

**HELICOBACTER PYLORI (H.PYLORI) MULTI-INGREDIENT / CO-PACKAGED / PRE-PACKAGED KITS**

Helidac®, Pylera®, Prevpac®, Omeclamox-Pak™

**INDICATIONS and USAGE:**

- **HELIDAC**– “The components of the HELIDAC Therapy (bismuth subsalicylate, metronidazole, and tetracycline hydrochloride), in combination with an H2 antagonist, are indicated for the eradication of *H. pylori* for treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or a history of duodenal ulcer). Appropriate doses of H2 antagonists for the treatment of active duodenal ulcers should be prescribed in all patients. The eradication of *H. pylori* has been demonstrated to reduce the risk of duodenal ulcer recurrence in patients with active duodenal ulcer disease. To reduce the development of drug-resistant bacteria and maintain the effectiveness of HELIDAC Therapy and other antibacterial drugs, HELIDAC Therapy should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.”<sup>1</sup>
- **PYLERA** “is a combination antibacterial indicated for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.”<sup>2</sup>
- **Prevpac** –“ The components in PREVPAC (PREVACID, amoxicillin, and clarithromycin) 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*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. To reduce the development of drug-resistant bacteria and maintain the effectiveness of PREVPAC and other antibacterial drugs, PREVPAC should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.”<sup>3</sup>
- **Omeclamox-Pak**,” a copackaged product containing a proton pump inhibitor, a macrolide antimicrobial, and a penicillin class antibacterial, is indicated for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or up to one-year history) to eradicate *H. pylori*.”<sup>4</sup>

**Criteria for Approval:**

1. Positive diagnostic test results confirming diagnosis of *Helicobacter Pylori*

**Length of Authorization:**

1. Coverage may be approved for one pre-packaged therapy from manufacturer.

**Dispensing Limit:**

1. The dispensing limit is a one pre-packaged therapy from manufacturer. (**Quantity Limit**)
  - a. Helidac (224 pills)
  - b. Pylera (120 pills)
  - c. Prevpac (112 pills)
  - d. Omeclamox-Pak (80 pills)

*Helicobacter Pylori* criteria

Version 1

Last updated 12/24/2012

Approved 01/18/2013

**References:**

<sup>1</sup> Helidac® package insert is available at: < <http://www.prometheuslabs.com/Resources/PI/Helidac.pdf> >  
Accessed 12/24/12

<sup>2</sup> Pylera® package insert is available at: < <http://www.pylera.com/pdf/prescribing-info.pdf> >  
Accessed 12/24/12

<sup>3</sup> Prevpac® package insert is available at: < <http://www.takeda.us/products/default.aspx> > ; under Prevpac  
Prescribing Information  
Accessed 12/24/12

<sup>4</sup> Omeclamox-Pak™ package insert is available at: <  
<http://www.omeclamox.com/PDF/PRNX005%20Omeclamox-Pak%20PI%20V9.pdf> >  
Accessed 12/24/12