

Multiple Myeloma™

U P D A T E

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Edward A Stadtmauer, MD
Sarah A Holstein, MD, PhD
Paul G Richardson, MD
Shaji K Kumar, MD

EDITOR

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CONTENTS

1 Audio CD



Multiple Myeloma™

U P D A T E

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Multiple Myeloma Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Multiple myeloma (MM) is a plasma cell neoplasm that accounts for approximately 12% of all hematologic cancers and carries with it one of the worst death to new cases ratios. Although MM only represented 1.8% of all new cancer cases diagnosed in the United States in 2017, practicing clinicians would be hard pressed to identify another area of oncology in which the research database — and available treatments — has evolved more rapidly over the past decade. In addition to significantly altering the natural history of MM, novel agents, including proteasome inhibitors, immunomodulatory agents and BTK inhibitors, have contributed to recent treatment gains for 2 related blood disorders — Waldenström macroglobulinemia (WM) and amyloidosis. Featuring the latest research developments along with expert perspectives, this CME activity will deliver to community-based oncology clinicians highly applicable, current clinical information delving into the individualized and multifaceted management of these disorders.

LEARNING OBJECTIVES

- Use patient and disease characteristics, including cytogenetic profile, to customize induction and maintenance therapeutic approaches in the transplant and nontransplant settings.
- Consider available research data and other clinical factors in the best-practice selection, sequencing and combination of current and recently approved novel agents in the nonresearch care of patients with relapsed/refractory MM.
- Design and implement a plan of care to recognize and manage side effects and toxicities associated with recently approved systemic therapies to support quality of life and continuation of treatment.
- Develop an evidence-based algorithm for the use of stem cell transplantation, chemotherapy and/or novel targeted agents for the management of amyloidosis.
- Consider clinical and other patient-related factors in the sequence and selection of systemic therapy for WM requiring active treatment.
- Develop risk-adapted treatment plans for patients with smoldering MM, considering the roles of observation and active treatment.

ACCREDITATION STATEMENT

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Penn State College of Medicine and Research To Practice. Penn State College of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

Penn State College of Medicine designates this enduring material for a maximum of 4.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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This activity is supported by educational grants from AbbVie Inc, Celgene Corporation, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, and Takeda Oncology.

Release date: February 1, 2018; Expiration date: February 1, 2019

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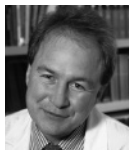
CME INFORMATION

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EDITOR — **Dr Love** is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Acerta Pharma, Adaptive Biotechnologies, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Baxalta Inc, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheragnostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, CTI BioPharma Corp, Dendreon Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, Halozyme Inc, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Kite Pharma Inc, Lexicon Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, NanoString Technologies, Natera Inc, Novartis, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro Inc, Teva Oncology and Tokai Pharmaceuticals Inc.

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Interview with Edward A Stadtmauer, MD

Tracks 1-12

Track 1	Evolution of B-cell maturation antigen (BCMA) targeting in multiple myeloma (MM)	Track 8	Subcutaneous delivery of daratumumab
Track 2	Chimeric antigen receptor (CAR) T-cell therapy-associated cytokine release syndrome and neurotoxicity	Track 9	Case: A 56-year-old man with R/R MM and t(11;14) receives venetoclax/bortezomib/dexamethasone
Track 3	Clinical management of cytokine release syndrome	Track 10	Case: A 54-year-old man with R/R MM receives ixazomib/lenalidomide/dexamethasone
Track 4	Durable remissions with BCMA CAR T-cell therapy in relapsed/refractory (R/R) MM	Track 11	Treatment approach for patients who experience relapse while receiving post-transplant lenalidomide maintenance therapy
Track 5	Initial efficacy and safety results with BCMA CAR T-cell therapy	Track 12	Case: A 76-year-old man with previously treated Waldenström macroglobulinemia (WM) experiences a prolonged response to ibrutinib
Track 6	Feasibility of administering CAR T-cell therapy in a community setting		
Track 7	Mechanism of action of monoclonal antibodies; daratumumab-associated infusion-related reactions		

Interview with Sarah A Holstein, MD, PhD

Tracks 1-20

Track 1	Case: A 58-year-old man with newly diagnosed high-risk MM experiences a very good partial response and moderate peripheral neuropathy with lenalidomide/bortezomib/dexamethasone (RVd) induction → autologous stem cell transplant (ASCT) but is unwilling to receive bortezomib maintenance therapy because of concerns about further neuropathy	Track 8	Duration of lenalidomide maintenance therapy
Track 2	Ixazomib as a component of maintenance therapy for high-risk MM	Track 9	Early versus delayed ASCT after induction therapy for MM
Track 3	Benefits of post-transplant maintenance therapy	Track 10	Clinical utility of minimal residual disease (MRD) assessment in MM
Track 4	RVd consolidation and maintenance therapy for high-risk MM	Track 11	Case: A 59-year-old man with R/R MM and high-risk cytogenetics receives pomalidomide/daratumumab/dexamethasone
Track 5	Selecting among options for maintenance therapy	Track 12	Triplet therapy options for R/R disease
Track 6	Ixazomib-associated gastrointestinal toxicity	Track 13	Advantages of subcutaneous daratumumab
Track 7	Carfilzomib- versus bortezomib-based induction therapy	Track 14	Case: A 41-year-old woman presents with lambda light chain MM and bone marrow amyloidosis
		Track 15	Case: A 72-year-old man develops myelodysplastic syndrome after receiving post-transplant consolidation RVd and subsequently receives multiple lines of therapy for R/R disease

Interview with Dr Holstein (continued)

Track 16	Case: A 52-year-old woman initially diagnosed with smoldering MM presents with widespread bone disease	Track 19	Activity and tolerability of panobinostat in combination with carfilzomib/dexamethasone
Track 17	Updated IMWG (International Myeloma Working Group) criteria on risk stratification in MM	Track 20	Status of the Phase III KEYNOTE-183 and 185 trials: Pembrolizumab in combination with an immunomodulatory drug (IMiD) and dexamethasone
Track 18	Management of high-risk R/R MM that progresses rapidly on triplet therapy		

Interview with Paul G Richardson, MD

Tracks 1-25

Track 1	Recent therapeutic advances in MM	Track 14	Recent FDA approval of ibrutinib for chronic graft-versus-host disease
Track 2	Changing landscape of smoldering MM	Track 15	Potential of ibrutinib-based combinations for R/R MM
Track 3	Impact of cytogenetics on treatment choice	Track 16	Activity and side effects of CAR T-cell therapy in MM
Track 4	Bisphosphonate therapy in MM	Track 17	Promising therapeutic vaccines and antibodies for MM
Track 5	Role of histone deacetylase inhibitors in the treatment of MM	Track 18	Effectiveness and tolerability of the investigational proteasome inhibitor marizomib for central nervous system MM and malignant glioblastoma
Track 6	Correlation between CD38 expression levels and response to daratumumab	Track 19	Activity of melflufen, a peptidase-activated derivative of melphalan
Track 7	Optimizing the frequency and convenience of daratumumab administration	Track 20	IFM/DFCI 2009 Phase III trial results: RVd with or without ASCT for newly diagnosed MM
Track 8	Clinical experience with the investigational anti-CD38 monoclonal antibody isatuximab	Track 21	Case: A 70-year-old woman with high-risk MM and bone metastases receives daratumumab on a clinical trial after disease progression on multiple lines of therapy
Track 9	ICARIA-MM: An ongoing Phase III trial of pomalidomide and dexamethasone with or without isatuximab for R/R MM	Track 22	Case: A 61-year-old man with R/R MM receives ixazomib/lenalidomide/dexamethasone on a clinical trial
Track 10	Sequencing of therapies to achieve optimal outcomes in MM	Track 23	Case: A 64-year-old man with R/R MM and bone metastases harbors a 13q deletion abnormality
Track 11	Recognition and management of immune paresis	Track 24	Venetoclax for MM with or without t(11;14)
Track 12	Potential utility of elotuzumab in combination with lenalidomide in the maintenance setting	Track 25	Comparison of proteasome inhibitors for MM
Track 13	Toxicities associated with long-term single-agent lenalidomide maintenance therapy; management of lenalidomide-associated diarrhea		

Interview with Shaji K Kumar, MD

Tracks 1-26

Track 1	Improving outcomes for newly diagnosed amyloid light chain (AL) amyloidosis	Track 13	Advances in the treatment of R/R MM
Track 2	Investigational strategies for the treatment of AL amyloidosis; factors predicting organ response	Track 14	Principles guiding the sequencing of therapies for R/R MM
Track 3	Presentation and treatment of localized AL amyloidosis	Track 15	Treatment approach for lenalidomide-refractory relapsed MM
Track 4	Advances in the treatment of WM	Track 16	Incorporating ixazomib into the treatment algorithm for R/R MM
Track 5	Incorporation of ibrutinib into the treatment of WM	Track 17	ELOQUENT-2 Phase III trial of elotuzumab/lenalidomide and dexamethasone for R/R MM
Track 6	Guiding principles in the treatment of WM	Track 18	Evaluation of elotuzumab as part of induction and/or maintenance therapy
Track 7	Diagnosis and management of smoldering MM	Track 19	Therapeutic options for patients with disease that is not refractory to lenalidomide or bortezomib or both
Track 8	ASCENT Phase II study of carfilzomib/lenalidomide/ dexamethasone and daratumumab with or without ASCT for patients with high-risk smoldering MM	Track 20	Choice of proteasome inhibitor in the relapsed setting
Track 9	MRD testing in MM and its application in clinical trials and practice	Track 22	Options for patients with “double-refractory” MM
Track 10	MRD negativity after induction therapy and prediction of benefit from transplant	Track 23	Venetoclax for patients with heavily pretreated t(11;14) MM
Track 11	Importance of risk stratification in the selection of initial therapy for MM	Track 24	PCR-based assay for Bcl-2 and association with response to venetoclax
Track 12	Carfilzomib-associated cardiac dysfunction and dyspnea	Track 25	BCMA CAR T-cell therapy in MM
		Track 26	Combining immune checkpoint inhibitors with IMiDs
		Track 26	ASCT for relapsed MM

Video Program

View the corresponding video interviews with (from left) Drs Stadtmauer, Holstein, Richardson and Kumar by Dr Love at www.ResearchToPractice.com/MMUpdate118/Video



QUESTIONS (PLEASE CIRCLE ANSWER):

1. Because it is universally expressed on malignant plasma cells, which of the following antigens is an attractive target for CAR T-cell-directed therapy in MM?*
 - a. BCMA
 - b. CD19
 - c. CD33

2. A study presented at the 2016 ASH Annual Meeting demonstrated that daratumumab _____ safely be administered via subcutaneous injection.*
 - a. Could
 - b. Could not

3. Which of the following proteasome inhibitors has demonstrated activity in myeloma affecting the central nervous system?*
 - a. Bortezomib
 - b. Ixazomib
 - c. Carfilzomib
 - d. Marizomib

4. Ibrutinib is FDA approved for the treatment of _____.
 - a. Chronic graft-versus-host disease
 - b. WM
 - c. Both a and b
 - d. Neither a nor b

5. Infusion-related reactions associated with the administration of daratumumab tend to persist over the course of the patient's treatment.
 - a. True
 - b. False

6. Which of the following side effects is NOT associated with ixazomib therapy?
 - a. Arthralgia
 - b. Gastrointestinal toxicity
 - c. Peripheral neuropathy
 - d. All of the above

7. Sensitivity to venetoclax for MM has primarily been observed in patients with t(11;14) disease.*
 - a. True
 - b. False

8. The Phase III randomized ELOQUENT-2 study evaluating elotuzumab/lenalidomide/dexamethasone versus lenalidomide/dexamethasone _____ a significant improvement in progression-free survival with the addition of elotuzumab for patients with R/R MM.
 - a. Demonstrated
 - b. Did not demonstrate

9. Which of the following categories reflects the mechanism of action of isatuximab?*
 - a. Anti-CD38 monoclonal antibody
 - b. Anti-PD-1/PD-L1 antibody
 - c. IMiD
 - d. Proteasome inhibitor

10. Recent data presented from the Myeloma X and XI trials demonstrated that lenalidomide maintenance therapy improved outcomes for transplant-eligible patients with _____.
 - a. High-risk MM
 - b. Standard-risk MM
 - c. Both a and b
 - d. Neither a nor b

* The content of this question refers to drugs or the use of drugs that have not yet received FDA approval.

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Multiple Myeloma Update — Volume 1, Issue 1

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal
	BEFORE			AFTER
Biologic rationale for and efficacy and tolerability of CAR T cells targeting BCMA in MM	4	3	2	1
Activity and ongoing investigation of the anti-CD38 antibody isatuximab for R/R MM	4	3	2	1
Biologic rationales for the effectiveness of venetoclax in patients with MM and for the lower risk of associated tumor lysis syndrome compared to chronic lymphocytic leukemia	4	3	2	1
Safety and effectiveness of subcutaneous daratumumab	4	3	2	1
Emerging research data with and nonresearch role, if any, of ixazomib as a component of induction and maintenance therapy	4	3	2	1

Practice Setting:

- Academic center/medical school
 Community cancer center/hospital
 Group practice
 Solo practice
 Government (eg, VA)
 Other (please specify).....

Approximately how many new patients with multiple myeloma do you see per year? patients

Was the activity evidence based, fair, balanced and free from commercial bias?

- Yes No
 If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
 Create/revise protocols, policies and/or procedures
 Change the management and/or treatment of my patients
 Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

- Yes No
 If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Use patient and disease characteristics, including cytogenetic profile, to customize induction and maintenance therapeutic approaches in the transplant and nontransplant settings. 4 3 2 1 N/M N/A
- Consider available research data and other clinical factors in the best-practice selection, sequencing and combination of current and recently approved novel agents in the nonresearch care of patients with relapsed/refractory MM. 4 3 2 1 N/M N/A
- Design and implement a plan of care to recognize and manage side effects and toxicities associated with recently approved systemic therapies to support quality of life and continuation of treatment. 4 3 2 1 N/M N/A
- Develop an evidence-based algorithm for the use of stem cell transplantation, chemotherapy and/or novel targeted agents for the management of amyloidosis. 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Consider clinical and other patient-related factors in the sequence and selection of systemic therapy for WM requiring active treatment. 4 3 2 1 N/M N/A
- Develop risk-adapted treatment plans for patients with smoldering MM, considering the roles of observation and active treatment. 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

.....

Would you recommend this activity to a colleague?

Yes No

If no, please explain:

PART 2 — Please tell us about the faculty and editor for this educational activity									
		4 = Excellent		3 = Good		2 = Adequate		1 = Suboptimal	
Faculty		Knowledge of subject matter				Effectiveness as an educator			
Edward A Stadtmauer, MD		4	3	2	1	4	3	2	1
Sarah A Holstein, MD, PhD		4	3	2	1	4	3	2	1
Paul G Richardson, MD		4	3	2	1	4	3	2	1
Shaji K Kumar, MD		4	3	2	1	4	3	2	1
Editor		Knowledge of subject matter				Effectiveness as an educator			
Neil Love, MD		4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

.....

.....

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QID 1877

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This activity is supported by educational grants from AbbVie Inc, Celgene Corporation, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, and Takeda Oncology.

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Release date: February 1, 2018
Expiration date: February 1, 2019
Estimated time to complete: 4.5 hours