

Clinical Edit Criteria Proposal

Drug/Drug Class: **H-Pylori Therapy Clinical Edit**

Prepared for:
Prepared by: **Missouri Medicaid**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Control the utilization for drug therapies used to treat H-Pylori infections by implementing a clinical edit in conjunction with the step therapy edits for H2 antagonists and proton pump inhibitors.

Why was this Issue Selected: During the twelve-month calendar period of June 2002 to May 2003, 182,659 claims were paid for PPI therapy at a cost of \$20,914,521. Over the same calendar period, 378,000 claims were paid for H2 therapy at a cost of \$6.5 million. These dollar amounts represent approximately 3% of the total prescription drug benefit.

Program-specific information:	Drug	Claims	Expenses
	• Prevpac [®]	1600	\$428,813
	• Helidac [®] Kit	415	\$67,000

Setting & Population: All patients prescribed drug therapy kits to treat H-Pylori infections.

Type of Criteria:

Increased risk of ADE **Non-Preferred Agent**

Appropriate Indications

Data Sources: **Only administrative databases** **Databases + Prescriber-supplied**

Approval Criteria

- Positive H-Pylori test (identified through any of the following)
 - Urea Breath test
 - Warthin-Starry Stain
 - Serology
 - Culture, CLO
 - Rapid Urease
 - Stool Antigen
- Concurrent diagnosis of PUD
- No required H2 antagonist or reference PPI trial

Approval Diagnoses

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Positive H-Pylori	041.86	--	720 days	
Peptic Ulcer Disease (PUD)	533.0 –533.9	--	720 days	

Denial Criteria

- Lack of evidence of positive H-Pylori test
- Lack of evidence of PUD diagnosis

Required Documentation

Appropriate Diagnosis
MedWatch form:

Progress notes:

Disposition of Edit

- **Denial:** Exception 682 “Clinical Edit”

References

1. Facts and Comparisons, p.1135-38C. 2003.
2. USPDI, Micromedex, 2003.
3. “Evidenced Based Medicine Analysis: Proton Pump Inhibitors”, UMKC-DIC, May 2003.