

***Title: Progressive Medication Program for Proton Pump Inhibitors (PPIs)***

<b>Origination:</b> 02/27/08	<b>Revised:</b> 12/09/09	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- Nexium is the S-isomer of omeprazole. It is a proton pump inhibitor and is approved for healing and maintenance of erosive esophagitis, for symptomatic gastro-esophageal reflux disease (GERD), to reduce the risk of NSAID-Associated Gastric Ulcer, for use in combination with antibiotics to eradicate *Helicobacter pylori* in Members with active and/or prior duodenal ulcer and for hypersecretory conditions including Zollinger-Ellison Syndrome.
- Aciphex (rabeprazole) is a proton pump inhibitor. It is approved for the treatment of symptomatic gastroesophageal reflux disease (GERD) or erosive esophagitis, the healing and maintenance of erosive or ulcerative GERD, the healing of duodenal ulcers, for use in combination with antibiotics to eradicate *Helicobacter pylori* in Members with active and/or prior duodenal ulcer and for hypersecretory conditions including Zollinger-Ellison Syndrome.
- Zegerid is the brand name for omeprazole/sodium bicarbonate. It is an immediate release product combining a proton pump inhibitor and a sodium bicarbonate buffer. Approved indications include the short-term treatment of active duodenal ulcer or active benign gastric ulcer, the short-term treatment of symptomatic GERD or erosive esophagitis, maintenance of healing of erosive esophagitis, and for stress gastritis prophylaxis in critically ill Members.

***Reference Statement***

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefit coverage.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

**Procedure:**

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1.0 Request for *initial therapy* with Aciphex, Nexium, or Zegerid requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:

1.1 Member has documented esophagitis, gastro-esophageal reflux disease, or duodenal ulcer;

**OR**

1.1 Member has documented Zollinger-Ellison Syndrome confirmed by one (1) of the following diagnostic labs:

1.1.1 Fasting serum gastrin concentration; **or**

1.1.1 Secretion stimulation test; **or**

1.1.1 Gastric acid secretion studies;

**OR**

1.1 Member is critically ill and requires stress gastritis prophylaxis;

**AND the following criteria depending on line of business:**

**For Commercial Members only:**

1.2 **For Commercial Members only**, need documented inadequate response to a one (1) month trial of adequately dosed omeprazole (Prilosec OTC) **or** Prevacid OTC;

**AND**

1.3 **For Commercial Member only**, need documented inadequate responses to a one (1) month trial of **ALL** of the following:

1.3.1 pantoprazole (Protonix); **AND**

1.3.2 lansoprazole (Prevacid); **AND**

1.3.3 Kapidex;

1.4 If Member meets all of the above criteria, initial therapy with Aciphex, Nexium, or Zegerid may be approved for a quantity of 30 per 30 days for (1) month;

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**Procedure, continued:**

- 1.0 Request for *initial therapy* with Aciphex, Nexium, or Zegerid requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following, continued:

**AND the following criteria depending on line of business, continued:**

**For Miami Dade County Members only:**

- 1.2 **For MDC Members only**, need documented inadequate response to a one (1) month trial of **ANY** of the following:
- 1.2.1 omeprazole (Prilosec OTC); **OR**
  - 1.2.2 lansoprazole (Prevacid); **OR**
  - 1.2.3 pantoprazole (Protonix);

**AND**

- 1.3 **For MDC Members only**, need documented inadequate response to a one (1) month trial of adequately dosed Kapidex;
- 1.4 If Member meets all of the above criteria, initial therapy with Aciphex, Nexium, or Zegerid may be approved for (1) month;

**For Medicare Members only:**

- 1.2 **For Medicare Members only**, need documented inadequate responses to a one (1) month trial of **ALL** of the following:
- 1.2.1 omeprazole (Prilosec OTC); **AND**
  - 1.2.2 lansoprazole (Prevacid); **AND**
  - 1.2.3 pantoprazole (Protonix);
- 1.3 If Member meets the above criteria, initial therapy with Aciphex, Nexium, or Zegerid may be approved for (1) month.

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**Procedure, continued:**

- 2.0 Request for *continuation of therapy* beyond initial authorization period with Aciphex, Nexium, or Zegerid requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
  - 2.1 Improved signs and symptoms;
  - 2.2 If Member meets criteria, therapy may be approved for one (1) year.

**References:**

1. Nexium Full Prescribing Information. AstraZeneca Pharmaceuticals LP, Wilmington, DE. Revised June 2009.
2. Hirschowitz B.I., Zollinger-Ellison Syndrome: Pathogenesis, diagnosis and Management, American Journal of Gastroenterology, 1997; 92 (4) 44-48.
3. Aciphex Full Prescribing Information, Eisai Co. Ltd, Tokyo, Japan. Revised January 2009.
4. Zegerid Full Prescribing Information. Santarus Inc., San Diego, CA. Revised January 2009.
5. Weinhouse G, Manaker S. Stress Ulcer prophylaxis in the intensive care unit. Up-To-Date, 2006.
6. Kahrilas PJ, Shaheen NJ, Vaezi MF, Hiltz SW, Black E, Modlin IM, Johnson SP, Allen J, Brill JV, American Gastroenterological Association. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology 2008 Oct;135(4):1383-91, 1391.e1-5.
7. DeVault KR, Castell DO. Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. Am J Gastroenterol 2005;100:190-200.

**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.