

NCCN Guidelines for Myeloid Growth Factors V.1.2016 – Web teleconference on 01/07/2016

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p><b>MGF-1</b> Internal request: Institutional Review comment to consider the removal of sargramostim (GM-CSF) from the list of recommended myeloid growth factors for prophylactic use.</p>	<p>Based on limited data, panel consensus supported the removal of sargramostim from the recommended options for prophylactic use.</p>	15	0	0	11
<p><b>MGF-A (1 of 4)</b> External request: Submission from Hospital Universitario de Getafe to consider moving docetaxel + trastuzumab to the list of regimens with an intermediate risk of febrile neutropenia from the list of high risk regimens.</p>	<p>Based on the data in the noted references and discussion, panel consensus was not to remove docetaxel + trastuzumab from the list of regimens with a high risk for febrile neutropenia. It is noted that the regimens listed in the guideline are meant to serve as examples only and the exact risk will depend on the agent, dose and treatment setting.</p> <p>See submission for references.</p>	0	15	0	11
<p><b>MGF-A (1 of 4)</b> External request: Submission from Hospital Universitario de Getafe to review the recommendation for G-CSF support with paclitaxel administration during the use of dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel) (adjuvant).</p>	<p>Based on the data in the noted reference and discussion, panel consensus was not to remove dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel) (adjuvant) or the footnote that states, "In general, dose-dense regimens require growth factor support for chemotherapy administration."</p> <p>Reference: 1. Citron ML, Berry DA, Cirincione C, et al. Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: first report of Intergroup Trial C9741/Cancer and Leukemia Group B Trial 9741. J Clin Oncol. 2003 Apr 15;21(8):1431-9.</p>	0	15	0	11
<p><b>MGF-A (2 of 4)</b> External request: Submission from Hospital Universitario de Getafe to consider additional data for the febrile neutropenia risk of docetaxel every 21 days.</p>	<p>Based on the data in the noted references, the panel agreed that there are additional references to further support the inclusion of docetaxel every 21 days on the list of regimens with an intermediate risk for febrile neutropenia. This regimen was already listed as intermediate risk. Therefore, no change has been made.</p> <p>See submission for references.</p>	15	0	0	11

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<p><b>MGF-A (2 of 4)</b> External request: Submission from Hospital Universitario de Getafe to consider additional data for the febrile neutropenia risk of paclitaxel every 21 days.</p>	<p>Based on the data in the noted references and discussion, panel consensus was not to remove paclitaxel every 21 days from the list of regimens with an intermediate risk for febrile neutropenia. Based on clinical experience, the panel felt that there is insufficient evidence to consider the regimen low risk, and the exact risk may be dependent on dose intensity and other factors.  See submission for references.</p>	0	15	0	11
<p><b>MGF-B (1 of 2)</b> External request: Submission from Amgen, Inc. to consider data for inclusion of the pegfilgrastim delivery kit/on body injector as an alternative delivery option for growth factor support in patients receiving myelosuppressive chemotherapy with a clinically significant risk of febrile neutropenia (FN).</p>	<p>Based on panel consensus, no additional changes have been made regarding the pegfilgrastim delivery kit/on body injector in version 1.2016 of the NCCN Guidelines for Myeloid Growth Factors. The following footnote was added in version 1.2015 based on data in the noted reference:</p> <ul style="list-style-type: none"> <li>• “An FDA-approved delivery device is available that can be applied the same day as chemotherapy and set to deliver the full dose of pegfilgrastim the following day. This may be an option for patients who cannot return to the clinic for next-day administration of pegfilgrastim.”</li> </ul> <p>Reference:</p> <ol style="list-style-type: none"> <li>1. Yang BB, Morrow PK, Wu X, et al. Comparison of pharmacokinetics and safety of pegfilgrastim administered by two delivery methods: on-body injector and manual injection with a prefilled syringe. <i>Cancer Chemother Pharmacol</i> 2015;75:1199-1206.</li> </ol>	0	15	0	11
<p><b>MGF-D (3 of 3)</b> External request: Submission from Sanofi U.S. requesting an update to the listed plerixafor dose and the inclusion of references for plerixafor registration trials.</p>	<p>Based on the noted reference and panel consensus, the plerixafor dose was changed to: “0.24 mg/kg/d for patients weighing &gt;83 kg; 20 mg (fixed dose), or 0.24 mg/kg/d for patients weighing ≤83 kg, maximum 4 doses (if creatinine clearance &gt;50 mL/min, maximum dose 40 mg/d).” References for plerixafor registration trials have also been added.</p> <p>References:</p> <ol style="list-style-type: none"> <li>1. Mozobil [package insert]. Cambridge, MA: Genzyme; 2015.</li> <li>2. DiPersio JF, Micallef IN, Stiff PJ, et al. Phase III prospective randomized double-blind placebo-controlled trial of plerixafor plus granulocyte colony-stimulating factor compared with placebo plus granulocyte colony-stimulating factor for autologous stem-cell mobilization and transplantation for patients with non-Hodgkin's lymphoma. <i>J Clin Oncol</i> 2009;27:4767-4773.</li> <li>3. DiPersio JF, Stadtmauer EA, Nademanee A, et al. Plerixafor and G-CSF versus placebo and G-CSF to mobilize hematopoietic stem cells for autologous stem cell transplantation in patients with multiple myeloma. <i>Blood</i> 2009;113:5720-5726.</li> </ol>	15	0	0	11
<p><b>MGF-D (1 of 3)</b> External request: Submission from Sanofi U.S. requesting that the current wording of “Plerixafor is indicated for...” be changed to, “NCCN recommends plerixafor for...”</p>	<p>Based on panel consensus the requested wording change was not made.</p>	0	15	0	11