Multiple Myeloma Update

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Disclosures

I have nothing to disclose.

I will not be discussing off-label indications.

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Objectives

1. Identify the current guideline-based therapeutic recommendations for the treatment of multiple myeloma
2. Describe the unique toxicity profiles of bispecific therapies used in the treatment of patients with multiple myeloma
3. Evaluate the role of bispecific therapies in the treatment of patients with multiple myeloma

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Our Journey Today

- Brief background of multiple myeloma
- Review currently available treatments for multiple myeloma
- Discuss recent myeloma drug approvals, focusing on bispecific therapies
  - Teclistamab
  - Talquetamab
  - Elranatamab
- Discuss unique adverse effects for the recently approved bispecific therapies
- Discuss place in therapy for the recently approved bispecific therapies

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Multiple Myeloma Background & Treatment

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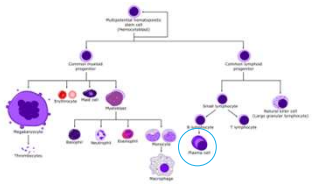
Multiple Myeloma Definition

Multiple Myeloma is a B-cell malignancy characterized by proliferation of plasma cells that accumulate in the bone marrow, leading to the production of monoclonal immunoglobulin (M-protein)



PALUMBO A, ANDERSON K. *N ENGL J MED.* 2011;64-1046-60

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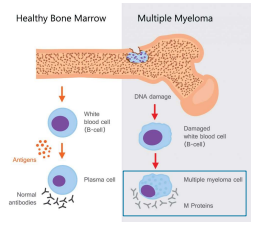
Multiple Myeloma Definition



RAJKUMAR SV, ANDERSON K. N ENGL J MED. 2011;64:1046-60 7

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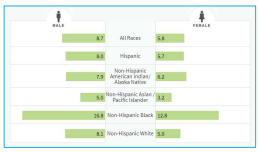
Multiple Myeloma Background

- Represents 1.8% of all new cancer cases
- United States 2023 estimates
  - New cases: 35,730
  - Deaths: 12,590
- Median Age at diagnosis: 69 years (65-74)
- Risk Factors
  - African Americans
  - Males
  - Environmental or work-related exposures to chemicals



CANCER FACTS & FIGURES 2023 AMERICAN CANCER SOCIETY 8

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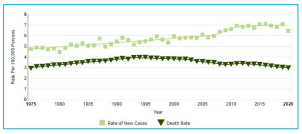
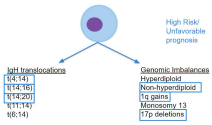
Multiple Myeloma Prognosis



- Incurable, but highly treatable
- Goals of Treatment: Disease control, improved quality of life, and prolong survival
- 5-Year Relative Survival: 59.8%



CANCER FACTS & FIGURES 2023 AMERICAN CANCER SOCIETY
RAJKUMAR SV, ANDERSON K. N ENGL J MED. 2011;64:1046-60
NCCN GUIDELINES, MULTIPLE MYELOMA, VERSION 3.2024 9

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Front-Line Myeloma Treatment

Transplant Eligible

- Preferred Regimens
  - Bortezomib/Lenalidomide/Dexamethasone **(category 1)**
  - Carfilzomib/Lenalidomide/Dexamethasone
- Other Recommended Regimens
  - Daratumumab/Lenalidomide/Bortezomib/Dexamethasone

Non-Transplant Eligible

- Preferred Regimens
  - Bortezomib/Lenalidomide/Dexamethasone **(category 1)**
  - Daratumumab/Lenalidomide/Dexamethasone **(category 1)**
- Other Recommended Regimens
  - Daratumumab/Bortezomib/Melphalan/Prednisone **(category 1)**
  - Carfilzomib/Lenalidomide/Dexamethasone
  - Daratumumab/Cyclophosphamide/Bortezomib/Dexamethasone

NCCN GUIDELINES. MULTIPLE MYELOMA. VERSION 1.2024. 10

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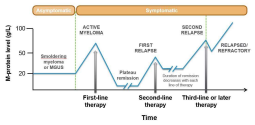
Relapsed/Refractory Myeloma



- Relapsing/remitting disease pattern
- With each relapse, becomes harder to capture and maintain a response
- Additionally, harder for patients to recover from treatment the further along they are
- Increased risk for adverse effects including opportunistic infections

CONCISE REVIEW OF DISEASE AND TREATMENT OPTIONS. INTERNATIONAL MYELOMA FOUNDATION. 2018 11

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Second & Third Line Myeloma Treatment

- Anti-CD38 Therapies
- Immunomodulators
- Proteasome Inhibitors
- Anti-SLAMF7 Therapies
- Oral Targeted Therapies (Selinexor & Venetoclax)

NCCN GUIDELINES. MULTIPLE MYELOMA. VERSION 1.2024. 12

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Fourth Line and Beyond Treatment: To Be Continued…

Preferred Regimens

- CAR T-Cell Therapy
  - Ciltacabtagene autoleucel
  - Idecabtagene autoleucel

Other Recommended Regimens

- Bendamustine
- High-Dose or Fractionated Cyclophosphamide
- Selinexor/Dexamethasone
- Belantamab mafodotin-blmf

NCCN GUIDELINES: MULTIPLE MYELOMA. VERSION 1.2024. 13

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Audience Response Question #1

Which of the following medications is currently preferred in the fourth line setting of relapsed/refractory multiple myeloma according to the most recent NCCN guidelines?

A. Venetoclax
B. Carfilzomib
C. Ciltacabtagene autoleucel
D. Melflufen

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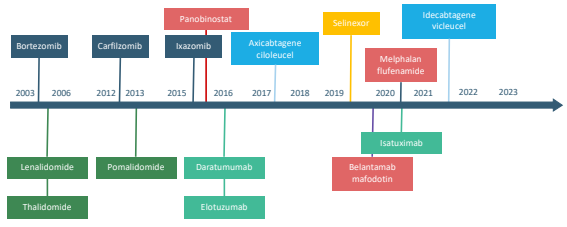
Multiple Myeloma Drug Approvals



NCCN GUIDELINES: MULTIPLE MYELOMA. VERSION 1.2024. 15

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Myeloma Bispecific Approvals

- **Teclistamab**
  - FDA Approved on October 25, 2022
- **Talquetamab**
  - FDA Approved on August 9, 2023
- **Elranatamab**
  - FDA Approved on August 14, 2023

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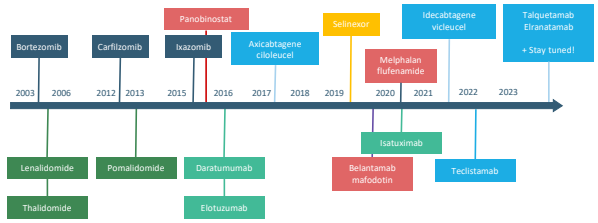
Multiple Myeloma Drug Approvals



NCCN GUIDELINES, MULTIPLE MYELOMA, VERSION 1.2024

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Teclistamab

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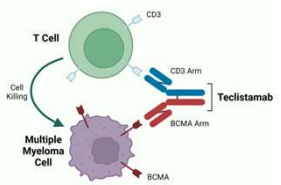
Teclistamab Background

Mechanism of Action

- Humanized antibody and bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
- Binds to the CD3 receptor on the surface of T-cells, and BCMA expressed on the surface of multiple myeloma cells
- This binding results in T-cell activation, the release of various proinflammatory cytokines, and the lysis of BCMA-expressing multiple myeloma cells

Administered subcutaneously and requires step-up dosing upon initiation of therapy



Black Box Warnings
- Cytokine Release Syndrome
- Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

MOREAU P, ET AL. *N ENGL J MED.* 2022;387(6):495-505.
TECVAYLI (TECLISTAMAB-CQYV) [PRESCRIBING INFORMATION]. HORSHAM, PA: JANSSEN BIOTECH; 2022. 19

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Teclistamab Dosing and Administration

Adult Dosing	Day	Dose	
Step-Up Dosing Schedule	Day 1	Step-up dose 1	0.06 mg/kg
	Day 4	Step-up dose 2	0.3 mg/kg
	Day 7	First treatment dose	1.5 mg/kg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg weekly

Step up rounding rules are provided in the prescribing information based on weight.

* Package insert states: Due to the risk of cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), patients should be hospitalized for 48 hours after all doses within the teclistamab step-up dosing schedule (step-up doses 1 and 2, as well as the first treatment dose)

** Step up dose 2 and first treatment doses may be administered 2 to 4 days after and, if necessary, up to 7 days after prior dose to allow for resolution of adverse reactions

MOREAU P, ET AL. *N ENGL J MED.* 2022;387(6):495-505.
TECVAYLI (TECLISTAMAB-CQYV) [PRESCRIBING INFORMATION]. HORSHAM, PA: JANSSEN BIOTECH; 2022. 20

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MajesTEC-1: Teclistamab

Key eligibility criteria:
- RRMM[2]
- ECOG PS 0 or 1
- Triple-class exposed (PI, IMiD, anti-CD38 mAb)
- No prior BCMA-directed therapy

Phase 1

Dose escalation: IV cohorts; SC cohorts

Dose expansion: RP2D 1.5 mg/kg SC QW

Phase 2

Phase 2 efficacy cohort

Primary endpoint
- ORR

Key secondary endpoints
- PK/PD
- DOR
- PFS
- OS
- MRD negativity
- AEs
- HRQoL

Definitions: ORR = Overall Response Rate, PK/PD = Pharmacokinetics/Pharmacodynamics, DOR = Duration of Response, PFS = Progression-Free Survival, OS = Overall Survival, MRD = Minimal Residual Disease, AEs = Adverse Effects, HRQoL = Health-Related Quality of Life

Patient Characteristics
Median lines of therapy: 5 (2–14)
High risk cytogenetics: 25%
Median Age: 64 years (33-84)

MOREAU P, ET AL. *N ENGL J MED.* 2022;387(6):495-505. 21

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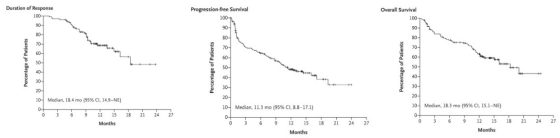
MajesTEC-1: Outcomes



MOREAU P, ET AL. N ENGL J MED. 2022;387(6):495-505. 22

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MajesTEC-1: Safety

Adverse Effect	Any Grade (%)	Grade 3 or 4 (%)
Neutropenia	71	64
Pyrexia	27	0.6
Injection site reactions	26	0
Fatigue	28	2.4
Cytokine release syndrome (CRS)	72	0.6
Neurotoxicity (ICANS)	14.5	0.6
Musculoskeletal pain	44	4.2
Pneumonia	24	15
Nausea	27	0.6
Diarrhea	29	3.6
Headache	24	0.6

	CRS	ICANS
Time to Onset (days)	2 (1-6)	4 (2-8)
Duration of Toxicity (days)	2 (1-9)	3 (1-20)

MOREAU P, ET AL. N ENGL J MED. 2022;387(6):495-505. 23

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Teclistamab: Considerations

REMS REQUIREMENTS

- Prescribers must counsel patients receiving teclistamab about risk of CRS and ICANS and provide a patient wallet card
- Pharmacists and healthcare settings that dispense teclistamab must be certified with the REMS and must verify prescribers are certified through the REMS
- Wholesalers and distributers must only distribute teclistamab to certified pharmacies or certified healthcare settings

SUPPORTIVE CARE

- Premedicate with acetaminophen, diphenhydramine, and dexamethasone through first full dose
- Antiviral to prevent herpes zoster infection
- Pneumocystis jirovecii prophylaxis
- Supplement IVIG for IgG < 400
- Consider antibiotic for first month of treatment to prevent bacterial infection

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Talquetamab

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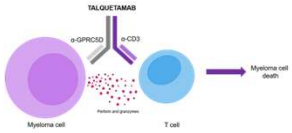
Talquetamab Background

Mechanism of Action

- Binds to the CD3 receptor on the surface of T-cells, and G protein-coupled receptor class C group 5 member D (GPRC5D) expressed on the surface of multiple myeloma cells
- This binding results in T-cell recruitment and activation, the release of various proinflammatory cytokines, and the lysis of BCMA-expressing multiple myeloma cells



Administered subcutaneously and requires step-up dosing upon initiation of therapy

Black Box Warnings
- Cytokine Release Syndrome
- Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

SCHINKE C, ET AL. J CLIN ONCOL. 2023;41(16 SUPPL):LB036.
TALVEY (TALQUETAMAB) [PRESCRIBING INFORMATION]. HORSHAM, PA: JANSSEN BIOTECH, INC; AUGUST 2023.

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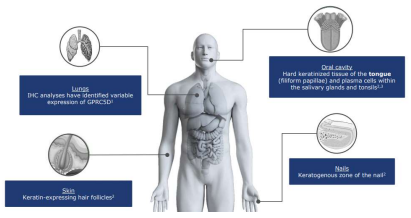
GPRC5D Expression



Definitions: GPRC5D = G-protein–coupled receptor class 5 member, IHC = immunohistochemistry

SMITH EL, ET AL. SCI TRANSL MED 2019

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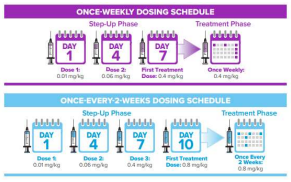
Talquetamab Dosing and Administration



Step up rounding rules are provided in the prescribing information based on weight.

* Package insert states: Due to the risk of cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), patients should be hospitalized for 48 hours after all doses within the talquetamab step-up dosing schedule (step-up doses 1 and 2 +/- 3, as well as the first treatment dose)

** Step up dose 2 +/- 3 and first treatment doses may be administered 2 to 4 days after and, if necessary, up to 7 days after prior dose to allow for resolution of adverse reactions

SCHINKE C, ET AL. / CLIN ONCOL. 2023;41(16 SUPPL):8036.
TALVEY (TALQUETAMAB) [PRESCRIBING INFORMATION]. HORSHAM, PA: JANSSEN BIOTECH, INC; AUGUST 2023.

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MonumenTAL-1: Talquetamab

Key eligibility criteria:
- RRMM[2]
- ECOG PS 0 or 1
- Triple-class exposed (PI, IMiD, anti-CD38 mAb)

Phase 1
Dose escalation: IV cohorts; SC cohorts
Dose expansion: Weekly (0.4 mg/kg) or Twice weekly (0.8 mg/kg) dosing

Phase 2
Phase 2 efficacy cohort

Primary End Points
Frequency and type of dose-limiting toxic effects, adverse events, and laboratory abnormalities

Secondary End Points
Response, pharmacokinetics, pharmacodynamics, and immunogenicity.

Minimal residual disease–negativity rate was an exploratory end point

Definitions: RRMM = Relapsed/refractory multiple myeloma, ECOG = Eastern Cooperative Oncology Group, PI = Proteasome inhibitor, IMiD = immunomodulator, mAb = Monoclonal antibody

Patient Characteristics
Median lines of therapy: 6 (2–17)
High risk cytogenetics: 16%
Median Age: 64 (39–84)

SCHINKE C, ET AL. / CLIN ONCOL. 2023;41(16 SUPPL):8036.

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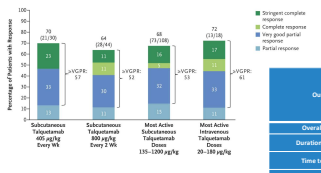
MonumenTAL-1: Outcomes



Outcomes	Treatment Group, Weekly + Bi-weekly Dosing (n= 30, 44)	Range or 95% CI, Weekly + Bi-weekly Dosing
Overall Response	70%, 64%	(51 to 85), (48 to 78)
Duration of Response	10.2 mths, 7.8 mths	(3.0 to NR), (4.6 to NR)
Time to Response	0.9 mths, 1.2 mths	(0.2 to 3.8), (0.3 to 6.8)
Progression-Free Survival	7.5 mths, N/A	(5.7–9.4), N/A
12 Mth Overall Survival – Reported 6/2023	77.4%, 76.4%	Not Reported

SCHINKE C, ET AL. / CLIN ONCOL. 2023;41(16 SUPPL):8036.

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MonumenTAL-1: Safety

Adverse Effect	Any Grade (%)	Grade 3 or 4 (%)
Neutropenia	36	32
Pyrexia	18	0
Thrombocytopenia	23	11
Anemia	43	23
Cytokine Release Syndrome (CRS)	75	0
Neurotoxicity	7.7	0
Infection	50	12
Skin-Related Event	70	2
Nail-Related Event	27	2
Weight Decrease	32	2
Dry Mouth	57	0
Dysphagia	27	0

	CRS	ICANS
Time to Onset (days)	2 (1-8)	3 (2-16)
Duration of Toxicity (days)	2 (1-29)	1 (1-15)

SCHINIE C, ET AL. J CLIN ONCOL 2023;41(16 SUPPL):58036. 31

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Talquetamab: Considerations

REMS REQUIREMENTS

- Prescribers must counsel patients receiving talquetamab about risk of CRS and ICANS and provide a patient wallet card
- Pharmacists and healthcare settings that dispense talquetamab must be certified with the REMS and must verify prescribers are certified through the REMS
- Wholesalers and distributers must only distribute talquetamab to certified pharmacies or certified healthcare settings

SUPPORTIVE CARE

- Premedicate with acetaminophen, diphenhydramine, and dexamethasone through first full dose
- Antiviral to prevent herpes zoster infection
- Pneumocystis jirovecii prophylaxis
- Supplement IVIG for IgG < 400
- Consider antibiotic for first month of treatment to prevent bacterial infection
- Breathable shoes and remove nail polish to reduce nail toxicities
- Consider antifungal therapy for patients with oral toxicities
- Hydrating and barrier creams for dry, irritated skin and consider topical steroids for refractory cases

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Elranatamab

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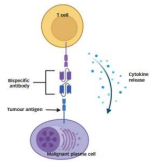
Elranatamab Background

Mechanism of Action

- Humanized antibody and bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
- Binds to the CD3 receptor on the surface of T-cells, and BCMA expressed on the surface of multiple myeloma cells
- This binding results in T-cell activation, the release of various proinflammatory cytokines, and the lysis of BCMA-expressing multiple myeloma cells



Administered subcutaneously and requires step-up dosing upon initiation of therapy

Black Box Warnings
- Cytokine Release Syndrome
- Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

ELSEDHEIN AM ET AL. *NAT MED*. 2023
ELREXFIO (ELRANATAMAB) [PRESCRIBING INFORMATION]. NEW YORK, NY: PFIZER INC; AUGUST 2023. 34

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Elranatamab Dosing and Administration

Adult Dosing	Day	Dose	
Step-up Dosing Schedule	Day 1	Step-up dose 1	12 mg
	Day 4	Step-up dose 2	32 mg
	Day 8	First treatment dose	76 mg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter	Subsequent treatment doses every week	76 mg
Bi-Weekly Dosing Schedule	Starting week 25	Subsequent treatment doses every 2 weeks	76 mg

Only therapy we have talked about today where dosing is FLAT and minimizes vial waste!

*Package insert states: Due to the risk of cytokine release syndrome (CRS), patients should be hospitalized for 48 hours after elranatamab step-up dose 1, and for 24 hours after elranatamab step-up dose 2.

** Step up dose 2 and first treatment doses may be administered 2 to 4 days after and, if necessary, up to 7 days after prior dose to allow for resolution of adverse reactions

ELSEDHEIN AM ET AL. *NAT MED*. 2023
ELREXFIO (ELRANATAMAB) [PRESCRIBING INFORMATION]. NEW YORK, NY: PFIZER INC; AUGUST 2023. 35

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MagnetisMM-3: Elranatamab

Key Eligibility Criteria
- RRMM refractory to ≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 mAb
- ECOG 0-2

Intervention

Cohorts	Dose	Frequency
Cohort A: No Prior BCMA-Targeted Therapy Cohort B: Prior BCMA-Targeted Therapy	12 mg on Day 1 and 32 mg on Day 4 of the first week SC elranatamab 76 mg QW on a 28-day cycle	Patients who received QW dosing for ≥6 cycles and achieved PR or better for ≥2 months were switched to Q2W dosing

Primary End Point
- ORR

Secondary End Points
- CR
- Time to Response
- Duration of Response
- PFS
- OS
- Safety
- Pharmacokinetics

Definitions: RRMM = Relapsed/Refractory Multiple Myeloma, ECOG = Eastern Cooperative Oncology Group, ORR = Overall Response Rate, DOR = Duration of Response, PFS = Progression-Free Survival, OS = Overall Survival, MRD = Minimal Residual Disease, PI = Proteasome inhibitor, IMID = immunomodulator, mAb = Monoclonal antibody, CR = Complete Response

Patient Characteristics
Median lines of therapy: 5 (2–22)
High risk cytogenetics: 25%
Median Age: 68 years (36-89)

ELSEDHEIN A ET AL. *NAT MED*. 2023 36

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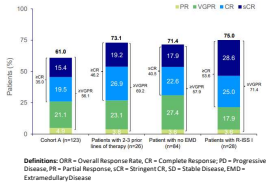
MagnetisMM-3: Outcomes



Definitions: ORR = Overall Response Rate, CR = Complete Response; PD = Progressive Disease, PR = Partial Response, sCR = Stringent CR, SD = Stable Disease, EMD = Extramedullary Disease

Outcomes	Treatment Group	Range or 95% CI
Overall Response	61%	(51.8-69.6)
Duration of Response	Not reached	N/A
Time to Response	1.2 mths	(0.9-7.4)
Progression-Free Survival	N/A - Kaplan–Meier estimate at 15 months was 50.9%	N/A
12 Mth Overall Survival	N/A - Kaplan–Meier estimate at 15 months was 56.7	N/A

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MagnetisMM-3: Safety

Adverse Effect	Any Grade (%)	Grade 3 or 4 (%)
Neutropenia	48.8	48.8
Pyrexia	30.1	4.1
Injection site reactions	26.8	0
Fatigue	36.63	3.3
Neurotoxicity (ICANS)	3.3	7
Cytokine release syndrome (CRS)	57.7	0
Upper respiratory tract infection	16.3	0
Pneumonia	16.3	8.1
Nausea	26.8	0
Diarrhea	42.3	1.6
Headache	23.6	0

	CRS	ICANS
Time to Onset (days)	2 (1-9)	3 (1-4)
Duration of Toxicity (days)	2 (1-19)	2 (1-18)

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Elranatamab: Considerations

REMS REQUIREMENTS

- Prescribers must counsel patients receiving elranatamab about risk of CRS and ICANS and provide a patient wallet card
- Pharmacists and healthcare settings that dispense elranatamab must be certified with the REMS and must verify prescribers are certified through the REMS
- Wholesalers and distributers must only distribute elranatamab to certified pharmacies or certified healthcare settings

SUPPORTIVE CARE

- Premedicate with acetaminophen, diphenhydramine, and dexamethasone through first full dose
- Antiviral to prevent herpes zoster infection
- Pneumocystis jirovecii prophylaxis
- Supplement IVIG for IgG < 400
- Consider antibiotic for first month of treatment to prevent bacterial infection

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Audience Response Question #2

Which of the following bispecific therapies discussed today has a unique adverse effect of nail changes and extreme skin dryness that requires patient counseling and education to prevent and treat?

A. Teclistamab
B. Talquetamab
C. Elranatamab
D. Daratumumab

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Myeloma Bispecific Approvals

Teclistamab
- FDA Approved on October 25, 2022

Talquetamab
- FDA Approved on August 9, 2023

Elranatamab
- FDA Approved on August 14, 2023

Each one of these medications was approved in the same treatment setting:
Treatment of relapsed or refractory multiple myeloma in adults who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

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Fourth Line and Beyond Treatment: Finalized

Preferred Regimens
- CAR T-Cell Therapy
  - Ciltacabtagene autoleucel
  - Idecabtagene autoleucel
- Bispecific Therapies
  - Teclistamab
  - Talquetamab
  - Elranatamab

Other Recommended Regimens
- Bendamustine
- High-Dose or Fractionated Cyclophosphamide
- Selinexor/Dexamethasone
- Belantamab mafodotin-blmf

NCCN GUIDELINES. MULTIPLE MYELOMA. VERSION 1.2024.

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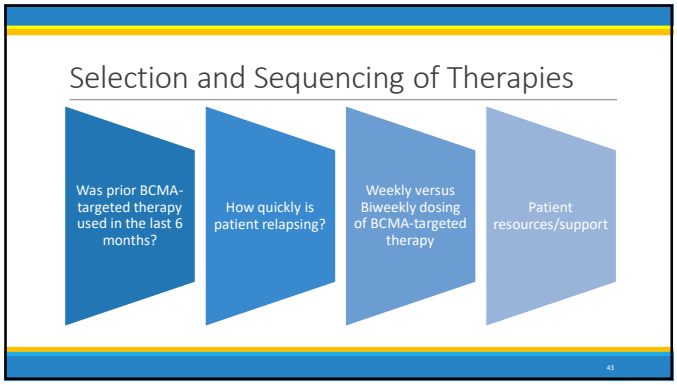
Selection and Sequencing of Therapies
Was prior BCMA-targeted therapy used in the last 6 months?
How quickly is patient relapsing?
Weekly versus Biweekly dosing of BCMA-targeted therapy
Patient resources/support
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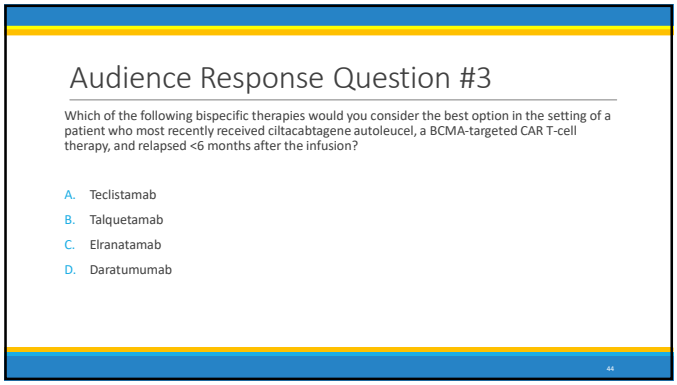
Audience Response Question #3
Which of the following bispecific therapies would you consider the best option in the setting of a patient who most recently received ciltacabtagene autoleucel, a BCMA-targeted CAR T-cell therapy, and relapsed <6 months after the infusion?
A. Teclistamab
B. Talquetamab
C. Elranatamab
D. Daratumumab
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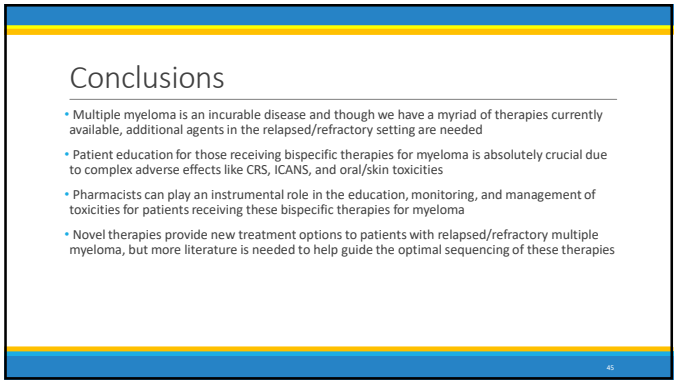
Conclusions
• Multiple myeloma is an incurable disease and though we have a myriad of therapies currently available, additional agents in the relapsed/refractory setting are needed
• Patient education for those receiving bispecific therapies for myeloma is absolutely crucial due to complex adverse effects like CRS, ICANS, and oral/skin toxicities
• Pharmacists can play an instrumental role in the education, monitoring, and management of toxicities for patients receiving these bispecific therapies for myeloma
• Novel therapies provide new treatment options to patients with relapsed/refractory multiple myeloma, but more literature is needed to help guide the optimal sequencing of these therapies
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Questions?

Thank you for your time and attention!

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Multiple Myeloma Update

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