

SUSTAIN

Systematic Uptake and Standardization of Treatment
Advances Through an Integrated Network for
BISPECIFIC ANTIBODY THERAPY

Provided by  UK HealthCare

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Today's Faculty



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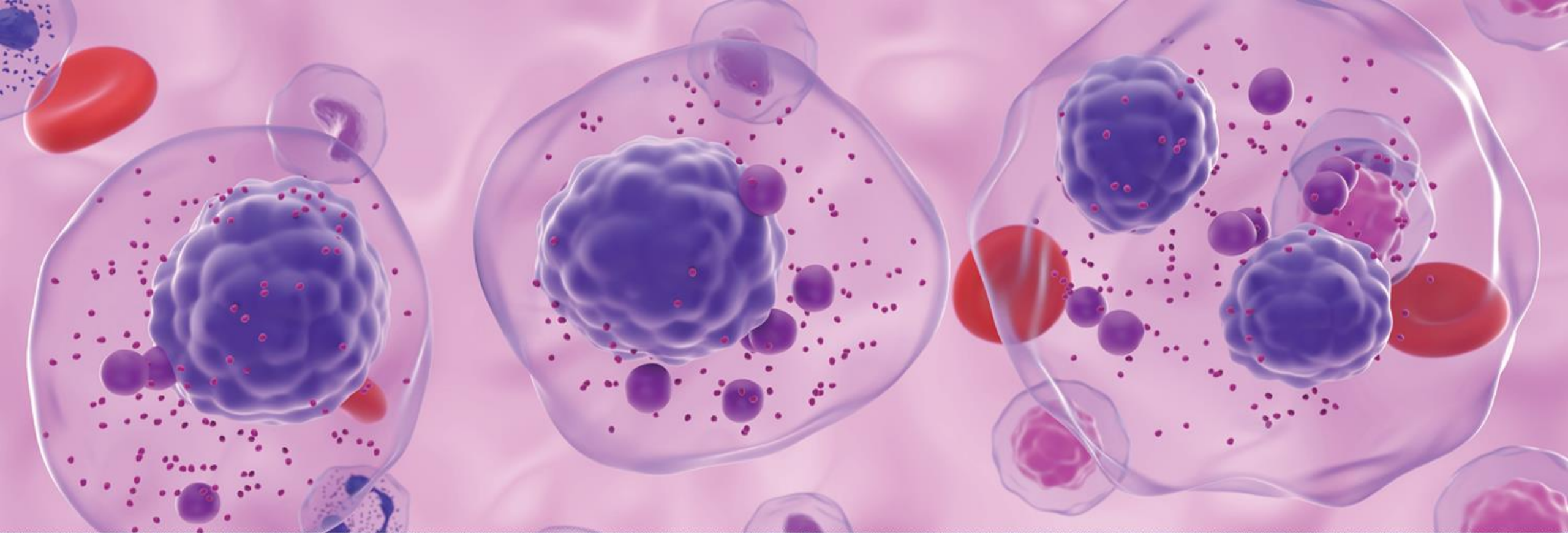
- **1.00 IPCE**

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Patient Selection Criteria: Identifying Appropriate Candidates for BsAb Therapy



Curriculum Learning Objective

- Develop and implement site-specific protocols for safe BsAb administration, including patient selection criteria, pre-medication regimens, dose escalation procedures, and post-infusion monitoring

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Session Objectives

- Describe the indications and contraindications for BsAbs in patients with R/R MM
- Develop plans on integrating a model for care coordination between academic and community centers
- Explain how patient risk factors influence eligibility for BsAbs

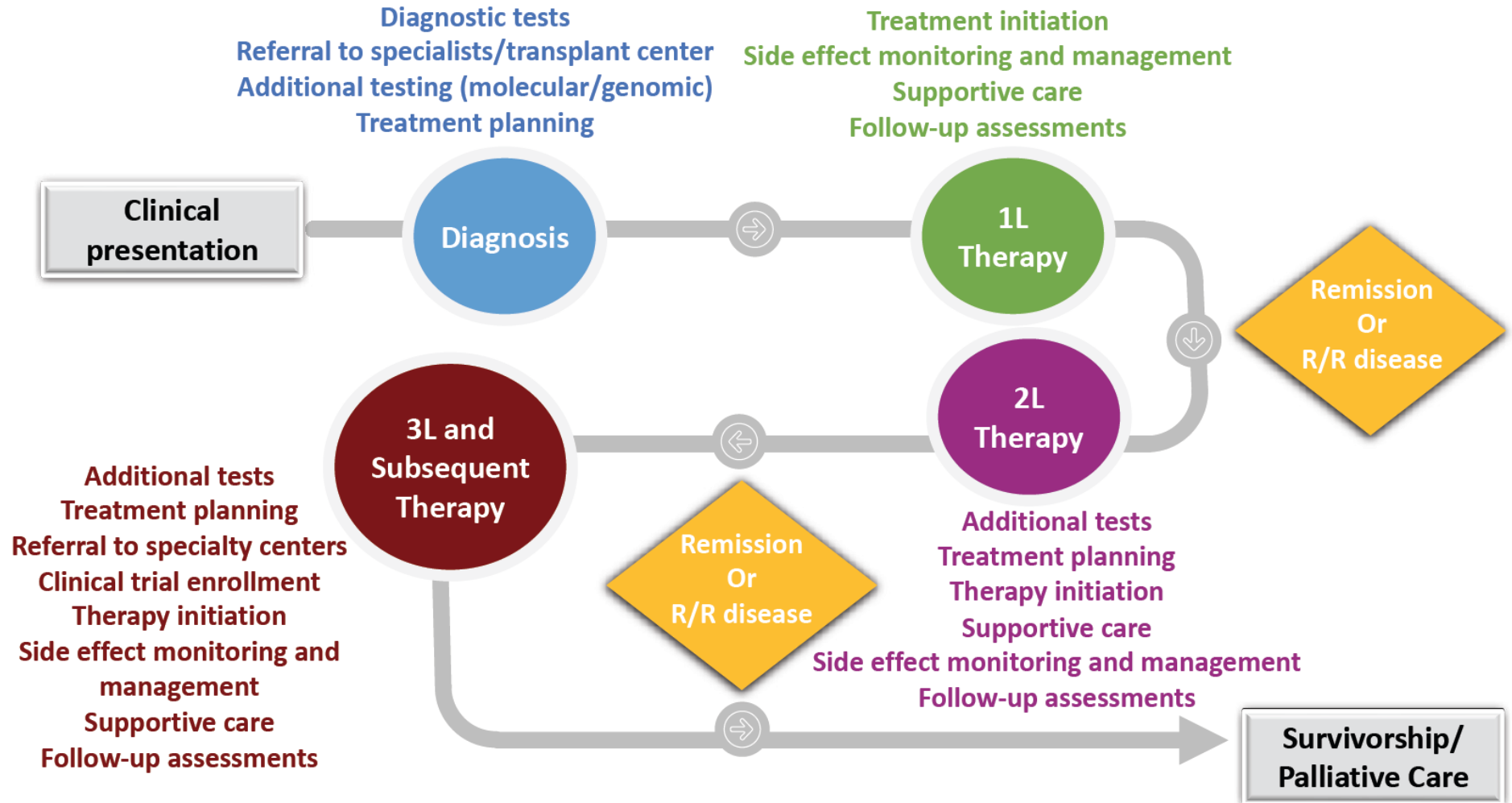
What Do You Know?



Which pre-medication regimen is appropriate for a patient receiving teclistamab during step-up dosing?

- A. Acetaminophen 650 mg, diphenhydramine 25 mg, and dexamethasone 20 mg
- B. Acetaminophen 650–1000 mg, diphenhydramine 50 mg, and dexamethasone 16 mg
- C. Acetaminophen 1000 mg, diphenhydramine 25 mg, and dexamethasone 40 mg
- D. Acetaminophen 325 mg, loratadine 10 mg, and dexamethasone 10 mg

Complexity of MM Patient Journey



1L = first line; 2L = second line; 3L = third line

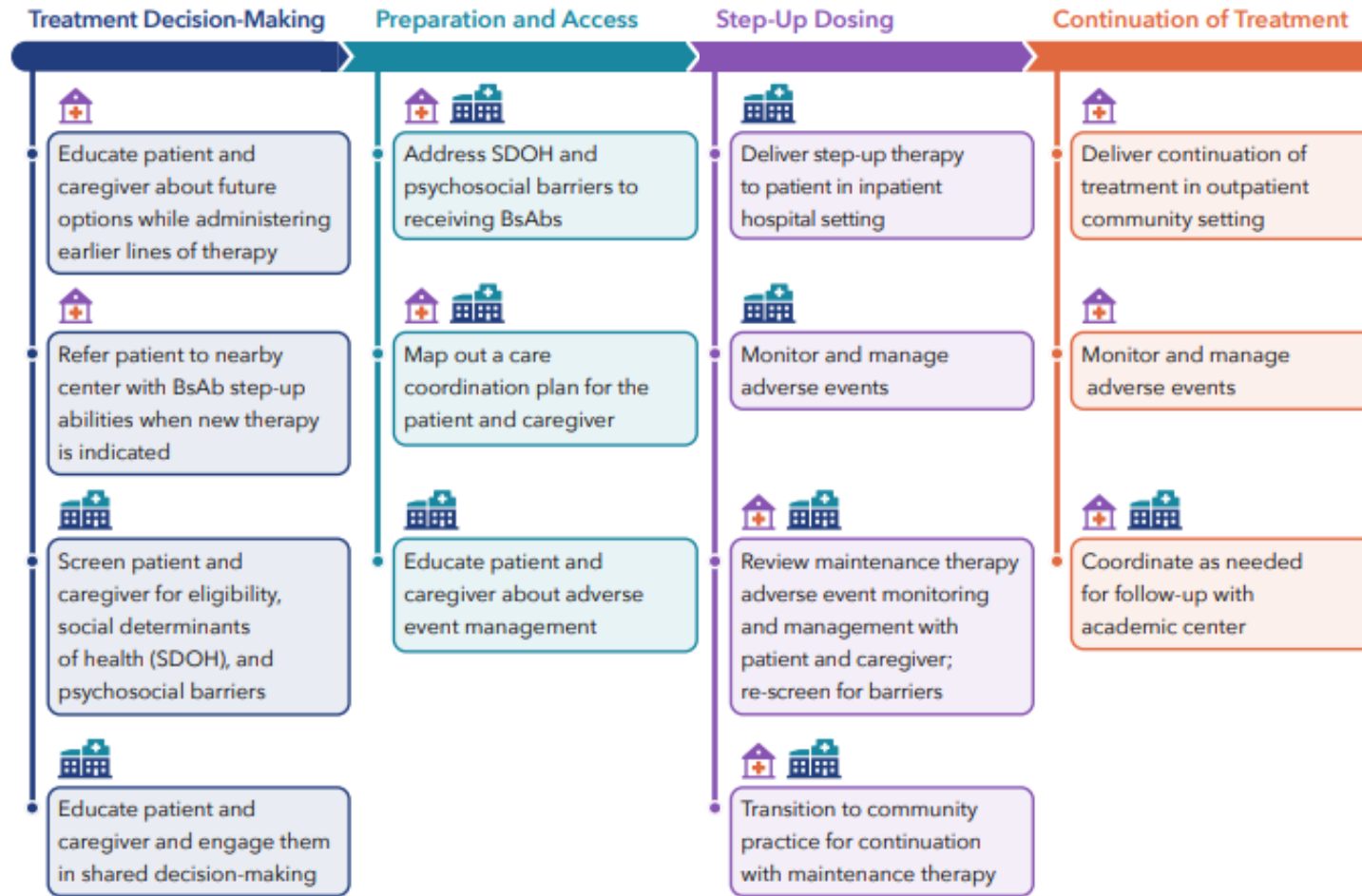
<https://aononline.org/navigation-tools/4635:optimizing-bispecific-antibody-therapy-in-multiple-myeloma-a-resource-guide-for-nurse-and-patient-navigators>

Sequencing of Therapies

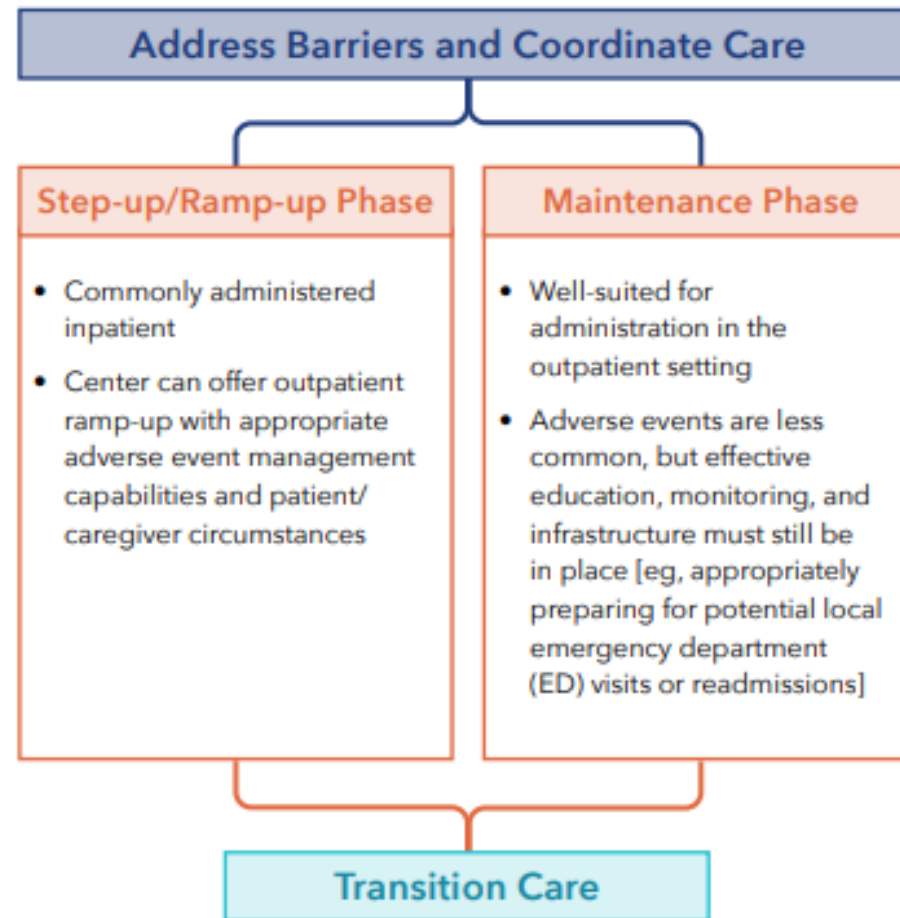
Teclistamab in combination with daratumumab and hyaluronidase: ≥ 1 line(s) of therapy, including a proteasome inhibitor, and an immunomodulatory agent

Elranatamab, Teclistamab, talquetamab, or livoseltamab: ≥ 4 lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Model for Care Coordination Between Academic and Community Cancer Centers for BsAb Maintenance



Addressing Barriers and Coordinating Care Between Academic and Community Center



REMS: Important Considerations

- Teclistamab and talquetamab REMS portal: <https://tec-talrems.com> or 1-855-810-8064
 - Same website for both teclistamab and talquetamab now as a combined REMS program
- Elranatamab REMS portal: <https://elrexfiorems.com> or 1-844-923-7845
- Linvoseltamab REMS portal: <https://www.lynozyficrems.com/> or 1-855-212-6391
- There are requirements for **prescribers**, **pharmacy/health care settings**, and **wholesalers**

Prescribers

Prescribers must be certified

- New prescribers must be certified in the program by enrolling and completing training (one time)
- Previously certified prescribers will have their certification automatically transferred to the new combined REMS (no action needed)
- Counsel patients on the risk of CRS/ICANS and dispense a **patient wallet card**

Pharmacy/Health Care Settings

- New settings must be enrolled (one time)
 - Teclistamab → Teclistamab/Talquetamab REMS transition: previously certified settings will have their enrollment transferred to the combined REMS (re-attestation required)
- Generate REMS dispense authorization code prior to each dose

Patient-Specific Factors for Treating Multiple Myeloma

Location



Access to transportation



Age



Sex



Ethnicity



Physical health



Disease burden



Medical history



Previous therapies



Adverse events



Financial



Quality of life



Geographical Location

Not every health center is equipped to use BsAbs

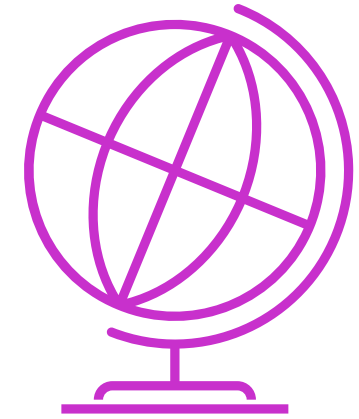
- Some patients may need to travel and stay near a qualified health center to receive BsAbs
- Health centers must be REMS certified

Selection of BsAb is based on availability of treatment centers with expertise with and access to the selected therapy

- Centers should also have the resources to manage potentially severe adverse effects

BsAbs are typically used in an outpatient setting

- Inpatient services are available at select treatment centers



You will learn more about developing institutional protocols for BsAbs in ECHO Session #6!

Access to Transportation

Patients receiving BsAbs will require reliable and easy access to transportation to a qualified health center

- Caregivers should also be aware

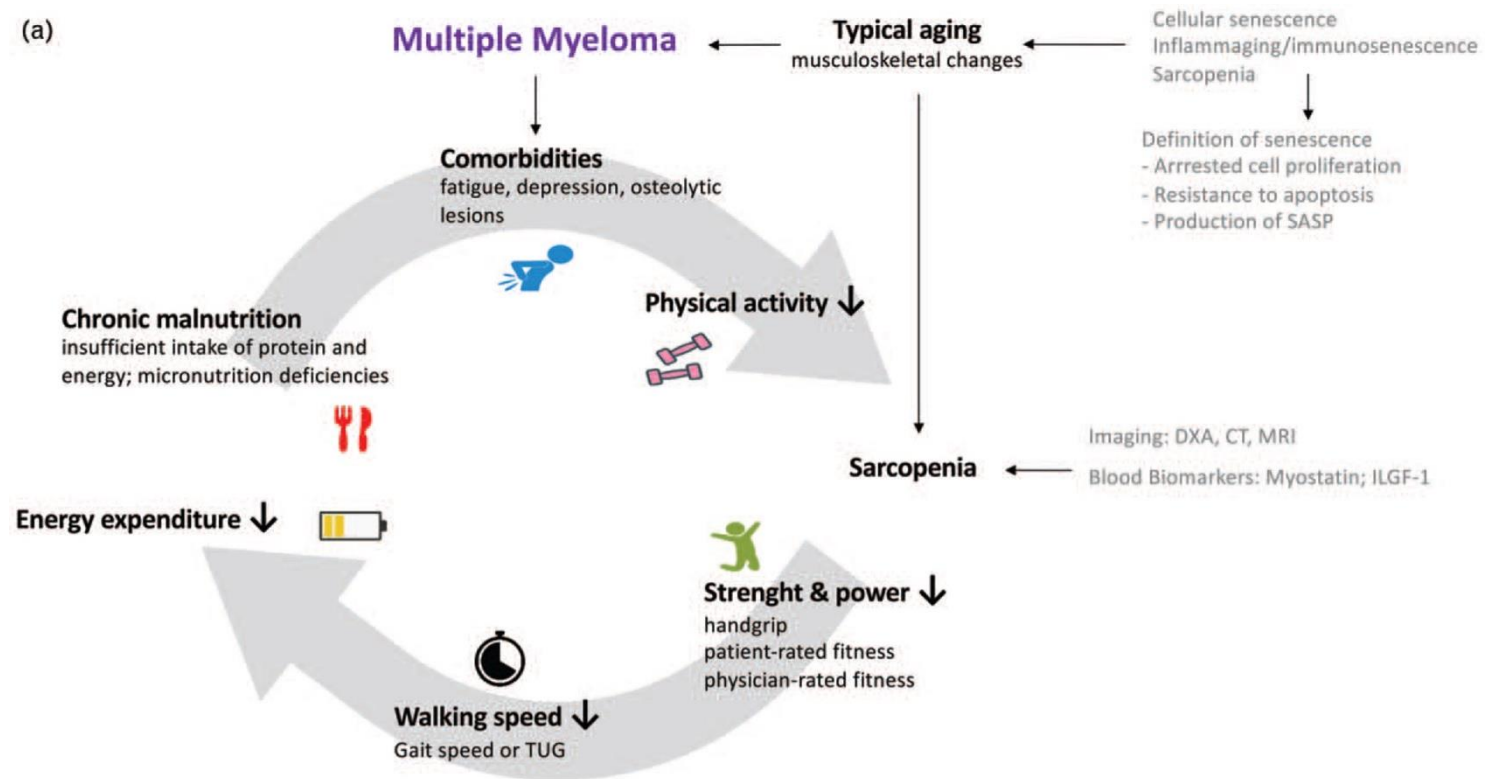
Patients are advised to stay near a medical center for monitoring and in case of serious adverse events

- Serious adverse events include cytokine release syndrome and neurotoxicity

Age

- R/R MM is most common in the elderly population
- Safety and efficacy of bispecific antibodies have only been evaluated in adults
- Geriatric patients often have comorbidities that may complicate treatment
 - May also be more susceptible to adverse events caused by BsAbs

Biological Process of Aging and Senescence in MM Patients



CT = computed tomography; DXA = dual X-ray absorption; MRI = magnetic resonance imaging; SASP = senescence-associated secretory phenotype; TUG = timed up-to-go test

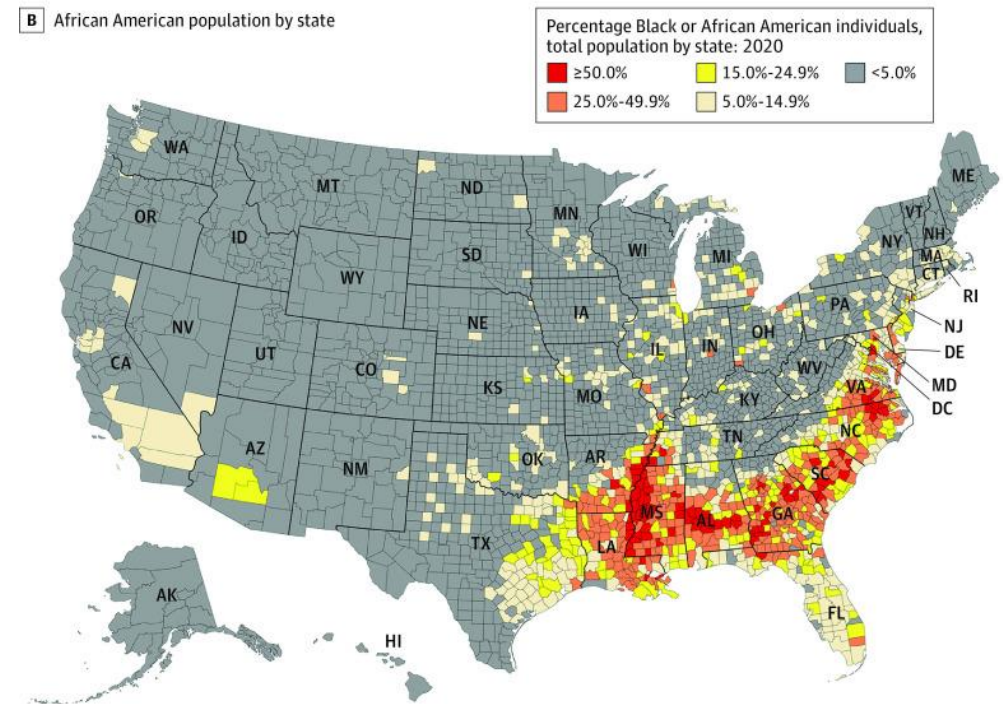
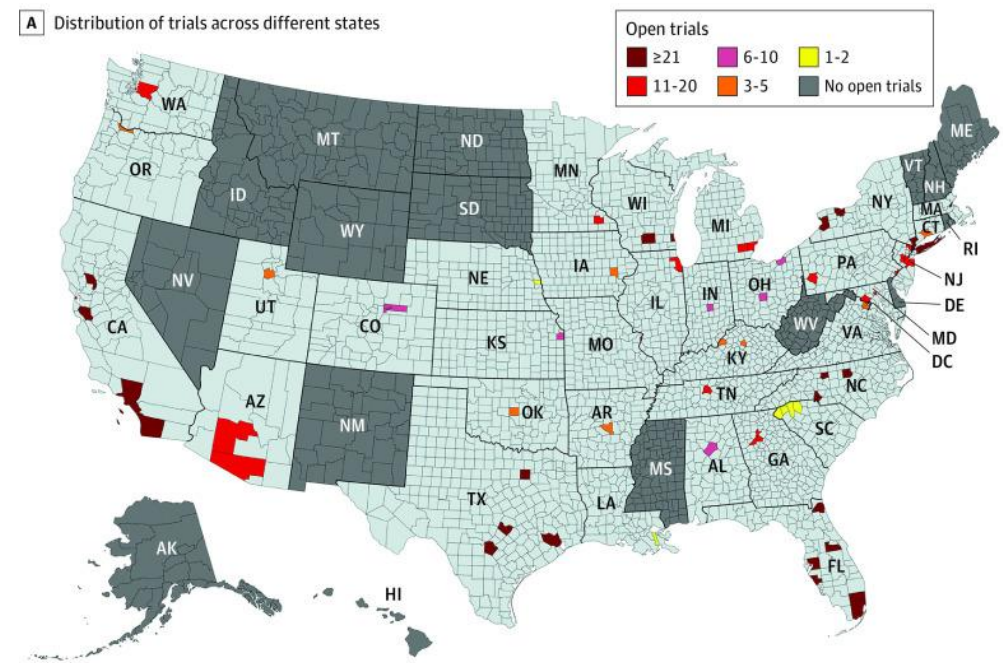
Sex

- BsAbs are available for patients of any sex
 - MM is more common in males
- Patients of reproductive potential should be advised to use effective contraceptives during treatment for up to 3 months after the last dose of treatment
 - BsAbs may cause harm to a fetus when administered in a pregnant person



Ethnicity






- MM is 2x more likely to occur in Black patients
- Large racial disparities exist for Black patients with MM when compared to non-Hispanic White patients, including:
 - Delayed diagnosis
 - Lower use of novel agents, including proteasome inhibitors, CAR-T cell therapy, and BsAbs
 - Lower utilization of palliative care
 - Lower clinical trial enrollment
- There is limited data available that robustly describes the efficacy and safety of BsAbs in this population







Physical Health

- Frailty Scale is used to evaluate patient health status more objectively than using chronological age
 - The scale helps define prognostic groups that are most likely to tolerate therapy
 - Frailty is assessed by the presence of a decrease from established norms in any 3/5 parameters: weight, gait speed, hand-grip strength, self-reported energy, and physical activity
- Patients may be stratified by how likely they are to tolerate adverse events related to BsAbs

CLINICAL FRAILTY SCALE

	1	VERY FIT	People who are robust, active, energetic and motivated. They tend to exercise regularly and are among the fittest for their age.
	2	FIT	People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g., seasonally.
	3	MANAGING WELL	People whose medical problems are well controlled , even if occasionally symptomatic, but often are not regularly active beyond routine walking.
	4	LIVING WITH VERY MILD FRAILITY	Previously "vulnerable," this category marks early transition from complete independence. While not dependent on others for daily help, often symptoms limit activities . A common complaint is being "slowed up" and/or being tired during the day.
	5	LIVING WITH MILD FRAILITY	People who often have more evident slowing , and need help with high order instrumental activities of daily living (finances, transportation, heavy housework). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, medications and begins to restrict light housework.

	6	LIVING WITH MODERATE FRAILITY	People who need help with all outside activities and with keeping house . Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.
	7	LIVING WITH SEVERE FRAILITY	Completely dependent for personal care , from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~6 months).
	8	LIVING WITH VERY SEVERE FRAILITY	Completely dependent for personal care and approaching end of life. Typically, they could not recover even from a minor illness.
	9	TERMINALLY ILL	Approaching the end of life. This category applies to people with a life expectancy <6 months , who are not otherwise living with severe frailty . (Many terminally ill people can still exercise until very close to death.)

SCORING FRAILITY IN PEOPLE WITH DEMENTIA

The degree of frailty generally corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

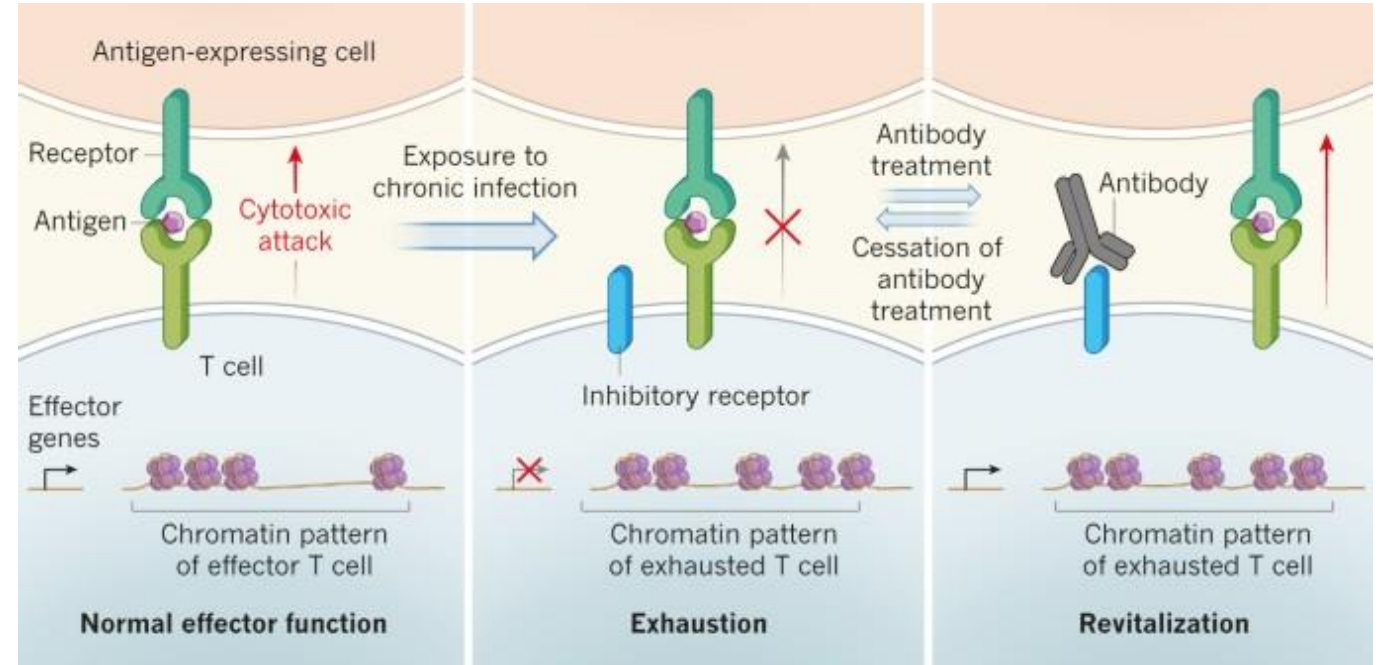
In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting. In **severe dementia**, they cannot do personal care without help. In **very severe dementia** they are often bedfast. Many are virtually mute.



Clinical Frailty Scale ©2005–2020 Rockwood, Version 2.0 (EN). All rights reserved. For permission: www.geriatricmedicineresearch.ca
Rockwood K et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489–495.

Disease Burden

- BsAbs are currently only available to patients with R/R MM
- Patients with higher disease burden are at an increased risk to develop infection, which can complicate treatment and lead to patient mortality
- In an animal model of MM, tumor burden limited BsAb efficacy via T cell exhaustion



Medical History

- Comorbidities can influence treatment options for patient with R/R MM
- Patients with other hematological cancers were excluded from BsAb clinical trials
- Patients with renal dysfunction and/or chronic heart failure are at an increased risk of developing an infection after receiving BsAbs



Previous Therapies

Patients with R/R MM are eligible to receive BsAbs *only* after receiving at least 3-4* previous lines of therapy, including:

- Proteasome inhibitors
- Immunomodulatory agents
- Anti-CD38 monoclonal antibody

Patients eligible for BsAbs are often refractory to first- and second-line therapies

If previous therapies were well tolerated, then patients may be good candidates to receive BsAbs

- **Teclistamab is indicated in combination with daratumumab and hyaluronidase after ≥ 1 line(s) of therapy, including a proteasome inhibitor, and an immunomodulatory agent**

Pre-Medications and Prophylaxis

- Patients treated with BsAbs are required to take and tolerate prophylactic pre-medications

	Teclistamab and Talquetamab	Elranatamab	Linvoseltamab
Pre-Medications	<ul style="list-style-type: none"> • Acetaminophen 650-1000 mg PO • Diphenhydramine 50 mg PO/IV (PO defaulted) • Dexamethasone 16 mg PO/IV (PO defaulted) 	<ul style="list-style-type: none"> • Acetaminophen 650 mg PO • Diphenhydramine 25 mg PO/IV (PO defaulted) • Dexamethasone 20 mg PO/IV (PO defaulted) 	<ul style="list-style-type: none"> • Acetaminophen 650 mg PO • Diphenhydramine 25 mg PO/IV (PO defaulted) • Dexamethasone 40 mg PO/IV
	<ul style="list-style-type: none"> • Given 1 hour prior to BsAb dose • Required for all step-up doses and the first treatment dose • PRN thereafter if CRS with prior dose or delay in treatment schedule 		
Infection prophylaxis	Antiviral prophylaxis for Herpes Zoster (HSV) reactivation and PJP prophylaxis		

CRS = cytokine release syndrome; PJP = pneumocystis jiroveci pneumonia; PO = by mouth; PRN = as needed

Teclistamab [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; March 2026; Elranatamab [prescribing information]. New York, NY: Pfizer Inc.; February 2026; Talquetamab [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; October 2025; Lynozyfic (linvoseltamab-gcpt) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025.

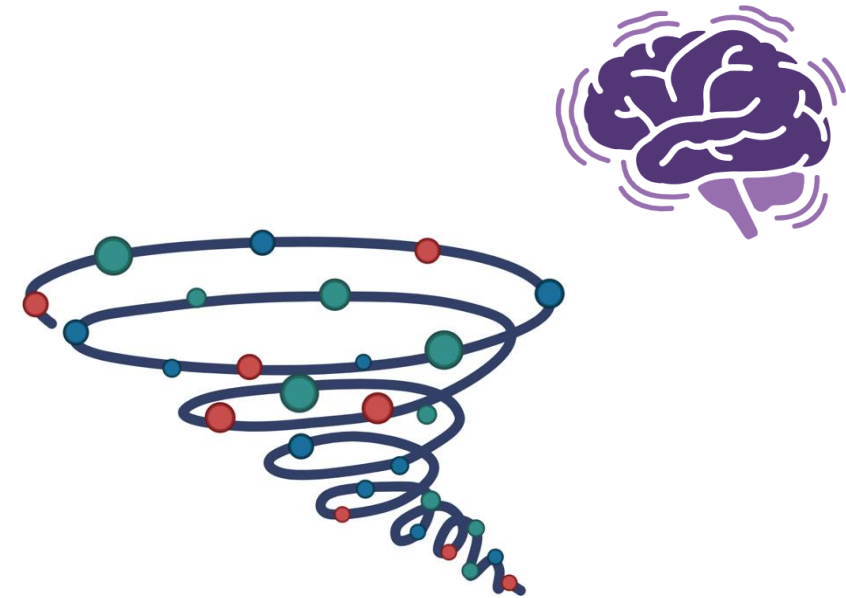
Prophylaxis for Infections

	Monitoring	Prophylaxis
Viral Infection	<ul style="list-style-type: none">• Monitor patient symptoms and clinical presentation• Screen for HBV before treatment initiation• CMV if infection suspected• EBV not routine, but consider	<ul style="list-style-type: none">• Antiviral against HSV/VZV for all patients
Bacterial Infection	<ul style="list-style-type: none">• Cultures and tests depends on infection site• Imaging for confirmation	<ul style="list-style-type: none">• Recommended if prolonged neutropenia, high risk of infections, or history of recurrent bacterial infections• Prophylaxis with levofloxacin until no longer neutropenic
Fungal Infection	<ul style="list-style-type: none">• Routine monitoring NOT recommended	<ul style="list-style-type: none">• PJP prophylaxis for all patients

CMV = cytomegalovirus; EBV = Epstein-Barr virus; HBV = hepatitis B virus; HSV = herpes simplex virus; VZV = varicella zoster virus

Adverse Events

- Patients with renal dysfunction and/or chronic heart failure are at an increased risk of developing an infection after receiving BsAbs
 - In a single center study, of the 39 enrolled patients with R/R MM, 35 (90%) had at least 1 episode of infection
 - A total of 15 (38%) had a microbial infection and 16 (41%) had at least one grade 3 or higher infection episode
- BCMA-directed agents tend to lead to higher rates of infections than GPRC5D-directed agents with longer follow-up
- **Cytokine release syndrome and neurotoxicities, like ICANS are the most common adverse events and require immediate medical attention**



You will learn more about how to manage adverse events in ECHO Sessions #3, #4, and #5!

Quality of Life

- Prolonging life and maintaining, or improving, quality of living are important patient goals to consider
 - Patient's value goals that align with being able to continue with activities of daily living and maintaining good physical and mental health
- Older patients may prioritize standard of living over AEs from a new therapy



Financial



BsAbs can be costly to patients and their caregivers



Insurance may cover none to only part of the therapy. Medicare/Medicaid covers some therapies.



Some centers can help access health insurance or programs that can help pay the costs of treatment





Key Takeaways

- MM is a complex disease to treat and manage; patient-specific factors should be considered when determining treatment options
- Not all patients will be eligible or have access to care centers with BsAbs
 - It is important to consider how social determinants of health influence treatment for R/R MM
- Understanding how to recognize and address toxicities with supportive care strategies are key to BsAb treatment success in the clinic

What did you learn?



Which pre-medication regimen is appropriate for a patient receiving teclistamab during step-up dosing?

- A. Acetaminophen 650 mg, diphenhydramine 25 mg, and dexamethasone 20 mg
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Case Studies

Please come off mute or use the chat feature to discuss with your colleagues and ask questions about your patient cases



Case Study #1

- Female in her 70s presenting for evaluation of MM with PMH for:
 - **Heart failure** with preserved ejection fraction
 - **Iron deficiency anemia**
 - **Chronic kidney disease (CKD)**
- **10/2017:** Underwent **kidney biopsy** for worsening renal disease
 - Results showed **membranoproliferative glomerulonephritis** with **heavy light chain deposition disease, IgG 3 lambda**
- **12/2019: Bone marrow biopsy** showing **small plasma cell clone** (5-7%) with a **cytoplasmic lambda restriction with 1q gain, trisomy 9, and trisomy 15**
 - Skeletal survey showed **no lytic lesions**



Case Study #1: Continuation

- **1/2020-9/23/2020: Received CyBorD**
 - Creatinine improved from 2.14 to 1.64 mg/dL
 - Improvement in proteinuria from 4069 mg/g to 265 mg/g
 - K/L ratio normalized at 1.04
 - Initially **stopped** due to **diarrhea and dehydration**
- **6/2022: K/L ratio dropped to 0.22** consistent with progression of disease
 - **Lambda increased to 152.8**
 - Declined referral to tertiary care center for autologous HSCT
- **7/2022: Bone marrow biopsy**
 - **Lambda restricted clonal plasma cells** representing **7-8%** of a mildly hypercellular bone marrow
 - Maturing trilineage hematopoiesis present
 - **FISH** for myeloma still shows gain of **1q21**, **trisomy9**, and **trisomy 15**
- **8/2022:** Restarted on **CyBorD**
- **11/2022: Stopped treatment** due to **worsening CHF** despite furosemide
 - Shortness of breath continued until bortezomib was stopped

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Case Study #1: Initiation of BsAbs

- **1/23-6/24: Received daratumumab, reduced dose of lenalidomide (due to CKD), and dexamethasone (DRd)**
 - Some response noted initially, with improvement in **free lambda chain** from **165.2 to 121 mg/L**
 - **Rapidly increased in July 2024** with **increase in creatinine** and **worsening pancytopenia**
- **7/2024: Lenalidomide switched to pomalidomide (DPd)**
- **12/2024: Started on Selinexor 80 mg qWeek** with dex
 - **Lambda light chain** decreased from **582 to 380 mg/L**
- **2/2025: Seen by UK for advanced cellular therapy**
 - Patient **not a candidate for CAR-T** and **discussed BsAb therapy**
- **3/2025: Patient consented for teclistamab**, however had concern for acute exacerbation of heart failure
 - Underwent one session of dialysis, then adjusted medication

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and “Take Course” then “Start Course”

2. Enter Attendance Code **MOCYEX** when prompted

3. Complete The Evaluation

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