

NCCN Guidelines for Multiple Myeloma V.1.2020 – Meeting on 05/23/19

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	Abstain	Absent
<p>MYEL-1</p> <p>External request: Submission from SkylineDx to consider including “SKY92 to assess prognostic risk” to “Initial Diagnostic Workup”</p>	<p>Based on a review of data and discussion, the panel consensus did not support the use of SKY92 to assess prognostic risk in the initial diagnostic workup of multiple myeloma due to insufficient available data.</p> <p>See Submission for references.</p>	0	15	0	13
<p>MYEL-1</p> <p>External request: Submission from Adaptive Biotechnologies Corporation to update the Initial Diagnostic Workup to include bone marrow for NGS-based analysis as part of the Initial Diagnostic Workup.</p>	<p>Based on a review of data and discussion, the panel consensus was to list NGS panel on bone marrow as “useful in Certain Circumstances” for initial diagnostic workup See submission for references.</p>	15	0	0	13
<p>MYEL-2</p> <p>External request: Submission from Adaptive Biotechnologies Corporation to update the Follow-up/Surveillance section to include bone marrow NGS-based analysis</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	15	0	13
<p>MYEL-3</p> <p>External request: Submission from Adaptive Biotechnologies Corporation to update the Follow-up/Surveillance section for solitary plasmacytoma to include NGS-based analysis.</p>	<p>Based on a review of data and discussion, the panel consensus supported the inclusion of NGS-panel as an option as clinically indicated during “Follow-Up/Surveillance” of smoldering multiple myeloma (asymptomatic).</p> <p>See Submission for references.</p>	15	0	0	13
<p>MYEL-4</p> <p>External request: Submission from Adaptive Biotechnologies Corporation to update the Follow-up/Surveillance section of symptomatic multiple myeloma to include measuring disease response by flow cytometry and/or NGS.</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>	0	15	0	13

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<p>MYEL-4</p> <p>External request: Submission from SkylineDx to replace, “Bone marrow aspirate and biopsy at relapse with FISH as clinically indicated” with “Bone marrow aspirate and biopsy at relapse with SKY92 <i>and/or</i> FISH as clinically indicated”</p>	Based on a review of data and discussion, the panel consensus did not support the addition of these specific recommendations into the Guidelines.	0	15	0	13
<p>MYEL-C</p> <p>External request: Submission from Adaptive Biotechnologies Corporation to update text to include a footnote that specifies that the methods of clonal assessments “<i>Clonal assessments can be performed by immunohistochemistry, flow cytometry, or NGS</i>”</p>	The panel consensus did not support this addition to the page with definitions for smoldering and multiple myeloma.	0	15	0	13
<p>MYEL-E (pages 2 and 3)</p> <p>External request: Submission from Adaptive Biotechnologies Corporation Page 2: Suggested modifying the criteria for Progressive Disease to read: <i>In patients without measurable serum and urine M-protein levels and without measurable involved FLC levels</i>, Bone marrow plasma-cell percentage, <i>measured by NGS or flow cytometry</i>, irrespective of baseline status (absolute increase must be ≥10%);</p> <p>Page 3: update footnote “d” to provide information on NGS consistent with that provided for flow cytometry.</p>	The panel consensus did not support the addition of these specific recommendations into the Guidelines as the tables on MYEL-D have been reprinted with permission from Elsevier.	0	15	0	13

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<p>MYEL-F</p> <p>External request: Submission from Janssen Biotech to include daratumumab in combination with cyclophosphamide, bortezomib, and dexamethasone (D-CyBorD) for newly diagnosed and relapsed multiple myeloma that are either transplant eligible or ineligible with a Category 2A evidence level rating.</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 and wait for additional data before inclusion into the guidelines.</p>	0	15	0	13
<p>MYEL-F (1 of 3)</p> <p>Internal request: Comment to consider changing the regimen bortezomib/doxorubicin/dexamethasone from a category 1 to a category 2A designation.</p>	<p>Based on a review of data and discussion, the panel consensus supported the changing the category of evidence of bortezomib/doxorubicin/dexamethasone from category 1 to 2A for transplant candidates and moving it from list of “Other Recommended” regimens to “Useful in Certain Circumstances”</p>	15	0	0	13
<p>MYEL-F (1 of 3)</p> <p>Internal request: Comment to consider adding carfilzomib/cyclophosphamide/dexamethasone as a primary therapy option.</p>	<p>Based on a review of data and discussion, the panel consensus was to add carfilzomib/cyclophosphamide/dexamethasone as a primary therapy option (Category 2A) that is Useful in Certain Circumstances for transplant candidates with a footnote saying that it is a “Treatment option for patients with renal insufficiency and/or peripheral neuropathy.”</p> <p>Boccia RV, Bessudo A, Agajanian R, et al. A Multicenter, Open-Label, Phase 1b Study of Carfilzomib, Cyclophosphamide, and Dexamethasone in Newly Diagnosed Multiple Myeloma Patients (CHAMPION-2). Clin Lymphoma Myeloma Leuk. 2017;17:433-437.</p>	15	0	0	13
<p>MYEL-F (1 of 3)</p> <p>External request: Submission from Takeda Oncology to include ixazomib in combination with cyclophosphamide-dexamethasone (ICd) as a Preferred Primary Therapy.</p>	<p>Based on a review of data and discussion, the panel consensus was to add ixazomib in combination with cyclophosphamide and dexamethasone (ICd) as a primary therapy option (Category 2A) that is Useful in Certain Circumstances for transplant candidates with a footnote saying that it is a “Treatment option for patients with renal insufficiency and/or peripheral neuropathy.”</p> <p>See Submission for references.</p>	15	0	0	13
<p>MYEL-F (1 of 3)</p> <p>Internal request: Comment to consider removing bortezomib/dexamethasone from the</p>	<p>Based on the discussion, the panel consensus was to remove bortezomib/dexamethasone as an option for primary therapy for transplant candidates with a footnote stating “Triplet regimens should be used as the standard therapy for patients with multiple myeloma; however,</p>	8	7	0	13

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guidelines as a primary therapy for transplant candidates.	patients who could not be considered for initiation of treatment with a 3-drug regimen can be started with a 2-drug regimen, with a third drug added once performance status improves.”				
MYEL-F (1 of 3) Internal request: Comment to consider removing lenalidomide/dexamethasone from the guidelines as a primary therapy for transplant candidates.	Based on the discussion, the panel consensus was to remove lenalidomide/dexamethasone as an option for primary therapy for transplant candidates with a footnote stating “Triplet regimens should be used as the standard therapy for patients with multiple myeloma; however, patients who could not be considered for initiation of treatment with a 3-drug regimen can be started with a 2-drug regimen, with a third drug added once performance status improves.”	8	7	0	13
MYEL-F (1 of 3) Internal request: Comment to consider the inclusion of ixazomib as a category 1 recommendation for maintenance therapy for transplant candidates. External request: Submission from Takeda Oncology to include ixazomib as a suggested Category 1 Preferred Regimen for Maintenance Therapy.	Based on a review of data and discussion, the panel consensus was to add ixazomib as an Other Recommended Regimen for maintenance therapy for transplant candidates. This is supported by high-level evidence and is therefore a category 1 recommendation See Submission for references.	15	0	0	13
MYEL-F (1 of 3 and 2 of 3) Internal request: Comment to add bortezomib/lenalidomide as Useful in Certain Circumstances for maintenance therapy for transplant and non-transplant candidates.	Based on the discussion, the panel consensus was to add bortezomib/lenalidomide as Useful in Certain Circumstances for maintenance treatment for transplant and non-transplant candidates. This is a category 2A recommendation.	14	1	0	13
MYEL-F (2 of 3)	The panel consensus was that adding dosing schedules was outside of the scope of the Guidelines recommendations.	0	15	0	13

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<p>External request: Submission from Janssen Biotech, Inc. to include dosage and administration options [the recently approved option to split the first prescribed daratumumab 16 mg/kg dose at Week 1 over two consecutive days (8 mg/kg on Day 1 and Day 2, respectively)] as a footnote to the relevant “Myeloma Therapy” tables.</p>					
<p>MYEL-F (2 of 3)</p> <p>External request: Submission from Janssen Biotech, Inc. to include daratumumab in combination with lenalidomide and dexamethasone (D-Rd) for the treatment of patients with newly diagnosed multiple myeloma who are transplant ineligible with a Category 1 evidence level rating.</p> <p>External request: Submission from Celgene to consider the inclusion of lenalidomide in combination with daratumumab and dexamethasone (D-Rd) as a Category 1, Preferred Regimen recommendation for primary therapy in non-transplant candidates.</p> <p>Internal request: Comment to consider adding daratumumab/lenalidomide/dexamethasone based on the MAIA trial.</p>	<p>Based on a review of data and discussion, the panel consensus was to add daratumumab/lenalidomide/dexamethasone (D-Rd) as a Preferred primary therapy option for non-transplant candidates. It is supported by high-level evidence and therefore a category 1 recommendation.</p> <p>See Submissions for references.</p>	15	0	0	13
<p>MYEL-F (3 of 3)</p> <p>External request: Submission from Janssen Biotech, Inc. to include daratumumab in combination with carfilzomib and dexamethasone (D-Kd) for the treatment of patients with</p>	<p>Based on a review of data and discussion, the panel consensus supported adding daratumumab in combination with carfilzomib and dexamethasone (D-Kd) as an Other Recommended therapy option for previously treated multiple myeloma. This is a category 2A recommendation.</p> <p>See Submission for references.</p>	15	0	0	13

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relapsed/refractory multiple myeloma with a category 2A evidence level rating.					
<p>MYEL-F (3 of 3)</p> <p>External request: Submission from Takeda Oncology to include ixazomib in combination with cyclophosphamide-dexamethasone (ICd) as a Therapy for Previously Treated Multiple Myeloma.</p>	<p>Based on a review of data and discussion, the panel consensus supported adding ixazomib in combination with cyclophosphamide and dexamethasone (ICd) as therapy for previously treated multiple myeloma. This is a category 2A recommendation.</p> <p>See Submission for references.</p>	15	0	0	13
<p>MYEL-F (3 of 3)</p> <p>Internal request: Consider adding carfilzomib/ cyclophosphamide/thalidomide/ dexamethasone.</p>	<p>Based on a review of data and discussion, the panel consensus supported adding carfilzomib/cyclophosphamide/thalidomide /dexamethasone as a therapy option that is Useful in Certain Circumstances for previously treated multiple myeloma. This is a category 2A recommendation.</p> <p>Mikhael, JR, Reeder CB, Libby III, EN, et al. A Phase I/II Trial Of Cyclophosphamide, Carfilzomib, Thalidomide and Dexamethasone (CYCLONE) In Patients With Newly Diagnosed Multiple Myeloma: Final Results Of MTD Expansion Cohort. Blood 2013;122:3179.</p>	15	0	0	13
<p>MYEL-F (3 of 3)</p> <p>External request: Submission from Celgene to consider pomalidomide in combination with bortezomib and dexamethasone (PVd) as a Category 1, Preferred Regimen recommendation for previously treated multiple myeloma.</p>	<p>Based on a review of data and discussion, the panel consensus was that pomalidomide/bortezomib/dexamethasone is supported by high-level evidence and will be listed as a category 1 recommendation.</p> <p>See Submission for references.</p>	15	0	0	13