

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

ESOMEPRAZOLE MAGNESIUM (NEXIUM)

Generic	Brand	HICL	GCN	Exception/Other
ESOMEPRAZOLE MAGNESIUM	NEXIUM		12867 12868	

OTC Nexium 24HR and OTC esomeprazole are covered at the member's lowest cost share without PA when it is prescribed by a health care provider and when it is dispensed at the pharmacy.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the member tried and failed or have a contraindication/intolerance to omeprazole (Prilosec) or pantoprazole (Protonix)?

If yes, continue to #2.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Esomeprazole Magnesium (Nexium) guideline, this medication is only covered for members who have previously tried and failed, or have a contraindication/intolerance to omeprazole (Prilosec) or pantoprazole (Protonix). Your provider did not indicate that you have tried and failed or have a contraindication/intolerance to one of these medications and therefore your request was not approved.

2. Is the request for brand-name prescription-only Nexium?

If yes, continue to #3.

If no, **approve generic Nexium (esomeprazole magnesium) for 12 months by HICL.**

(PAC NOTE: Please check the 'Generic Only' box in the Other Overrides section.)

Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for esomeprazole (generic Nexium) has been approved for a 12-month period.

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INITIAL CRITERIA (CONTINUED)

3. Has the member, at any time, tried and failed or have a contraindication/intolerance to esomeprazole magnesium (generic Nexium)?

If yes, **approve brand Nexium for 12 months by HICL**. Please use status code #057.

Requests for products not on formulary, please use the approval text provided.

APPROVAL TEXT: Your request for brand-name Nexium has been approved for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

If no, do not approve.

Please enter a proactive PA in the system for generic Nexium (esomeprazole magnesium) for 12 months by HICL.

PAC NOTE: Please check the 'Generic Only' box in the Other Overrides section. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Esomeprazole Magnesium (Nexium) guideline, brand name prescription Nexium is only covered for members who have tried and failed therapy with, or have a contraindication or intolerance to, esomeprazole (generic Nexium). Your provider did not indicate that you have tried and failed therapy with, or have a contraindication or intolerance to this medication, and therefore your request was not approved. A prior authorization has been approved for esomeprazole (generic for Nexium) for a 12-month period.

RENEWAL CRITERIA

1. Has the patient experienced improvement while on therapy?

If yes, **approve for 12 months by HICL**. Please use status code #057.

For generic esomeprazole, please check the 'Generic Only' box in the Other Overrides section, and use the approval text provided.

APPROVAL TEXT: Your request for generic esomeprazole has been approved for a 12-month period.

Requests for products not on formulary, please use the approval text provided.

APPROVAL TEXT: Your request for Nexium has been approved for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Esomeprazole Magnesium (Nexium) guideline, authorization for renewal requires documentation of improvement of symptoms while on therapy with [**requested medication**]. Your provider did not indicate that your symptoms have improved and therefore your request was not approved.

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RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary alternatives within the PPI (proton pump inhibitor) class before initiating treatment with more expensive agents that have limited or no clinical advantage. In comparable doses, OTC Nexium 24HR has similar safety and efficacy as prescription Nexium or esomeprazole magnesium with a fraction of associated costs. Prior authorization ensures that prescription Nexium or esomeprazole magnesium is approved in cases which are medically necessary.

FDA APPROVED INDICATIONS

- Gastroesophageal reflux disease:
 - Healing of erosive esophagitis: Short-term (4 to 8 weeks) treatment in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For infants 1 month to younger than 1 year with acid-mediated erosive esophagitis, treat up to 6 weeks (esomeprazole magnesium only).
 - Maintenance of healing of erosive esophagitis: To maintain symptom resolution and healing of erosive esophagitis.
- Symptomatic gastroesophageal reflux disease: Short-term (4 to 8 weeks) treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) in adults (esomeprazole magnesium and esomeprazole strontium) and children 1 year and older (esomeprazole magnesium only).
- Helicobacter pylori eradication:
 - Triple therapy (esomeprazole plus amoxicillin and clarithromycin): In combination with amoxicillin and clarithromycin for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or within the past 5 years) to eradicate H. pylori.
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome: Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.
- Risk reduction of nonsteroidal anti-inflammatory drug-associated gastric ulcer: Reduction in the occurrence of gastric ulcers associated with continuous nonsteroidal anti-inflammatory drug (NSAID) therapy in patients at risk of developing gastric ulcers (e.g., 60 years and older, history of gastric ulcers).

REFERENCES

- AstraZeneca. Nexium package insert. Wilmington, DE. October 2016.
- Pfizer. Nexium 24HR (esomeprazole magnesium) prescribing information. Madison, NJ. May 2016.
- Esomeprazole. Lexi-Interact [database online]. Hudson, OH. Lexicomp Inc; 2015. Available at: <http://online.lexi.com>. [Accessed March 28, 2016].
- Facts & Comparisons 4.0 [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2010. Available at: <http://online.factsandcomparisons.com/index.aspx>. [Accessed: March 28, 2016].

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