

Date: June 15, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D. Chairman DRC

At its 06/15/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of newer antiemetic agents in adults and children.

Specifically considered were

Newer antiemetics under consideration (equipotent doses assumed)

Aprepitant (Emend) [oral]

Dolasetron (Anzemet) [oral, injectable]

Granisetron (Kytril) [oral, injectable]

Ondansetron (Zofran) [tablet, orally disintegrating tablet, injectable]

Palonosetron (Aloxi) [injectable]

Indications under consideration in adults and children

Nausea, vomiting or retching in children and adults

With the understanding that equipotent doses of each drug are used, the Committee reached the following conclusions based upon its perception of the bulk of the best available evidence.

1. The Committee elected not to discuss aprepitant at this time due to insufficient evidence. However, they felt that it should be available via the Prior Authorization Process.
2. None of the captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for use in adults and children with the aforementioned problems.
3. There is insufficient evidence to conclude that any of the captioned agents is superior in efficacy to the others in children or adults with the aforementioned problems. However, at least one oral and one injectable formulation should be available.

4. There is insufficient evidence to conclude that any of the remaining agents differ to a significant degree either qualitatively or quantitatively in adverse effects.

5. None of the captioned drugs have been associated with significantly fewer adverse events on the basis of gender, race, pregnancy, co-morbidities or concomitant use of other medications.

6. Ondansetron should be available for children and for pregnant patients.

Henry F. Simmons, Jr.

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