

Sep 10<sup>th</sup>, 2015

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NCCN Guidelines Panel: Antiemesis

On behalf of Merck & Co., Inc., I respectfully request the NCCN Antiemesis Panel to review the enclosed information for EMEND (aprepitant) capsules on the NCCN Guidelines for Antiemesis.

Specific changes requested:

In sections AE-2 and AE-3, we respectfully request to expand the recommendation for EMEND (aprepitant) capsules to include patients 12 years of age and older and patients less than 12 years who weigh at least 30 kg for the prevention of acute and delayed nausea and vomiting associated with high emetic risk chemotherapy (AE-2) as well as for the prevention of acute and delayed nausea and vomiting associated with moderate emetic risk chemotherapy (AE-3).

FDA Clearance:

FDA has recently approved EMEND (aprepitant) capsules, in combination with other antiemetic agents, in patients 12 years of age and older and patients less than 12 years who weigh at least 30 kg for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)

Rationale:

The FDA approval of this expanded indication for EMEND (aprepitant) was based on results from a randomized, double-blind, active-comparator-controlled clinical study that assessed EMEND in combination with ondansetron (EMEND regimen) compared to ondansetron alone (control regimen) for the prevention of CINV in patients 12 to 17 years of age and patients less than 12 years of age who weighed at least 30 kg receiving HEC or MEC.

The following resources are submitted in support of this proposed change:

1. EMEND (aprepitant) capsules, for oral use, prescribing information. Merck & Co., Inc.



emend\_pi.pdf

2. Kang et al., Aprepitant for the prevention of chemotherapy-induced nausea and vomiting in children: a randomised, double-blind, phase 3 trial. *Lancet Oncol* 2015; 16: 385–94.



Kang et al Lancet  
Oncol 2015.pdf

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Craig Granowitz', written in a cursive style.

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