PHARMACY BENEFITS MANAGEMENT

STRATEGIC HEALTHCARE GROUP

CRITERIA FOR USE OF LANSOPRAZOLE TWICE DAILY DOSING

Lansoprazole is a proton pump inhibitor (PPI) which has proven efficacy for the treatment of gastric and duodenal ulcers, symptomatic gastroesophageal reflux disease (GERD) and severe erosive esophagitis. Since the VA wide conversion of omeprazole to lansoprazole, medical centers have utilized various conversion regimens, the most widespread of which was omeprazole 20mg to lansoprazole 15mg, and omeprazole 40mg to lansoprazole 30mg.

Individual patient response, however, may vary and deviate from the expected dose response. Such patients require further intervention through reinforcement of diet and lifestyle modifications, as well as dose titration or substitution of PPI therapy. The following guideline specifies situations wherein deviation from the usual recommended dose is indicated and provides treatment alternatives for patients who continue to experience GERD symptoms while on lansoprazole 30mg/day. The recommendations within this guideline are based on the assumption that PPI therapy has been initiated only after failure of an adequate trial of high-dose H2-receptor antagonist, and in conjunction with continuous reinforcement of diet and lifestyle modification.

Lansoprazole 30mg BID (60mg/day) is appropriate in the following conditions:

1. Treatment of complicated GERD* (eg., ulcer bleeding, esophageal ulcer, strictures, and extraesophageal manifestations of GERD). Re-evaluate at 8 weeks to determine if dose may be decreased to 30mg QD.
2. Documented Barrett's metaplasia if inadequate acid suppression on 30mg QD*.
3. Persistent symptoms of GERD despite an adequate trial of alternate GERD regimens listed below.
4. Active bleeding in documented duodenal or gastric ulcers.
5. Hypersecretory conditions such as Zollinger-Ellison Syndrome (ZES).
6. As part of H. pylori treatment to be discontinued after completion of H. pylori therapy (in the case of complicated ulcers, PPI therapy should be extended an additional 6 weeks).

*****In PPI naïve patients, treatment dose should begin at lansoprazole 30mg QD.

Note: To ensure that the above indications are adhered to, PBM-MAP recommends that prescriptions for lansoprazole 30mg BID be channeled through a prior authorization process (i.e., GI or drug usage review group). Medical centers may consider limiting this to a 60-day supply with an automatic decrease to 30mg QD by pharmacy, **unless appropriate justification is documented by the prescriber**.

Suggested alternatives for uncomplicated GERD with inadequate symptom control on lansoprazole 30mg/day

1. Add QHS H2-receptor antagonist and titrate dose as needed (eg., ranitidine 150-300mg QHS, particularly for nocturnal symptoms).† **$**
2. Add prokinetic agent if symptoms associated with motility disorder (Please note that cisapride will no longer be marketed as of mid July '00 and will only be made available through limited access). **$$**
3. Increase lansoprazole dose to 30mg BID or (60mg/day) for no more than 60-day supply and re-evaluate in 8 weeks. **$$$**

†- based on histamine's hypothesized role in the circadian nocturnal acid secretion profile and decreased number of actively secreting acid pumps during the night in the absence of meal stimulation.
$ - denotes relative cost of each alternative but does not reflect actual value

Note: Since omeprazole is a non-formulary agent, submission of the proper Non-Formulary Drug Request form should be executed in the event a patient is switched to omeprazole due to intolerance to or inadequate response with lansoprazole therapy.