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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 (fosaprepitant dimeglumine) for Injection, for intravenous use, in reference to NCCN Guidelines for Antiemesis V2.2016.

Specific changes requested:

In section AE-6 (option A), we respectfully request that EMEND (fosaprepitant dimeglumine) for Injection be updated to category 1 for moderately emetogenic chemotherapy.

FDA approval:

EMEND for injection is indicated in adults, in combination with other antiemetic agents, for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).[1]

Rationale:

An article published in Annals of Oncology (October 8, 2015) reported results from a randomized, double-blind phase III study (Protocol 031), which demonstrated that the single day fosaprepitant regimen was well tolerated and provided superior control of chemotherapy-induced nausea and vomiting (CINV) versus a standard 3-day control regimen in patients receiving non–anthracycline and cyclophosphamide (AC)-based moderately emetogenic chemotherapy (MEC) regimen. This was the first large, global, randomized, controlled superiority trial to prospectively evaluate treatment with a single-dose IV NK_1 receptor antagonist in a well-characterized heterogeneous MEC population and multiple tumor types, which included 1000 patients in the intent-to treat population.[2]

At ESMO 2016 in Copenhagen (October 7-11), an Oral Presentation (October 8, 2016) reported results from an ad-hoc analysis exploring the heterogeneity of this phase III MEC study (Protocol 031). These results further support the primary findings that single-day fosaprepitant regimen is effective for CINV prevention in patients receiving non-AC MEC with or without carboplatin and in both single-day and multiple-day chemotherapy regimens, corroborating the strength of evidence and supporting fosaprepitant as category 1.[3]

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

1. EMEND (fosaprepitant dimeglumine) for Injection prescribing information. Merck & Co., Inc.
2. Weinstein C *et al*. Single-dose fosaprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with moderately emetogenic chemotherapy: results of a randomized, double-blind phase III trial. *Annals of Oncology 27: 172–178, 2016*

3. Weinstein C *et al*. Exploration of the heterogeneity of moderately emetogenic chemotherapy on response to fosaprepitant in a randomized phase III trial. ESMO 2016 Oral Presentation/abstract 1435O. *Annals of Oncology: volume 27, supplement 6, October 2016*

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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