AMERICAN SOCIETY OF HEMATOLOGY
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Louis Jacques, M.D.
Director
Coverage and Analysis Group Office of Clinical Standards & Quality (OCSQ)
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: National Coverage Determination (NCD) Concerning Aprepitant for Chemotherapy-Induced Emesis (110.18)

Dear Dr. Jacques,

The American Society of Hematology (ASH) supports the NCCN in its request for a reconsideration of the April 4, 2005 National Coverage Determination (NCD) concerning Aprepitant for Chemotherapy-Induced Emesis (110.18). ASH represents over 14,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. ASH Members include hematologists and hematologist/oncologists who regularly render services to Medicare beneficiaries.

Aprepitant is currently covered under the Oral Antiemetic Drug benefit category. Since the Aprepitant NCD became effective in 2005, the manufacturer received expanded FDA approval for aprepitant use in the prevention of nausea and vomiting associated with moderately emetogenic chemotherapy (MEC). The combination of dexamethasone and palonosetron has been shown to be superior to dexamethasone plus dolasetron, granisetron or ondansetron in preventing nausea and vomiting associated with MEC or with highly emetogenic chemotherapy (HEC). An update of the NCD should be undertaken as emetogenic classifications have been revised to include new anticancer chemotherapy agents and evidence based guidelines have also been updated and published.

This NCD is of particular interest to practicing hematologist/oncologists as these moderately emetogenic chemotherapy drugs are widely used in the treatment of hematologic malignancies, with both curative and palliative intent, including acute and chronic leukemias (myeloid and lymphoid), Hodgkin and non-Hodgkin lymphomas, and myelodysplastic syndrome. Effective anti-emetic therapy is necessary to permit patients to tolerate these potentially life-saving treatments.

In its February 14, 2012 letter requesting the aprepitant NCD reconsideration, NCCN made the following request, which ASH fully supports:

- Expand the use of aprepitant in combination with dexamethasone and a 5-HT3 antagonist to include the patient population receiving anticancer chemotherapeutic agents currently considered moderately emetogenic. MEC agents classified using the Hesketh emetogenic classification system or listed in at least two published evidence-based guidelines include alemtuzumab, azacitidine, bendamustine, carboplatin, clofarabine, cyclophosphamide, cytarabine, daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, irinotecan, and oxaliplatin.

- Expand coverage of aprepitant in combination with dexamethasone and a 5-HT3 antagonist for use with future chemotherapy agents classified as highly emetogenic or moderately emetogenic using the Hesketh emetogenic classification system or listed in at least two published evidence-based guidelines.

- Expand the current NCD acceptable list of 5-HT3 antagonists for use with aprepitant and dexamethasone to include palonosetron.

ASH also supports NCCN's specific requests for the Aprepitant NCD Reconsideration:

- Allow use of therapeutically equivalent doses of any available 5-HT3 antagonist, dexamethasone, and aprepitant formulations (oral, transdermal, intravenous).

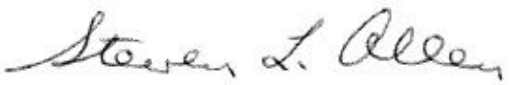
- Allow for oral dexamethasone taken by the patient at home during the time period of chemotherapy administration.

- Allow for the intravenous administration of dexamethasone in place of oral dexamethasone.

- Allow for aprepitant in combination with 5-HT3 antagonists in patients shown to be dexamethasone (corticosteroid) intolerant or if the physician wishes to avoid dexamethasone (corticosteroids) because the patient is a diabetic.

ASH appreciates the opportunity to offer input on this important Medicare coverage policy. Please contact ASH Government Relations and Practice Manager Stephanie Kaplan (*skaplan@hematology.org* or 202-776-0544) with any questions or for additional information.

Sincerely,



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