

Date: January 17, 2008

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 01/17/09 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of various proton pump inhibitors and received public input on medications for neuropathic pain.

Indications under consideration

Gastroesophageal reflux disease [GERD], peptic ulcer disease [PUD], NSAID-induced ulcer in adults and children

Agents under consideration

Esomeprazole [Nexium]

Lansoprazole [Prevacid]

Omeprazole [Prilosec]

Omeprazole/sodium bicarbonate [Zegerid]

Pantoprazole [Protonix]

Rabeprazole [Aciphex]

Discussion

After reviewing the conclusions reached at the DRC meeting of 05/17/07 concerning PPIs and its current understanding of the bulk of the best available evidence regarding equivalent doses of the captioned agents for the specified indications, the Committee unanimously decided to leave its recommendations to DCC and DHS unchanged. They follow.

There is insufficient evidence at this time to consider Zegerid as a separate agent.

There is not enough pediatric data at this time to consider treatment in children with the same level of confidence that exists for adults.

None of the agents differ in comparative safety or occurrence of clinically significant adverse events to the degree that one or more should be stricken from further consideration.

The five agents do not differ to a clinically significant degree in their ability to manage symptoms of GERD in most adults.

The five agents do not differ from a clinical standpoint in their ability to manage peptic ulcers in adults.

The five agents do not differ from a clinical standpoint in their ability to manage NSAID-induced ulcers in adults.

The five agents do not differ among adult subgroups based upon demographics, other medications, or comorbidities in terms effectiveness or number of adverse effects.

Solutabs should be available for patients with feeding tubes and for those who cannot swallow tablets or capsules.

Respectfully submitted,

Henry F. Simmons, Jr., MD., Ph.D.
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