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Indiana Medicaid Drug Utilization Review Board Newsletter

Management of Heartburn

Heartburn has been estimated to occur in about 40% of the U.S. population.¹ It often presents as a substernal burning or pain accompanied by regurgitation. The burning sensation results when harsh stomach juices reflux into the esophagus and irritate its delicate lining. This commonly occurs when the lower esophageal sphincter, a natural valve that retains stomach acid in the stomach, relaxes or malfunctions. When the sphincter relaxes, stomach juices may flow upward into the esophagus thus exposing it to harsh acid from the stomach.²

Treatment regimens for heartburn vary depending on severity. The greatest beneficial impact of heartburn relief has been shown on measures of psychological well-being, measures of physical functioning and well-being. Effective treatment that completely resolves symptoms ultimately results in clinically significant improvement in quality of life. Clinical goals of treatment include relief of symptoms, initiation/acceleration of healing, prevention of recurrence, and prevention of complications. Optimal treatment achieves these goals within the framework of effectiveness, safety, and justifiable costs.¹

Heartburn is caused by various lifestyle and dietary factors, and may be managed by lifestyle adjustments when it occurs episodically. Patients who complain of heartburn often experience symptoms after meals that are either very large, eaten late in the evening, or that consist of high-fat or spicy foods. Foods that lower the pressure of the lower esophageal sphincter, such as fried or fatty foods, chocolate, peppermint, coffee, tea or alcohol, should be avoided. In addition, citrus fruits, coffee, carbonated beverages, and tomatoes may cause mucosal irritation and should also be avoided. Decreasing portion size at mealtimes or eating three to four hours prior to lying down may also lessen the incidence of reflux. Patients should also be encouraged to lose weight (if obese), decrease or eliminate alcohol consumption, and stop smoking.³ For patients with nocturnal symptoms, elevating the head of the bed four to six inches may prevent stomach acid from flowing into the esophagus while sleeping.

When lifestyle adjustments are not enough, the next line of defense is medications. The goal of anti-secretory treatment is to maintain an intragastric pH level ≥ 4 .¹ Many heartburn sufferers find some relief from the wide variety of medicines available over-the-counter such as antacids and histamine-2-receptor antagonists. Antacids neutralize existing stomach acid and provide relatively rapid but short-term relief

of heartburn symptoms. Since only existing acid is neutralized, the use of antacids is limited to relief of symptoms rather than prevention of acid secretion. Antacids have a short duration of action and, therefore, must be administered several times a day. Adverse reactions to antacids are generally limited to gastrointestinal disturbances. Magnesium salts often cause diarrhea due to their osmotic effect whereas both calcium and aluminum containing antacids have been reported to cause constipation. Antacids may interact with many drugs, altering their rate or extent of absorption by increasing gastric pH, adsorbing or binding drugs, or increasing urinary pH. Consequently, antacids should be given two hours before or after the administration of other medications to avoid interaction.³

H₂-receptor antagonists competitively and reversibly inhibit histamine at H₂-receptors located on the gastric parietal cell, resulting in reduced gastric acid secretion. Although, the H₂-receptor antagonists are relatively benign drugs, adverse effects have been reported, including headache, dizziness, fatigue, diarrhea, thrombocytopenia, and rash.³ Drug interactions may also be of concern if metabolism of the H₂-antagonist is dependent upon cytochrome P-450. Examples of H₂-receptor antagonists include cimetidine, famotidine, nizatidine, and ranitidine. All agents are available both over-the-counter and with a prescription.

When clinical outcomes have not been achieved with antacids and H₂-antagonists, treatment with proton pump inhibitors is often required to prevent further complications. The proton pump actively secretes hydrogen ions in exchange for potassium ions, causing a subsequent decrease in pH. Proton pump inhibitors (PPIs) bind irreversibly and non-competitively to the H⁺/K⁺-

adenosine triphosphatase (ATPase) pump, thereby inhibiting acid secretion.³ All PPIs have a similar mechanism of action but differ somewhat in how they bind to sites adjacent to the cysteine residues on the proton pumps.⁴ The most common side effects reported with PPIs in clinical trials included nausea, diarrhea, constipation, abdominal pain, headache, and dizziness.³ Examples of proton pump inhibitors include esomeprazole, omeprazole, pantoprazole, lansoprazole, and rabeprazole. Currently, only omeprazole is available without a prescription.

Patients who do not experience relief through lifestyle modifications and/or medication, or patients who require continuous medication, may need a more complete diagnostic evaluation² to determine the appropriate course of treatment. Ultimately, it is the prescriber's responsibility to select the most cost-effective drug therapy that will result in the most favorable clinical outcomes and greatest patient satisfaction.³ With proper treatment or use of non-pharmacological measures, most heartburn sufferers can effectively treat and relieve their heartburn symptoms.

References:

1. McGuigan JE. Treatment of gastroesophageal reflux disease: to step or not to step. *Am J Gastroenterol.* 2001;96:1679-1681.
2. Heartburn Alliance [accessed 2006 Jun 19]. Heartburn Overview. Available at <http://www.heartburnalliance.org/section3/1005.jsp>.
3. Vivian EM, Thompson MA. Pharmacologic strategies for treating gastroesophageal reflux disease. *Clin Ther.* 2000;22(6):654-672.
4. Pham CQD, Sadowski-Hayes LM, Regal RE. Prevalent prescribing of proton pump inhibitors: prudent or pernicious?. *P&T.* 2006;31(3):159-167.

Program Assistance

All prior authorization requests or questions regarding the PDL should be directed to the ACS Clinical Call Center at 1-866-879-0106.

PDL Listing

The fee-for-service PDL listing may be found at the following website:

<http://www.indianapbm.com/>

**Top 25 Drugs 2nd Quarter 2006
By Total Amount Paid**

Drug	Total Paid	Total Claims
Risperdal	\$3,425,372	13,631
Antihemophilic Factor	\$3,108,205	110
Zyprexa	\$3,029,317	7,223
Seroquel	\$2,954,961	11,739
Abilify	\$2,595,201	7,323
Depakote	\$1,631,358	11,505
Topamax	\$1,372,319	5,834
Novoseven	\$1,170,133	9
Lipitor	\$1,147,419	11,430
Zoloft	\$1,111,657	11,580
Lamictal	\$1,100,733	4,792
Fentanyl	\$1,011,996	3,709
Geodon	\$965,791	3,663
Trileptal	\$825,076	4,626
Protonix	\$805,520	6,725
Advair	\$784,821	4,829
Oxycodone	\$757,305	4,820
Zocor	\$750,082	5,309
Effexor	\$732,529	5,508
Amphetamine salts	\$728,599	7,781
Bupropion	\$715,361	7,392
Plavix	\$697,923	5,491
Methylphenidate	\$687,364	8,441
Lexapro	\$675,848	8,522
Nexium	\$587,582	3,904

**Top 25 Drugs 2nd Quarter 2006
Ranked by Claims Paid**

Drug	Total Claims	Total Paid
Hydrocodone/APAP	42,109	\$331,527
Aspirin	39,140	\$27,386
Docusate	37,040	\$85,289
Acetaminophen	31,903	\$87,803
Calcium/Vit D	30,728	\$96,418
Alprazolam	30,281	\$317,136
Multivitamins	24,933	\$32,281
Loratadine	24,725	\$307,963
Lorazepam	20,337	\$122,059
Clonazepam	19,939	\$112,266
Prilosec OTC	16,268	\$443,094
Albuterol	16,173	\$160,030
Risperdal	13,631	\$3,425,372
Ferrous Sulfate	13,097	\$13,868
Levothyroxine	11,967	\$133,353
Seroquel	11,739	\$2,954,961
Diazepam	11,626	\$216,956
Furosemide	11,589	\$47,640
Zoloft	11,580	\$1,111,657
Depakote	11,505	\$1,631,358
Lipitor	11,430	\$1,147,419
Lisinopril	10,915	\$76,699
Ranitidine	9,543	\$228,215
Multivitamins with Minerals	9,198	\$13,060
Potassium	8,978	\$120,765