Managing Gastroesophageal Reflux Disease (GERD): An Update

Impact on Employers

Roughly 4% of working Americans have gastroesophageal reflux disease (GERD), a chronic condition that occurs when stomach acid routinely backs up into the esophagus. Over time, the acid irritates the esophagus and causes symptoms including heartburn, morning hoarseness, trouble swallowing, chest pain, asthma or a dry persistent cough. Untreated GERD may cause serious complications such as Barrett’s esophagus, which in rare cases can lead to a deadly cancer known as esophageal adenocarcinoma.

The average incremental cost to an employer for each employee with GERD in 2007 was estimated to be $3,355 a year, including medical costs (65%); prescription drug costs (17%); and indirect costs such as absenteeism and disability (19%). Employees with GERD had more physician, hospital, emergency department and laboratory costs than employees without GERD. The same study also found that employees with GERD were more likely to have coexisting conditions including heart, respiratory and musculoskeletal problems.

Employers can reduce direct medical and indirect costs associated with GERD by helping employees prevent the disease and, when necessary, assist them in choosing the most effective treatment for their circumstances. At the same time, effective employer health plan policies will help reduce the recognized overprescribing of GERD medications for occasional heartburn.

This guide provides actions for employers who want to use comparative effectiveness research (CER) findings about management strategies for gastroesophageal reflux disease (GERD) in their health plans and programs. It is based on research funded by the federal Agency for Healthcare Research and Quality (AHRQ). See the Resources section at the end of this guide for consumer decision-support information on GERD.
Agency for Healthcare Research & Quality
Comparative Effectiveness Research Findings

The AHRQ Effective Health Care Program funded an update to the 2005 review comparing the effectiveness, benefits and adverse effects of medical, surgical and endoscopic treatments for GERD. *Management Strategies for Adults with Gastroesophageal Reflux Disease: An Update* was prepared by the Tufts Medical Center Evidence-based Practice Center and published in September 2011.

The review compared the efficacy and safety of the following medical, surgical and endoscopic treatments for GERD:

- **Medications**
  - Proton pump inhibitors (PPIs)
  - Histamine type 2 receptor antagonists (H2RAs)

An eight-week trial of PPI and lifestyle modifications is standard treatment for GERD.

- **Surgical Treatments**
  - Laparoscopic total and partial fundoplication
  - Laparoscopic fundoplication with and without division of short gastric vessels
  - Open total and partial fundoplication

Fundoplication strengthens the valve between the esophagus and the stomach. The top part of the stomach is wrapped around the bottom of the esophagus to strengthen the closure and keep acid and food from coming back up into the esophagus. In partial fundoplication, the top part of the stomach is wrapped only part way around the esophagus. Laparoscopic surgery allows for small incisions, whereas open surgery requires a larger cut to complete the procedure. Fundoplication may be recommended for people with severe symptoms, and most plans cover it.

**Quick Facts**

- GERD is a chronic condition generally defined as heartburn and/or acid regurgitation that occurs two or more days a week.
- GERD is often difficult to treat; approaches to treatment depend on the severity of symptoms, and may also vary based on how the patient responds.
- Treatment options include medication, surgery and the following lifestyle changes:
  - Quitting smoking;
  - Drinking less alcohol;
  - Eating small meals;
  - Avoiding foods that may make symptoms worse, such as spicy or fatty foods, mint, chocolate, tomato-based foods, coffee and citrus fruits;
  - Avoiding lying down for three hours after a meal; and
  - Raising the head of one’s bed 6-8 inches (using extra pillows alone will not help).
- The cost of over-the-counter (OTC) medications varies based on the store, medication brand and the amount of medication taken; however, most cost between $13 and $30 per month.

- **Endoscopic Treatments**
  - EndoCinch™
  - Stretta®
  - EsophyX™

Endoscopic treatments are relatively new and entail putting a thin tube (endoscope) down the patient’s throat to the esophagus to perform the variation of fundoplication or delivery of radio-frequency energy.
Findings:

Overview
The research review found that medications are effective, and that PPIs are more effective than H2RAs. Prescription, generic and over-the-counter PPIs are equally effective. Fundoplication is at least as effective as medication for some patients, but has a higher risk for adverse effects. It is not clear whether patients who have surgery are subsequently free from having to take GERD medications. There is not enough evidence on endoscopic procedures to compare their effectiveness with other treatments.

Medication
- PPIs were more effective than H2RAs for esophageal healing, resolving symptoms, patient satisfaction and adherence. *(Moderate strength of evidence)*
- Prescription, generic and over-the-counter (OTC) PPIs are equally effective for healing esophagitis (inflammation of the esophagus) for up to one year. There was no difference in outcomes based on different dosages and dosing regimens. Taking a PPI every day appears more effective than taking the medication only when symptoms appear. *(Moderate strength of evidence)*
- People who are obese or who have severe baseline irritation of the esophagus do not respond as well to medications. Older age was associated with improved symptoms at six months. *(Moderate strength of evidence)*
- PPIs may help a cough, but not hoarseness associated with GERD. *(Low strength of evidence)*
- There were not enough data to determine the effectiveness of medications on asthma symptoms caused by GERD.
- Potential side effects from PPIs included diarrhea, nausea, vomiting, abdominal pain, upset stomach and headache. *(Low strength of evidence)*
- PPIs may increase one’s chances of getting an intestinal infection, pneumonia or a bone fracture, although these side effects are less common. *(Low strength of evidence)*

Medications commonly used to treat GERD

**Proton Pump Inhibitors (PPIs)**

*Cause the stomach to produce less acid. Many are prescription only.*

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Prescription generic available</th>
<th>OTC Available</th>
<th>Average monthly cost* (varies per dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole</td>
<td>Prilosec</td>
<td>yes</td>
<td>yes</td>
<td>Prilosec OTC $24</td>
</tr>
<tr>
<td>Omeprazole with sodium bicarbonate</td>
<td>Zegerid</td>
<td>no</td>
<td>yes</td>
<td>Prescription generic $19</td>
</tr>
<tr>
<td>Lansoprazole</td>
<td>Prevacid</td>
<td>no</td>
<td>yes</td>
<td>OTC $21</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>Protonix</td>
<td>yes</td>
<td>no</td>
<td>Prescription $245-$249</td>
</tr>
<tr>
<td>Rabeprazole</td>
<td>Aciphex</td>
<td>no</td>
<td>no</td>
<td>OTC $23</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>Nexium</td>
<td>no</td>
<td>no</td>
<td>Prescription $237-$267</td>
</tr>
<tr>
<td>Dexlansoprazole</td>
<td>Dexitant</td>
<td>no</td>
<td>no</td>
<td>Generic $137-$142</td>
</tr>
</tbody>
</table>
Histamine Type 2 Receptor Antagonists (H2RAs)
Cause the stomach to produce less acid. Available by prescription or over the counter in low doses.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>Famotidine</td>
<td>Pepcid AC, Calmicid, Fluxid, Mylanta</td>
</tr>
<tr>
<td>Nizatidine</td>
<td>Axid, Axid AR</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>Zantac, Tritec, Wal-Zan</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>Tagamet</td>
</tr>
</tbody>
</table>

Antacids
Neutralize stomach acid. Available without prescription.

<table>
<thead>
<tr>
<th>Antacids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mylanta, Rolaid, Tums.</td>
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*Cost estimate source: Consumer Reports Best Buy Drugs, accessed on 3/14/12.

Surgery
- There was no significant difference in effectiveness between laparoscopic total and partial fundoplication; between laparoscopic fundoplication with and without division of short gastric vessels; and between open total and partial fundoplication. (Moderate strength of evidence)
- Surgery appears to be as effective as medication and can decrease, but not necessarily eliminate, the use of medications. (Moderate strength of evidence)
- Adverse effects of surgery may include bloating and difficulty swallowing. (Low strength of evidence)
- Serious side effects (i.e., infection and heart attack) may be more common with surgery than with medications. (Low strength of evidence)

Endoscopy
- Endoscopic procedures are relatively new and there is not enough evidence to determine how well these procedures control GERD symptoms.
- Endoscopic treatments can cause chest or abdominal pain, bleeding and bloating. (Low strength of evidence)

Medical/Surgical/Endoscopic Comparisons
- PPIs and surgery are similarly effective for improving symptoms and decreasing esophageal acid exposure. (Moderate strength of evidence)
- Serious adverse effects could be more common for surgery than for medication treatment. (Low strength of evidence)
- There was insufficient evidence to compare the effectiveness of endoscopic treatments to medication or surgery.
- There was insufficient evidence to assess whether medication and surgical treatments are equally effective in preventing long-term complications.
- There are few long-term studies; thus, the long-term comparative benefits and risks of surgery versus medication have not been determined.
Employers can use pharmacy and medical plan design elements, as well as health management programs and services, to help employees prevent GERD and, when needed, treat it appropriately.

**Pharmacy Plan Strategies**
- Narrow down the PPI formulary options and/or use tiers or other methods to drive the use of generics and preferred brands.
- Use quantity limits for PPIs in the formulary. Additional quantities must be requested through prior authorization and meet established medical criteria such as being treated for Barrett’s esophagus or a gastrointestinal bleed.
- Use step therapy requiring that a course of OTC medication and/or a generic be used before a prescription brand is covered.

_The recommendations above represent the typical approach by large employer health plans. Some employers choose to grandfather existing PPI users when adding a step therapy program._

**Medical Plan Strategies**
- Provide medical decision-support services to help members understand the advantages and disadvantages of medical versus surgical treatments, and what to expect after surgery.
- Use pre-certification/notification for fundoplication surgery and offer medical decision tools to the patient.
- Do not cover endoscopic anti-reflux procedures except as part of coverage with an evidence development policy.

_Endoscopic anti-reflux procedures are typically not covered in large employer health plans._

**Employee Education and Supports**
- Educate employees about lifestyle habits related to GERD and how to tell the difference between heartburn and chronic GERD.
- Educate employees about the relative advantages and disadvantages of different treatment options and the risks associated with some treatments. For example, the research indicates that PPIs may reduce the effectiveness of blood thinners that may be prescribed after someone has had a heart attack or a stent placement.
Conclusion

Chronic GERD is a common condition among working-age adults. Employers can use pharmacy and medical plan design elements, as well as health management programs and services, to help employees prevent GERD and treat it appropriately.

Medications commonly used to treat GERD are effective, with PPIs being the most effective drugs. Prescription, generic and OTC PPIs are equally effective. Therefore, employers can use formulary management and pharmacy plan design to direct patients to preferred medications. Although surgery, known as fundoplication, appears to be as effective as medication and may decrease the need for medication, it carries a greater risk for adverse events. Not enough is known about the comparative risks and benefits of endoscopic procedures to recommend them.

Resources

Treatment Options for GERD or Acid Reflux Disease: A Review of the Research for Adults
This guide describes GERD and explains research about the types of treatments, including the benefits and risks of each, and can help patients talk informatively with their doctors about GERD.

Questions are the Answer
Agency for Healthcare Research and Quality
This is an easy-to-use consumer website that helps patients take an active role in their health care by asking questions so that they understand their condition and options.
http://www.ahrq.gov/questionsaretheanswer/

For Free Print Copies of the Consumer and Clinician Guides
AHRQ Publications Clearinghouse – 800.358.9295
Consumer Guide: Treatment Options for GERD and Acid Reflux Disease: A Review of the Research for Adults, September 23, 2011
AHRQ Pub. No. 11-EHC049-A
Clinician Guide: Managing Chronic Gastroesophageal Disease, September 23, 2011
AHRQ Pub. No. 11-EHC-049-3

REFERENCES
2 Ibid.
A GUIDE FOR EMPLOYERS

Using Comparative Effectiveness Research

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All materials are in the public domain. Additional copies of this Guide are available at www.businessgrouphealth.org.

About the National Business Group on Health

The Business Group is the only non-profit organization devoted exclusively to representing large employers’ perspectives on national health issues and providing solutions to its members’ most important health care and health benefits challenges. The Business Group fosters the development of a safe health care delivery system and treatments based on scientific evidence. Members share strategies for controlling costs, improving patient safety and quality of care, increasing productivity and supporting healthy lifestyles.