Division: Pharmacy Policy	**Subject: Prior Authorization Criteria**
Original Development Date: Original Effective Date: Revision Date:	July 11, 2016

Proton Pump Inhibitors-Therapy Beyond 6 months Duration

LENGTH OF AUTHORIZATION:
Continuation of therapy: 6 months

CLINICAL NOTES
Prescription-only proton pump inhibitors are indicated for treatment and maintenance of duodenal ulcer, gastroesophageal reflux disease, pathological hypersecretory conditions, gastric ulcers and NSAID-induced gastric ulcers. They may also be used in combination with amoxicillin and clarithromycin for the eradication of *H. pylori.*

For the treatment of GERD, package insert labeling supports therapy for up to 8 weeks, for the treatment of erosive esophagitis, labeling supports therapy for up to 8 weeks but an additional 8 weeks may be considered if needed. For the maintenance treatment of erosive esophagitis and pathological secretory conditions, duration of therapy is not stated but studies did not extend beyond 12 months, however some patients with these conditions have been treated continuously for more than 5 years.

An automated prior authorization is in place to bypass the maximum 6-month duration of therapy edit for patients with a history of any of the following diagnoses on file: Zollinger-Ellison syndrome, Barrett's esophagus, gastric malignancy, cystic fibrosis or history of gastric bypass.

REVIEW CRITERIA FOR REQUESTS TO EXTEND PPI THERAPY BEYOND 6 MONTHS OF THERAPY FOR ALL OTHER PATIENTS:

Supporting documentation for one of the following diagnoses/conditions and meets the following criteria:

- Gastroesophageal Reflux Disease[1]:
  - Patient had initial response to treatment with PPI therapy AND
  - Patient has experienced recurrent symptoms (heartburn, regurgitation) since discontinuing PPI therapy AND
  - Patient has documented history of esophagitis OR
  - If the patient does not have a history of esophagitis, the prescriber indicates PPI will be administered in lowest effective dose, including possible intermittent or PRN therapy

- Patients at high risk of peptic ulcer disease due to concomitant drug therapy[2]:
  - Patients requiring concomitant therapy with an NSAID and a cardioprotective dose of ASA (<325 mg/day) OR
  - Patients requiring concomitant therapy with ASA and an anticoagulant (including unfractionated heparin, LMWH, warfarin or a novel oral anticoagulant

[1] AGA Institute The American Gastroenterological Association Medical Position Statement of the Management of Gastroesophageal Reflux Disease Gastroenterology 2008; 135:1383-1391 Available at: http://www.gastrojournal.org/article/S0016-5085(08)01606-5/pdf Accessed May 18, 2016
[2] Bhatt D, Scheiman J, Abraham N, et al. ACCF/ACG/AHA 2008 Expert Consensus Document on Reducing the Gastrointestinal Risks of Antiplatelet Therapy and NSAID Use: A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. 2008; 118:1894-1909.