

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	Abstain	Absent
<p>MYEL-1 External request: Submission from Adaptive Biotechnologies to add the phrase “baseline characterization of myeloma clone to define tumor burden, assess presence of somatic hypermutation. And facilitate subsequent minimal residual disease (MRD) analysis” under the “Initial Diagnostic Workup” section.</p>	<p>Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines.</p> <p>See Submission for references.</p>	0	13	0	13
<p>MYEL-D (3 of 3) External request: Submission from Adaptive Biotechnologies to add additional context to footnote a (underlined): “...information on MRD after each treatment stage is recommended to <u>enable serial MRD assessments over time</u> (e.g. after induction, high-dose therapy/ASCT, consolidation, maintenance, and as medically indicated).”</p>	<p>Based on the discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines.</p> <p>See Submission for references.</p>	0	13	0	13
<p>MYEL-D (3 of 3) External request: Submission from Adaptive Biotechnologies to add additional context to footnote d to parallel footnote b related to NGF: “Bone marrow NGS should be done using a validated and standardized method. Standardized NGS MRD methods are available for clinical use in the US through academic institutions and through a CLIA, CAP, and ISO certified commercial laboratory (clonoSEQ®, Adaptive Biotechnologies). It is recommended that at least one million total nucleated cells be assessed. The NGS method employed should have a sensitivity of detection of at least 10-5 nucleated cells. Both fresh and archived samples may be analyzed.”</p>	<p>Based on the discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines due to the content on the page being licensed.</p> <p>See Submission for references.</p>	0	13	0	13

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<p>MYEL-E (1 of 3) and (2 of 3) Internal request: Institutional Review comment to consider the inclusion of cyclophosphamide/lenalidomide/dexamethasone under “Useful in Certain Circumstances” as primary therapy for Multiple Myeloma.</p>	<p>Based on the data in the noted reference and discussion, the panel consensus was to include cyclophosphamide/lenalidomide/dexamethasone as an option for Primary Therapy as “Useful in Certain Circumstances”. This is a category 2A recommendation.</p> <ul style="list-style-type: none"> Khan ML, Reeder CB, Kumar SK, et al. A comparison of lenalidomide/dexamethasone versus cyclophosphamide/lenalidomide/dexamethasone versus cyclophosphamide/bortezomib/dexamethasone in newly diagnosed multiple myeloma. Br J Haematol 2012; 156:326-33. 	13	0	0	13
<p>MYEL-E (1 of 3) External request: Submission from Celgene Corporation to include information of the combination of lenalidomide/carfilzomib/dexamethasone (KRd) for high-risk smoldering myeloma as induction therapy followed by autologous stem cell transplant (ASCT), KRd consolidation and lenalidomide/dexamethasone maintenance therapy.</p>	<p>Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines.</p> <p>See Submission for references.</p>	0	13	0	13
<p>MYEL-E (2 of 3) Internal request: Institutional Review comment to consider the inclusion of daratumumab/melphalan /bortezomib/prednisone regimen as an option for primary therapy for non-transplant candidates.</p> <p>External request: Submission from Janssen Biotech, Inc. to include daratumumab for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for high-dose chemotherapy with autologous stem cell transplant with a Category 1 evidence level rating for the following treatment option:</p>	<p>Based on a review of data and discussion, the panel consensus supported the inclusion of daratumumab in combination with bortezomib /melphalan/prednisone as a category 1, preferred option, for newly diagnosed multiple myeloma who are ineligible for high-dose chemotherapy with autologous stem cell transplant.</p> <ul style="list-style-type: none"> Mateos MV, Dimopoulos MA, Cavo M, et al. Daratumumab plus bortezomib, melphalan, and prednisone for untreated myeloma. N Engl J Med 2018;130:518-528. <p>See Submission for references.</p>	13	0	0	13

NCCN Guidelines for Multiple Myeloma V.1.2019 – Web teleconference on 05/18/18

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		YES	NO	Abstain	Absent
combination therapy with bortezomib/melphalan/prednisone.					
MYEL-E (2 of 3) External request: Submission from Takeda Pharmaceutical Company Limited to include ixazomib in combination with cyclophosphamide and dexamethasone as a suggested category 2A preferred regimen for therapy for previously treated multiple myeloma.	Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines due to insufficient available data. See Submission for references.	0	13	0	13
MYEL-E (2 of 3) External request: Submission from Takeda Pharmaceutical Company Limited to include ixazomib as a category 2A preferred regimen for maintenance therapy.	Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines. See Submission for references.	0	13	0	13
MYEL-E (2 of 3) External request: Submission from Takeda Pharmaceutical Company Limited to include ixazomib plus lenalidomide as a suggested category 2A preferred regimen for maintenance therapy.	Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines due to insufficient available data. See Submission for references.	0	13	0	13
MYEL-E (3 of 3) External request: Submission from Takeda Pharmaceutical Company Limited to include ixazomib in combination with cyclophosphamide and dexamethasone as a suggested category 2A preferred regimen for therapy for previously treated multiple myeloma.	Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines due to insufficient available data. See Submission for references.	0	13	0	13