NCCN Guidelines Panel: Antiemesis

On behalf of Merck & Co., Inc., I respectfully request the NCCN Antiemesis Panel to review the enclosed information for EMEND (fosaprepitant dimeglumine) for Injection, for intravenous use, in reference to NCCN Guidelines for Antiemesis.

Specific changes requested:

In section AE-3 (option A), we respectfully request that EMEND (fosaprepitant dimeglumine) for Injection become a required drug as part of the triple regimen on Day 1 (not as optional: “AND” instead of “WITH/WITHOUT”) for the prevention of acute and delayed emesis in patients receiving moderately emetogenic chemotherapy and consider updating to category 1.

FDA approval:

The indication for EMEND (fosaprepitant dimeglumine) for Injection in adults for use in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic chemotherapy (MEC) is currently under review by FDA. Consistent with current guideline-based MEC definitions, patients receiving highly emetogenic chemotherapy regimens, including anthracycline and cyclophosphamide (AC), were excluded from this study.

Rationale:

An article published in Annals of Oncology (Advance Access published on October 8, 2015) reported results from a randomized, double-blind phase III study which has demonstrated that single-dose fosaprepitant added to a 5-HT3 receptor antagonist and dexamethasone was well tolerated and demonstrated superior control of chemotherapy-induced nausea and vomiting (CINV) versus control regimen in patients receiving non-anthracycline and cyclophosphamide (AC)-based moderately emetogenic chemotherapy (MEC) regimen.

The following resources are submitted to assist the committee with their review:

1. EMEND (fosaprepitant dimeglumine) for Injection prescribing information. Merck & Co., Inc.


[Ann Oncol 2015 - Early Online - Oct 8, 2015]
Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

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