

# HERC Coverage Guidance – Upper Endoscopy for Gastroesophageal Reflux Disease (GERD) and Dyspepsia Symptoms Disposition of Public Comments

## Commenter:

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## Comments Grouped by Topic

#	Comment	Disposition
1	Here are some recent guidelines from three separate GI societies regarding diagnostic approaches to GERD and dyspepsia. There are well reasoned decision trees that are worth reviewing. There are additional cost analyses that are interesting. I believe these support my contention that recognition of alarm symptoms, age > 50 and persistent GERD symptoms after a 2 week trial of treatment warrant upper endoscopy.	Thank you for this additional information.
2	American Society for Gastrointestinal Endoscopy. (2007). Role of endoscopy in the management of GERD. <i>Gastrointestinal Endoscopy</i> , 66(2), 219-224.  <i>Rated poor quality by CEBP<sup>1</sup></i>	<p>Recommendations pertinent to this guidance include the following:</p> <ul style="list-style-type: none"> <li>“Endoscopy is recommended for patients who have symptoms suggesting complicated GERD or alarm symptoms (2A).”</li> </ul> <p>2A recommendation is described as intermediate strength; unclear benefit; based on RCTs</p> <p>Alarm symptoms are listed as GERD symptoms persistent or progressive despite medical therapy (length of therapy not specified), dysphagia/odynophagia, involuntary weight loss (&gt;5%), GI bleeding/anemia, presence of mass/stricture/ulcer, persistent vomiting, suspected extra-esophageal manifestations of GERD (latter indication contradicted by Katz and Kahrilas).</p> <ul style="list-style-type: none"> <li>“Endoscopy should be considered in patients at risk for Barrett’s esophagus (BE) (level of evidence = 2C).”</li> </ul> <p>2C recommendation is described as very weak recommendation, alternative approaches likely to be better under some circumstances; unclear benefits; based on observational studies.</p> <p>Risk factors for BE listed as prolonged (&gt;5 years) GERD symptoms, white race, male sex, age &gt;</p>

<sup>1</sup> The Center for Evidence-based Policy (CEbP) assesses the methodological quality of guidelines using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration (<http://www.agreetrust.org/resource-centre/practice-guidelines/>). Guideline are assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases.

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		<p>50, + family history</p> <p>No evidence provided to support screening for those at risk of BE (white race, male sex) and evidence to support other alarm symptoms also not provided. No change made to guidance recommendation.</p>
3	<p>Katz, P.O., Gerson, L.B., &amp; Vela, M.F. (2013). Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. <i>American Journal of Gastroenterology</i>, 108, 308-328. doi: 10.1038/ajg.2012.444</p> <p><i>Rated poor quality by CEBP</i></p>	<p>Recommendations pertinent to this guidance include the following:</p> <p>“Upper endoscopy is not required in the presence of typical GERD symptoms. Endoscopy is recommended in the presence of alarm symptoms and for screening of patients at high risk for complications. Repeat endoscopy is not indicated in patients without Barrett’s esophagus in the absence of new symptoms.”</p> <p>Alarm symptoms are specified as dysphagia, but not otherwise described. Those at high risk for complications are likewise not defined.</p> <p>“Upper endoscopy should be performed in refractory patients with typical or dyspeptic symptoms principally to exclude non-GERD etiologies.”</p> <p>Definition of refractory not provided, but author notes that poor compliance and inappropriate dosing are significant factors in lack of response to PPI and should be corrected first. Eight week course of PPIs is recommended as initial treatment.</p> <p>“Upper endoscopy is not recommended as a means to establish a diagnosis of GERD-related asthma, chronic cough, or laryngitis.”</p> <p>Coverage guidance recommendation revised to recommend against coverage of repeat endoscopy in the absence of significant new symptoms or presence of BE.</p>
4	<p>Talley, N.J., Vakil, N., &amp; the Practice Parameters Committee of the American College of Gastroenterology. (2005). Guidelines for the Management of Dyspepsia. <i>American Journal of Gastroenterology</i>, 100, 2324-2337. doi: 10.1111/j.1572-0241.2005.00225.x</p> <p><i>Rated poor quality by CEBP</i></p>	<p>Recommendations pertinent to this guidance include the following:</p> <p>Patients with dyspepsia should undergo EGD if they are &gt; 55 or have alarm symptoms, defined as:</p> <ul style="list-style-type: none"> <li>• Bleeding or anemia</li> <li>• Early satiety</li> <li>• Unexplained weight loss &gt; 10% of body weight</li> <li>• Progressive dysphagia or odynophagia</li> </ul>

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		<ul style="list-style-type: none"> <li>• Persistent vomiting</li> <li>• Personal or family history of esophagogastric malignancy</li> <li>• History of peptic ulcer</li> <li>• Lymphadenopathy</li> <li>• Abdominal mass</li> </ul> <p>Repeat EGD is not recommended unless completely new symptoms or alarm features develop.</p> <p>Use of antisecretory therapy can mask a cancer at endoscopy, but does not appear to alter the outcome.</p> <p>Refractory GERD not defined, but recommendation is for initial 4-8 week course of PPI.</p> <p>Coverage guidance recommendation revised to recommend against coverage of repeat endoscopy in the absence of significant new symptoms or presence of BE.</p>
5	<p>Kahrilas, P.J., Shaheen, N.J., Vaezi, M.F., Hiltz, S.W., Black, E., Modlin, I.M., et al. (2008). American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease. <i>Gastroenterology</i>, 135(4), 1383-1391, 1391.e1-5.</p> <p><i>Rated good quality by CEBP</i></p>	<p>Recommendations pertinent to this guidance include the following:</p> <p><b><i>How Do Antisecretory Therapies Compare in Efficacy and Under What Circumstances Might One Be Preferable to Another? What Is an Acceptable Upper Limit of Empirical Therapy in Patients With Suspected Typical Esophageal GERD Syndromes Before Performing Esophagogastroduodenoscopy?</i></b></p> <p>PPIs are recommended for initial empiric treatment (Grade A). Authors state “Patients whose heartburn has not adequately responded to twice-daily PPI therapy should be considered treatment failures, making that a reasonable upper limit for empirical therapy.” However, length of initial trial of PPIs is not specified.</p> <p><b><i>What Is the Role and Priority of Diagnostic Tests (Endoscopy With or Without Biopsy, Esophageal Manometry, Ambulatory pH Monitoring, Impedance-pH Monitoring) in the Evaluation of Patients With Suspected Esophageal GERD Syndromes?</i></b></p> <p><b>Grade B: recommended with fair evidence that it improves important outcomes</b></p> <ol style="list-style-type: none"> <li>I. Endoscopy with biopsy for patients with an esophageal GERD syndrome with troublesome dysphagia.</li> <li>II. Endoscopy to evaluate patients with a suspected esophageal GERD syndrome</li> </ol>

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		<p>who have not responded to an empirical trial of twice-daily PPI therapy.</p> <p><b>Grade Insuff: no recommendation, insufficient evidence to recommend for or against</b></p> <p>I. Using alarm symptoms (other than troublesome dysphagia) as a screening tool to identify patients with GERD at risk for esophageal adenocarcinoma.</p> <p><b><i>Does GERD Progress in Severity, Such That Symptomatic Patients Without Esophagitis Develop Esophagitis and Barrett’s Metaplasia, or Are These Distinct Disease Manifestations That Do Not Exist Along a Continuum? If Patients Do Progress, at What Rate Does This Occur, and Does It Warrant Endoscopic Monitoring?</i></b></p> <p><b>Grade D: recommend against, fair evidence that it is ineffective or harms outweigh benefits</b></p> <p>I. Routine endoscopy in subjects with erosive or nonerosive reflux disease to assess for disease progression.</p> <p><b><i>What Is the Role of Endoscopy in Longterm Management of Patients With GERD, and Under What Circumstances Should Mucosal Biopsy Specimens Be Obtained When Endoscopy Is Performed?</i></b></p> <p><b>Grade B: recommended with fair evidence that it improves important outcomes</b></p> <p>I. Endoscopy with biopsy for patients with an esophageal GERD syndrome with troublesome dysphagia.</p> <p><b>Grade Insuff: no recommendation, insufficient evidence to recommend for or against</b></p> <p>I. Routine upper endoscopy in the setting of chronic GERD symptoms to diminish the risk of death from esophageal cancer.</p> <p>II. Endoscopic screening for Barrett’s esophagus and dysplasia in adults 50 years or older with &gt;5–10 years of heartburn to reduce mortality from esophageal adenocarcinoma.</p> <p>Coverage guidance recommendation revised to recommend against coverage of repeat endoscopy in the absence of significant new symptoms or presence of BE.</p>
6	American Society for Gastrointestinal Endoscopy. (2012). The role of endoscopy in Barrett’s esophagus and other premalignant conditions of the esophagus. <i>Gastrointestinal Endoscopy</i> , 76(6), 1087-1094.	<p>Recommendations pertinent to this guidance include the following:</p> <p>1. Endoscopic screening for BE can be considered in select patients with multiple risk factors for Barrett’s esophagus (BE) and esophageal adenocarcinoma (EAC), but patients should be informed that there is insufficient evidence to affirm that this practice prevents cancer or prolongs life.</p> <p>Risk factors are defined as male sex, white race, age &gt; 50, + family history, increased duration</p>

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	<i>Rated poor quality by CEbP</i>	<p>of reflux symptoms, smoking and obesity.</p> <p>2. We recommend no further endoscopic screening for BE after a screening examination with negative findings.</p> <p>Coverage guidance recommendation revised to recommend against coverage of repeat endoscopy in the absence of significant new symptoms or presence of BE.</p>