PREVPAC (lansoprazole, clarithromycin, and amoxicillin),
PYLERA (bismuth subcitrate, metronidazole, tetracycline),
OMECLAMOX-PAK (omeprazole, clarithromycin, and amoxicillin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Prevpac and Omeclamox-Pak are a copackaged product containing a proton pump inhibitor, a macrolide antimicrobial, and a penicillin class antibacterial that, when taken together, is indicated for the eradication of *Heliobacter pylori* infection in patients with duodenal ulcer disease that is active or up to a one year history. Pylera is a copackaged product containing two antimicrobials; metronidazole, tetracycline and bismuth subcitrate potassium. Pylera is also used to eradicate *Helicobacter pylori* (H. pylori) in patients with H. pylori infection and duodenal ulcer disease; Pylera is FDA-approved for use only in combination with omeprazole. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence (1-3).

It is important to treat H. pylori infection because it has been identified as a risk factor in the development of peptic ulcer, duodenal ulcer, atrophic gastritis, gastric cancer, and mucosal-associated lymphoid tissue (MALT) lymphoma, as well as, a possible risk factor for the development idiopathic thrombocytopenic purpura and anemia (1-3).

Regulatory Status
The components in Prevpac, Pylera and Omeclamox-Pak are indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori (1-3).

Summary
Prevpac, Pylera and Omeclamox-Pak are indicated for the treatment of patients with *Heliobacter pylori* infection and duodenal ulcer disease (active one-year history) to eradicate *H. pylori*. They should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. Prevpac and Omeclamox-Pak should only be used in patients with no clarithromycin resistance. Patients taking Pylera will need to be co-administered with omeprazole (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Prevpac and Omeclamox while maintaining optimal therapeutic outcomes.
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References