*. 2024;42:2702-12.

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Institutional Barriers: Community Oncology Gaps

The CAR T-Cell Journey: 12 to 20+ Weeks of Delays

1	2	3	4	5
Referral to Academic Center	**Evaluation and Leukapheresis**	**Manufacturing and Shipping**	**Bridging Therapy**	**Conditioning and Infusion**
4–8 weeks	2–4 weeks	4–6 weeks	Variable	~2 weeks

Community Oncology Workforce and Adoption Challenges

- 2025 Community Oncology Report: workforce shortages, clinical trial inequities, and complex practice operations are top challenges
- BsAb adoption in community settings remains a great unmet need; eligible patients may receive less effective later-line therapies instead
- Leukapheresis bottleneck: 4- to 8-week wait just to be seen, then 2 to 4 more weeks for the procedure
- Limited inpatient bed availability for step-up dosing constrains BsAb adoption, even at willing institutions

McKesson Biopharma. Advancing Community Oncology Report. https://www.mckesson.com/biopharma/advancing-community-oncology-report.

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Systemic Barriers: The One Big Beautiful Bill Act

One Big Beautiful Bill Act (OBBBA)—Signed July 4, 2025

Key Provisions Affecting Cancer Patients

- $625 billion in Medicaid cuts over the next decade
- Work requirements: 80 hours/month for adults aged 19 to 64 years on Medicaid
- Retrospective eligibility verification every 6 months
- Restricts states' ability to use provider taxes to finance Medicaid
- Reduced ACA marketplace subsidies; 7.8 million may become uninsured
- Georgia's work requirement: only 7,500 enrolled vs 25,000 projected; cost: $54 million

Impact on Oncology

- 1.2 million missed cancer screenings projected within 2 years
- 406,000 missed mammograms, 680,000 missed CRC screenings, 67,000 missed lung screenings
- Late-stage presentations expected to surge
- Thousands of excess deaths, hundreds of thousands of preventable hospitalizations
- Rural radiation oncology programs especially threatened
- Cancer patients in active treatment may lose coverage during 6-month reverification

AMA. https://www.ama-assn.org/health-care-advocacy/federal-advocacy/4-big-beautiful-bill-changes-will-reshape-care-2026; NCODA. https://ncoda.org/news/changes-under-one-big-beautiful-bill-act-may-not-be-so-beautiful-for-oncology; Shubeck S, et al. *JAMA Oncol*. 2026;12:319-21; Cancer Therapy Advisor. https://www.cancertherapyadvisor.com/news/big-beautiful-bill-medicaid-deaths-hospitalizations-economic-losses; Panse D, et al. *Cureus*. 2025;18:e103553.

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Systemic Barriers: Reimbursement and Manufacturing

Reimbursement Gaps

- CAR T-cell base payment FY2026: $314,176—a 17% increase, yet still below actual treatment costs
- Medicaid covers CAR T-cell therapy only in certain states; reimbursement varies by state and product
- BsAb reimbursement complexity: outpatient vs inpatient, step-up dosing coding challenges
- Provider tax restrictions under OBBBA limit states' Medicaid financing flexibility
- 2026 Medicare PFS proposed new cell/gene therapy and therapeutic apheresis payment rules

Manufacturing and Regulatory

- CAR T-cell manufacturing: complex, time-consuming; production creates 4- to 6-week bottleneck
- Limited manufacturing capacity creates supply constraints globally
- Central/South America, and much of Africa and Asia, have zero access to CAR T-cell products
- In-vivo CAR T-cell: could eliminate manufacturing entirely; early phase data promising
- REMS has eased for CAR T-cell therapy but remains for BsAbs, limiting community adoption

Xu J, et al. *Lancet*. 2025;406:228-31; Association for the Advancement of Blood and Biotherapies. https://www.aabb.org/news-resources/news/article/2025/11/05/cms-finalizes-2026-medicare-pfs-rule--updates-biotherapies-payment-policies.

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How These Barriers Impact Outcomes

Mortality While Waiting

Approximately 25% of patients referred for CAR T-cell die before receiving therapy. Disease progression during manufacturing delays worsens postinfusion outcomes.

Compounding Disparities

Example: An elderly Black woman in rural Appalachia on Medicaid faces age bias, racial bias, geographic distance, and financial toxicity; she now faces OBBBA coverage threats simultaneously.

Community Care Gaps

Eligible patients in community settings receive less effective later-line therapies. Knowledge gaps in CRS/ICANS management lead to adverse events.

Key message: Access, not biology, drives disparities. When patients receive BCMA therapy, outcomes are comparable across demographics.

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Strategies: Clinical and Institutional Solutions

- **ECHO-Model Education:** Connect community providers with academic experts to build competency in BsAb administration, CRS/ICANS management, and infection prophylaxis
- **Hub-and-Spoke Partnerships:** Academic hub handles leukapheresis/infusion; community spoke manages follow-up monitoring and supportive care
- **Outpatient Step-Up Dosing:** Emerging data support outpatient BsAb dosing in select patients, reducing hospitalization burden
- **Implicit Bias Training:** ASCO/ACCC pilot programs for clinical trial diversity; standardized referral criteria reduce subjective decisions
- **Language-Concordant Care:** Bilingual consent forms, professional interpreters, and culturally adapted patient education materials

AJMC. https://www.ajmc.com/view/closer-to-home-implementing-bispecific-antibodies-for-multiple-myeloma-across-care-setting.

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Strategies: Clinical Solutions

Patient distress: Evaluate patients to assist with any barriers or challenges to treatment

Have you had concerns about any of the items below in the past week, including today?

Practical concerns

- ❑Taking care of myself
- ❑Taking care of others
- ❑Safety
- ❑Work
- ❑School
- ❑Housing/utilities
- ❑Finances
- ❑Insurance
- ❑Transportation
- ❑Child care
- ❑Having enough food
- ❑Access to medicine
- ❑Treatment decisions

National Comprehensive Cancer Network. Distress Management. Version 2.2026. April 24, 2026.

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Strategies: Policy and Equity Solutions

Policy and Reimbursement

- Advocate for Medicaid exemptions from work requirements for patients in active cancer treatment
- Streamline REMS to reduce community certification barriers
- Value-based reimbursement models for CAR T-cell and BsAb therapy
- In-vivo CAR T-cell could eliminate manufacturing delays entirely
- State-level advocacy for Medicaid coverage mandates for CAR T-cell therapy

Health Equity

- Increase diversity in clinical trials; underrepresentation limits evidence generalizability
- Patient navigation programs for referral, scheduling, and insurance support
- Telemedicine and satellite partnerships for rural/ underserved populations
- Track access metrics by race, geography, and insurance at institutional level
- Community health worker integration for culturally concordant outreach

Xu J, et al. *Lancet*. 2025;406:228-31; Banerjee R, et al. *Blood Cancer J.* 2024;14:149.

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The Path Forward: What You Can Do

Refer Earlier
Identify patients for BCMA therapy at first relapse, not as a last resort. Early referral reduces wait-related mortality.

Build Partnerships
Establish hub-and-spoke collaborations with transplant/CAR T-cell therapy centers. Share follow-up responsibility.

Pursue REMS Certification
If your practice sees RRMM patients, invest in BsAb REMS certification to offer onsite therapy.

Track Your Access Data
Monitor referrals by age, race, sex, geography, and insurance. Make disparities visible and actionable.

Advocate for Patients
Support Medicaid exemptions for cancer patients. Engage professional societies. Your voice matters in policy.

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Questions and Discussion

Multiple Myeloma ECHO® Program

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