Washington State Health Care Authority
Health Technology Assessment

Upper Endoscopy for Gastroesophageal Reflux Disease & Upper Gastrointestinal Symptoms

Health Technology Assessment Program

FINAL EVIDENCE REPORT

Appendices

April 12, 2012

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Upper Endoscopy for Gastroesophageal Reflux Disease (GERD) and Upper Gastrointestinal (GI) Symptoms - Appendices

April 2012

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Appendix A. MEDLINE® Search Strategy

Database: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) <1946 to February Week 1 2012>

Search Strategy:

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1 exp Endoscopy/ (226579)

2 exp Endoscopes/ (19136)

3 1 or 2 (235467)

4 (endoscop$ or gastroscop$ or esophagoscop$ or duodenoscop$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] (153420)

5 3 or 4 (279025)

6 exp Stomach Diseases/di (18998)

7 exp Esophageal Diseases/di (18094)

8 exp Duodenal Diseases/di (8222)

9 exp Upper Gastrointestinal Tract/ (160060)

10 exp diagnosis/ (5821301)

11 di.fs. (1767793)

12 10 or 11 (6464793)

13 9 and 12 (67560)

14 6 or 7 or 8 or 13 (97729)

15 exp "signs and symptoms, digestive"/ (115435)

16 14 and 15 (4556)

17 5 and 16 (1880)

18 (dyspep$ or heartburn$ or ((upset$ or sore$ or ache$ or pain$ or complain$ or symptom$ or bother$) adj5 (stomach$ or esophag$ or belly))).mp. (18154)

19 14 and 18 (4669)

20 5 and 19 (2697)

21 17 or 20 (3626)

22 limit 21 to (english language and yr="2002 -Current") (1432)

23 limit 22 to humans (1416)

24 limit 23 to (controlled clinical trial or meta analysis or randomized controlled trial) (74)

25 limit 23 to systematic reviews (26)

26 exp cohort studies/ (1142513)

27 23 and 26 (506)

28 24 or 25 or 27 (556) **[Effectiveness search results]**

29 exp Postoperative Complications/ (376177)
30 exp Intraoperative Complications/ (32412)
31 29 or 30 (397886)
32 3 and 9 and 31 (1597)
33 exp Gastrointestinal Diseases/ (674951)
34 32 and 33 (993)
35 exp gastroscopy/ae (625)
36 exp esophagoscopy/ae (621)
37 exp duodenoscopy/ae (96)
38 35 or 36 or 37 (1188)
39 34 or 38 (2134)
40 limit 39 to (english language and yr="2002 -Current") (733)
41 limit 40 to humans (711)
42 41 not 28 (670) **[Complications search results]**
43 exp "Costs and Cost Analysis"/ (160841)
44 exp gastroscopy/ (13200)
45 exp esophagoscopy/ (10818)
46 exp duodenoscopy/ (2528)
47 44 or 45 or 46 (24497)
48 exp gastrointestinal diseases/di (112080)
49 15 or 18 (125022)
50 exp Diagnostic Techniques, Digestive System/ (124025)
51 48 or 49 or 50 (320837)
52 43 and 47 and 51 (228)
53 limit 52 to (english language and yr="2002 -Current") (90) **[Cost Effectiveness search results]**

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Appendix B. Excluded Studies

Studies Related to Effectiveness

Study design not relevant

Abe, Y., Iijima, K., Ohara, S., Koike, T., Ara, N., Uno, K., . . . Shimosegawa, T. (2011). A japanese case series of 12 patients with esophageal eosinophilia. *Journal of Gastroenterology, 46*(1), 25-30.

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Rolff, H. C., Simonsen, L. R., & Rosenberg, J. (2011). Clinical findings confirm national guidelines regarding primary gastroscopy for upper gastrointestinal symptoms. *Danish Medical Bulletin, 58*(5), A4363.

Sayilir, A., Kurt, M., Onal, I. K., Beyazit, Y., & Suvak, B. (2011). An unusual complication of peptic ulcer disease: Double pylorus. *Gastroenterology Nursing, 34*(5), 401-402. doi:http://dx.doi.org/10.1097/SGA.0b013e31822c69f9

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Subasinghe, D., & Samarasekera, D. N. (2010). Delay in the diagnosis of esophageal carcinoma: Experience of a single unit from a developing country. *Indian Journal of Cancer, 47*(2), 151-155.

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Non-English Language

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Population not relevant

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Appendix C. Summary of Findings Table for Systematic Reviews and Technology Assessments

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
Delaney	Meta-analysis of 1) Initial endoscopy vs acid suppression (6 studies) and 2) *H. pylori* test and treat vs endoscopy (5 studies)	Adults presenting to primary care or endoscopy unit with uninvestigated dyspeptic symptoms	1) Effectiveness of early investigation vs empiric medication fo symptom score improvement 2) Effectiveness of *H. pylori* test and treat vs endoscopy for symptom score improvement	1) RR 0.89 (95% CI 0.77 to 1.02, p = 0.70) 2) RR 0.95 (95% CI 0.79 to 1.15) *trial-level meta-analysis*	Good Excluded patients with reflux as predominant symptom.
Ford	Individual patient data meta-analysis of *H. pylori* test and treat vs early endoscopy (5 studies)	Adults presenting to primary care or endoscopy unit with uninvestigated dyspeptic symptoms	2) Effectiveness of *H. pylori* test and treat vs early endoscopy on risk of symptoms at 12 months	RR 0.95 (95% CI 0.92-0,99) favoring endoscopy	Good Unblinded trials
Vakil 2006¥	Meta-analysis (retrospective studies and case-control studies with healthy	n=57,363 (17 studies) Inclusion: Prospective data collection, >16 yrs of age, no specific patient selection, dyspepsia/alarm symptoms	Diagnostic performance of alarm features, computer models, clinical opinion, anemia, weight loss for prediction of	POOLED ESTIMATES *≥1 alarm feature (n= 46,161;7 studies)* Sensitivity (0% sensitivity studies excluded): 67% (95% CI: 54%, 83%) with heterogeneity ($Q=7.6_4$, P=11) Specificity (0% sensitivity studies excluded): 66% (95% CI: 55%, 79%) with highly significant	Good Financial interests were not disclosed

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
	controls were excluded)	recorded, record of endoscopic diagnosis, symptoms and endoscopic diagnosis compared, >100 patients evaluated, >1 upper GI cancer diagnosed Exclusion: Not always reported in studies, however GI bleeding and GI surgery were common exclusion factors	malignancy Follow-up N/A	heterogeneity ($Q=1779_4$, $P<0.001$) LR+: 2.74 (95% CI: 1.47, 5.24) *Clinical Opinion (n=3159; 3 studies)* Sensitivity: 29% (95% CI: 10%, 88%) Specificity: 97% (95% CI: 96%, 99%) LR+: Not reported *Computer Models (n=8043; 5 studies)* Sensitivity (0% sensitivity studies excluded): 96% (95% CI: 92%, 100%) with no heterogeneity ($Q=4.4_4$, $P=0.36$) Specificity (0% sensitivity studies excluded): 34% (05% CI: 27%, 44%) with significant heterogeneity ($Q=170_4$, $P<0.0001$) LR+ for malignancy: 1.49 (95% CI: 1.33, 1.67) *Overall Accuracy of all Approaches* Pooled DOR: 7.49 (95% CI: 4.37, 12.8) with significant heterogeneity ($\chi^2=44_{16}$, $P<0.001$) No funnel plot asymmetry. Moderate accuracy of AUC 0.80 (95% CI 0.73, 0.85) according to ROC. LR+: Not reported *Weight Loss (n=48,499; 8 studies)* Sensitivity: 49% (95% CI: 37%, 65%) with significant heterogeneity ($Q=34.0_7$, $P<0.001$)	

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Specificity: 84% (95% CI: 81%, 87%) with significant heterogeneity ($Q=143_7$, $P<0.001$) LR+: Not reported *Dysphagia (n=9646; 5 studies)* Sensitivity: 39% (95% CI: 23, 66) with significant heterogeneity ($Q=19.5_4$, $P<0.001$) Specificity: 85% (95% CI: 78, 92) with significant heterogeneity ($Q=852_4$, P<0.001) LR+: Not reported *Anemia (n=42,3247; 4 studies)* Sensitivity (0% sensitivity study excluded): 13% (95% CI: 8%, 20%) with no heterogeneity ($Q=0.66_2$, $P=0.72$) Specificity (0% sensitivity study excluded): 95% (95% CI: 92%, 97%) with significant heterogeneity ($Q=77_2$, $P<0.001$) LR+: Not reported	
From Vakil 2006 Bytzer 1992	Single center Blinded	n=878 Inclusion: Dyspepsia patients Exclusion: Acute GI bleeding; previous gastric surgery	Diagnostic performance of computer model for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 1.9% (0.9%, 3.6%) NPV: 99.3% (97.8%, 99.8%) LR+: 1.4 (0.87, 1.7) LR-: 0.54 (0.19, 1.2) DOR: 2.6 (0.6, 14.9)	NA
From Vakil 2006 Bytzer 1996	2 centers Blinded	n=1233 Inclusion: Dyspepsia patients	Diagnostic performance of clinical opinion for	*Overall Accuracy (95% CI)* PPV: 9.1% (1.1%, 29%) NPV: 98.9% (98%, 99.4%)	NA

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
		Exclusion: Acute GI bleeding; previous gastric surgery	prediction of malignancy	LR+: 8.1 (2.1, 25.6) LR-: 0.88 (0.63, 0.98) DOR: 9.2 (0.9, 44.8)	
From Vakil 2006 **From Vakil 2006** Heikkinen 2000	4 centers Blinded	n=400 Inclusion: Dyspepsia patients Exclusion: Not reported	Diagnostic performance of clinical opinion for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 8.3% (2.1%, 38%) NPV: 99.6% (99%, 99.9%) LR+: 1.4 (1.03, 1.5) LR-: 0.45 (0.18, 0.96) DOR: 4.2 (0.1, 36)	NA
From Vakil 2006 Manes 2002	21 centers Blinded	n=706 Inclusion: Presenting with dyspepsia during a 1-wk period Exclusion: Not reported	Diagnostic performance of alarm features for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 11% (3%, 25%) NPV: 99.7% (99%, 100%) LR+: 13.7 (5.9, 22.5) LR-: 0.35 (0.1, 0.74) DOR: 39.2 (5.3, 439)	NA
From Vakil 2006 Meineche-Schmidt 2002	82 centers Blinding unclear	n=1441 Inclusion: Presenting with dyspepsia during a 2-yr period Exclusion: Not reported	Diagnostic performance of alarm features, weight loss, dysphagia, anemia for prediction of malignancy	*Overall Accuracy of Alarm Features (95% CI)* PPV: 0.7% (0.2%, 1.7%) NPV: 99.5% (99%, 100%) LR+: 1.2 (0.5, 1.9) LR-: 0.84 (0.36, 1.3) DOR: 1.5 (0.3, 7.8) *Weight Loss (95% CI)* PPV: 1.5% (0.3%, 4.3%) NPV: 99.6% (99%, 99.9%) LR+: 2.8 (1.02, 5.3) LR-: 0.72 (0.35, 0.997)	NA Patients were not consecutive

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Dysphagia (95% CI) PPV: 1.5% (0.3%, 4.3%) NPV: 99.6% (99.1%, 99.9%) LR+: 2.8 (1.02, 5.3) LR-: 0.72 (0.35, 0.996) PPV: 0% (0%, 9.7%) NPV: 99.5% (98.9%, 99.8%) LR+: 0 (0, 13.8) LR-: 1 (0.63, 1)	
From Vakil 2006 Numans 2001	9 centers Blinding unclear	n=2014 Inclusion: Dyspepsia; first endoscopic evaluation Exclusion: Not reported	Diagnostic performance of computer model, weight loss, dysphagia for prediction of malignancy	*Overall Accuracy of Computer Model (95% CI)* PPV: 1.6% (0.9%, 2.7%) NPV: 99.2% (97%, 99.9%) LR+: 1.1 (0.83, 1.2) LR-: 0.56 (0.16, 1.6) DOR: 28.7 (2.8, 152) *Weight loss (95% CI)* PPV: 6.7% (3.7%, 11%) NPV: 98.9% (98%, 99.6%) LR+: 2.9 (1.9, 3.7) LR-: 0.43 (0.22, 0.71) *Dysphagia (95% CI)* PPV: 7.1% (3.9%, 11.9%) NPV: 98.8% (97.6%, 99.5%) LR+: 3 (1.9, 4) LR-: 0.48 (0.21, 0.68)	NA

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
From Vakil 2006 Sung 2001	4 centers Blinding unclear	n=2627 Inclusion: Dyspepsia for ≥4 wks Exclusion: Predominant heartburn, regurgitation, or diarrhea	Diagnostic performance of alarm features, weight loss, dysphagia, anemia for prediction of malignancy	*Overall Accuracy of Alarm features (95% CI)* PPV: 1.2% (0.7%, 1.8%) NPV: 99.6% (99%, 99.9%) LR+: 1.4 (1.03, 1.5) LR-: 0.45 (0.18, 0.96) DOR: 3.0 (1.0, 12.3) *Weight loss (95% CI)* PPV: 15.8% (3.4%, 39.6%) NPV: 99.2% (98.8%, 99.5%) LR+: 21.2 (6.8, 60) LR-: 0.87 (0.68, 0.96) *Dysphagia (95% CI)* PPV: 3.4% (0.09%, 17.8%) NPV: 99.2% (98.7%, 99.5%) LR+: 4 (0.7, 20.4) LR-: 0.97 (0.8, 1) *Anemia (95% CI)* PPV: 1.25% (0.03%, 6.8%) NPV: 99.1% (98.7%, 99.5%) LR+: 1.4 (0.25, 7) LR-: 0.99 (0.81, 1.02)	NA
From Vakil 2006 Fjosne 1986	Single center No blinding	n=1526 Inclusion: All patients referred for upper GI endoscopy	Clinical opinion for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 35% (25%, 47%) NPV: 98.3% (97.5%, 99%) LR+: 15.6 (10.5, 22.4)	NA

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
		Exclusion: Not reported		LR-: 0.49 (0.35, 0.63) DOR: 32.1 (16.4, 62)	
From Vakil 2006 Hansen 1998	Single center Blinding unclear	n=612 Inclusion: Dyspepsia; >18 yrs of age Exclusion: Upper GI bleeding; jaundice; acute abdomen; previous upper GI surgery	Diagnostic performance of alarm features	*Overall Accuracy (95% CI)* PPV: 0% (0%, 26%) NPV: 99.3% (98%, 99.8%) LR+: 0 (0-27) LR-: 1.02 (0.44, 1.01) DOR: 0 (0, 82)	NA
From Vakil 2006 Mann 1983	Single center Blinding unclear	n=235 Inclusion: Endoscopy referral Exclusion: Not reported	Diagnostic performance of computer model for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 8% (3.9%, 14%) NPV: 99.1% (95%, 100%) LR+: 1.8 (1.2, 2.1) LR-: 0.19 (0.03, 0.78) DOR: 9.5 (1.3, 415)	NA Computer model used data that was prospectively collected but retrospectively fitted to findings in the study population and is likely to overestimate accuracy
From Vakil 2006 Holdstock 1986	Single center Blinding unclear	n=1279 Inclusion: Endoscopy referral Exclusion: Gastric surgery; previous endoscopy	Diagnostic performance of computer model for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 6.7% (5%, 8.7%) NPV: 100% (99.3%, 100%) LR+: 1.8 (1.6, 1.8) LR-: 0 (0, 0.16)	NA Unclear whether patients were

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				DOR: ∞(10 to ∞)	consecutive
From Vakil 2006 Voutilainen 2003	Single center Blinding unclear	n=3378 Inclusion: Endoscopy referral over 1-yr period Exclusion: Not reported	Diagnostic performance of alarm features for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 1.1% (0.6%, 1.9%) NPV: 99.8% (99.5%, 99.9%) LR+: 2.2 (1.4, 2.7) LR-: 0.44 (0.2, 0.79) DOR: 5 (1.6, 18.1)	NA Unclear whether patients were consecutive
From Vakil 2006 Thomson 2003	39 centers Blinded	n=1037 Inclusion: Dyspepsia Exclusion: Documented upper GI pathology; previous GI surgery; previous endoscopy; *H. Pylori* treatment ≤6 mos before study; proton pump inhibitor ≤30 days before study	Diagnostic performance of alarm features for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 0% (0%, 12%) NPV: 99.8% (99%, 100%) LR+: 3.9 (3.1, 4.6) LR-: 0.52 (0.4, 0.64) DOR: 7.4 (4.8, 11.6)	NA
From Vakil 2006 Lieberman 2004	Multicenter No blinding	n=36,357 Inclusion: Upper GI endoscopy; alarm symptoms other than dysphagia	Diagnostic performance of alarm features, weight loss, anemia for prediction of malignancy	*Overall Accuracy of Alarm features (95% CI)* PPV: 0.9% (0.7%, 1.2%) NPV: 99.9% (99.8%, 100%) LR+: 3.9 (3.1, 4.6) LR-: 0.52 (0.4, 0.64) DOR: 7.4 (4.8, 11.6) *Weight loss (95% CI)* PPV: 2.7% (1.9%, 3.7%) NPV: 99.9% (99.8%, 99.9%) LR+: 11.2 (8.6, 14) LR-: 0.6 (0.49, 0.7)	NA Unclear whether patients were consecutive; 2% of patients excluded because of incomplete data

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Anemia (95% CI) PPV: 1% (0.5%, 1.7%) NPV: 99.8% (99.7%, 99.8%) LR+: 4.1 (2.4, 6.7) LR-: 0.89 (0.81, 0.95)	
From Vakil 2006 Kapoor 2005	Single center No blinding	n=3637 Inclusion: Suspected upper GI cancer; GP requested immediate (within 2 wks) endoscopy Exclusion: Not reported	Computer model, weight loss, dysphagia, anemia for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 4% (2.9%, 5.2%) NPV: 99.3% (98.2%, 99.8%) LR+: 1.4 (1.2, 1.5) LR-: 0.24 (0.09, 0.56) DOR: 5.8 (2.1, 22.3) *Weight loss (95% CI)* PPV: 6.8% (4.8%, 9.2%) NPV: 97.6% (96.7%, 98.4%) LR+: 1.9 (1.5, 2.3) LR-: 0.64 (0.48, 0.8) *Dysphagia (95% CI)* PPV: 6.5% (4.7%, 8.75%) NPV: 97.6% (96.6%, 98.4%) LR+: 1.8 (1.4, 2.1) LR-: 0.62 (0.46, 0.8) *Anemia (95% CI)* PPV: 4.9% (2.3%, 9.1%) NPV: 96.3% (95.3%, 97.2%) LR+: 1.3 (0.7, 2.4)	NA

Reference	Study Design	Patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				LR-: 0.97 (0.86, 1.03)	
From Vakil 2006 Crean 1994	Single center No blinding	n=1540 Inclusion: Upper GI symptoms; recruited when participating clinician available Exclusion: Not reported	Diagnostic performance of weight loss for prediction of malignancy	Overall *Accuracy (95% CI)* PPV: 8.3% (5.9%, 11.4%) NPV: 98.7% (97.9%, 99.3%) LR+: 2.7 (2.2, 3.2) LR-: 0.38 (0.24, 0.57)	NA Patients were not consecutive
From Vakil 2006 Adang 1995	Single center No blinding	n=2900 Inclusion: Upper GI symptoms or GI bleeding Exclusion: Not reported	Diagnostic performance of weight loss, dysphagia	*Overall Accuracy of Weight loss (95% CI)* PPV: 11.7% (7%, 18.1%) NPV: 98% (97.4%, 98.5%) LR+: 5.3 (3.3, 8) LR-: 0.79 (0.68, 0.88) *Dysphagia (95% CI)* PPV: 5.2% (2.4%, 9.6%) NPV: 99.8% (99.5%, 99.9%) LR+: 10.4 (6.1, 14.5) LR-: 0.42 (0.21, 0.68)	NA 3% of patients had limited or no endoscopic results or
From Vakil 2006 Johannessen 1990	Single center Blinding unclear	n=930 Inclusion: Referred for upper GI endoscopy; alimentary tract symptoms Exclusion: Missing symptom data; insufficient endoscopy data	Diagnostic performance of weight loss for prediction of malignancy	*Overall Accuracy (95% CI)* PPV: 2.8% (1.1%, 5.7%) NPV: 99.7% (98.9%, 100%) LR+: 2.9 (1.7, 3.7) LR-: 0.3 (0.09, 0.75)	NA

Appendix D. Summary of Findings Table for Individual Studies

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
Bowrey 2006	Cross-sectional study using a prospectively compiled database	n=4018 Esophagogastric carcinoma , 123 Median age, yrs: 66; 69 (*P*=0.02) Sex (M:F): 13:65; 80:24 (NS) Inclusion: Referral and completion of gastroscopy Exclusion: Not reported	Association between alarm symptoms and esophagogastric cancer and between age and carcinoma Differences in disease characteristics between asymptomatic and symptomatic carcinoma. Median follow-up (to assess survival): 120 mos (range 87-161)	*Association of age w/ esophagogastric carcinoma (n=4009):* Age (yrs): <35 vs ≥35, 0 vs 3.3%; <45 vs ≥45, 0.4%, 3.9%; <55% vs ≥55, 0.9% vs 5.1% Frequency of cancer increased significantly w/ increasing age (x^2=126; *P*<0.00001) *Prevalence of alarm symptoms in patients with esophagogastric carcinoma:* 85% (104/123) *% patients with esophagogastric carcinoma (n=123) who had UICC stage III-IV cancer, according to alarm symptom:* Epigastric mass, 100%; anemia, 89%; vomiting, 62%; dysphagia, 78%; weight loss, 87%; uncomplicated dyspepsia, 48% *Differences in patients with esophagogastric carcinoma (n=123): No Alarm Symptoms, Alarm Symptoms* UICC tumor stage I-IV, n (%) (global *P*<0.001): I: 8 (42%); 9 (9%), II: 2(11%); 18(17%) III: 7(37%); 28 (27%) IV: 2(11%); 52(50%) Surgical resection, n (%): 18(95%); 52 (50%); *P*<0.001	Fair Financial disclosure was not reported Not clear if study population is representative of wider pt population; no ORs reported; not clear if the structured pt questionnaire adequately detected presence of alarm symptoms or not; no simultaneous adjustment for multiple factors (e.g., age, sex, presence of alarm symptoms

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Median survival (mos), n (95% CI): 39 (9-69); 11 (8-14) (*P*=0.01) 5-yr survival, n (%): 8(42); 13(13); *P*=0.005 (only survivors were those pts who had undergone resection)	
Connor 2004	Retrospective chart review	n=264 Mean age 57 yrs Men: 95% NSAID use: 51% Symptoms: dyspepsia only, 70%; dyspepsia + GERD, 23%; dyspepsia + nausea + vomiting, 6%; dyspepsia + GERD + nausea + vomiting, 1% Diagnosis: Barrett's esophagus, 6.1%; erosive esophagitis, 23.8%; gastric ulcer, 7.2%; duodenal ulcer, 2.3% Inclusion: Upper endoscopy for dyspepsia; dyspepsia symptoms ≥3 mos Exclusion: Concurrent alarm symptoms (weight loss, anemia, dysphagia, GI bleeding, or abdominal mass); peptic ulcer disease; previous upper GI	Association between presence of Barrett's esophagus and/or erosive esophagitis and patient demographics (age, gender, race), ASA/NSAID use, and presence of hiatal hernia in patients undergoing endoscopy No follow-up	30% of patients had esophageal lesions Demographics (Barrett's; erosive esophagitis): Number: 16; 62 Age, yrs: 60.1; 57.2 % Men: 100; 98.2 Caucasian race, %: 93.8, 78.9 The only association that was significant was hiatal hernia, which was significantly associated with the presence of either Barrett's esophagus or erosive esophagitis (*P*=0.0032)	Poor Conflicts of interest not reported Retrospective; tertiary care center with elderly and cormorbid patient base; univariate analysis only
Madan 2005	Case series	n=70 Mean age: 34.4±11.11 yrs Men/Women: 47/23	Study conducted to find a single test or	39/109 patients recruited were excluded from analysis, primarily because data on all 6 tests were not available.	Fair Conflicts of interest

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
		Duration of symptoms: 2.88±3.27 yrs Inclusion: 19-79 yrs of age; heartburn and/or regurgitation ≥2 days/wk for ≥6 wks Exclusion: Dysphagia symptoms; evidence of stricture; alarm symptoms (weight loss, GI bleed, anemia)	combination of tests to serve as a gold standard for diagnosis of GERD. All patients underwent omeprazole challenge; endoscopy; histology; barium swallowing; scintigraphy; 24-hr pH monitoring For purposes of evaluating each test, a concordance of ≥3 positive tests was used as the gold standard No follow-up	NOTE: *J* statistic is a measure of diagnostic performance that simultaneously reflects sensitivity and specificity. <u>Test results for all patients</u> *Positive result, Sensitivity, Specificity, PPV, NPV, Accuracy, J-value:* Omeprazole challenge: 70%, 84.4%, 56%, 77.5%, 66.6%,74.2%, 0.4 Endoscopy: 47.1%, 64.4%, 84%, 87.8%, 56.7%, 0.48 Histology: 68.6%, 82.2%, 60%, 78.75, 65.1%, 74.2%, 0.42 Barium swallow: 20%, 26.65, 92%, 85.7%, 41%, 50%, 0.18 Scintigraphy: 11.4%, 15.5%, 96%, 87.5%, 38.7%, 38.7%, 44.2%, 0.11 pH monitoring: 68.6%, 77.7%, 92%, 94.5%, 69.6%, 82.2%, 0.69 (BEST SINGLE TEST) Among patients with endoscopy-negative reflux disease, erosive esophagitis were significantly older (*P*=0.006) and had a history of regular alcohol consumption (*P*=0.048) than those who had no erosive eophagitis <u>Test results for endoscopy-negative patients (n=54)</u>	not reported Variability in duration of symptoms (long-term treatment with antisecretory drugs could alter endoscopic aspect and/or histologic data), but authors did not comment on representativeness of study sample; 35% of enrolled patients were excluded from study; no estimation of variability in sensitivity/specificity values

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Positive result, Sensitivity, Specificity, PPV, NPV, Accuracy, J-value: Omeprazole challenge: 93.75%, 57.1%, 62.5%, 92.3%, 72.9%, 0.5 pH monitoring: 93.3%, 90.4%, 87.5%, 955, 91.6%, 0.83 (BEST SINGLE TEST) Histology: 100%, 57.1%, 64%, 100%, 75.6%, 0.57 Scintigraphy: 12.5%, 95.2%, 66.6%, 58.85, 59.4%, 0.07 Barium swallow: 6.25%, 90.4%, 33.3%, 55.8%, 54%, -0.04 Best combination of tests: OCT+endoscopy+histology has a sensitivity of 100% for GERD. Given the high prevalence of GERD in the study sample (91.4%), pH monitoring could be reserved for patients with negative results in the combination test.	
Marmo 2005	Cross-sectional (data prospectively entered by endoscopist) Training sample was used to	Training sample, 5224 External validation sample, 3684 (reflects exclusion of 911 from training sample and 645 from validation sample because of complicated dyspepsia) *Final Training; Validation:*	Diagnostic performance of predictors derived from training sample for detecting malignancy in uncomplicated dyspepsia Diagnostic	In both samples, patients w/ malignancy were significantly (*P*<0.0001) older than patients w/out (66.2 vs 49.7; 59.5 vs 45.3) and women w/malignancy were older than men w/ malignancy (72.7 vs 63.6, *P*<0.05; 61.7 vs 49.6, *P*=0.08) *Training sample results using age and sex as predictors:* Women less likely than men to have malignancy. Age cut-off 35 yrs for men	Good Financial disclosure was not reported Lack of blinding of endoscopist

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
	establish a 5th percentile age cutoff value	Mean age: 49.3 yrs; 48.6 yrs Men: 58%, 58% % pts w/ malignancy who were >45 yrs: 82%; 75% % patients w/malignancy who were women: 27.3%; 50% In overall population, before exclusion of complicated dyspepsia, training and validation samples were very similar demographic and clinical characteristics. Inclusion: Uninvestigated (no prior x-ray or endoscopy) and uncomplicated (no alarm symptoms or chronic use of NSAIDs) dyspepsia; complete diagnostic examination of the esophagus, stomach, and duodenum; no proven preprocedure upper GI diagnosis; no previous variceal treatment dilation, stenting, tumor ablation, or foreign body removal; no recent endoscopy or barium meal Exclusion: Not reported	surrender=ratio of # patients w/ malignancy plus satisfaction of age/sex cutoff criteria to # patients with malignancy and not meeting cutoff criteria. No follow-up	and 57 yrs for women. NNE to detect 1 cancer: Age >45, 160; female sex, 367; age >35 and male sex, 154; age >57 and female sex, 108 *Diagnostic performance in validation sample (95% CI):* <u>Age according to guidelines cutoff (<45 vs >45 yrs):</u> OR=0.4194 (0.114 to 1.399) NNE: 400 <45;174 >45 Diagnostic surrender: 75% (47.6 to 92.7) Sensitivity: 0.57% (0.3 to 1) Specificity: 99.7% (99.3 to 99.9) LR +: 2.262 (1.233 to 9.777) LR -: 0.996 (0.992 to 1.001) <u>Sex (male vs female):</u> OR: 1.383 (0.472 to 4.65) NNE: 270 men; 196 women Diagnostic surrender: 50% (24.6 to 75.3) Sensitivity: 0.37% (0.16 to 0.74) Specificity: 99.4% (98.9 to 99.7) LR+: 0.723 (0.282 to 1.858) LR-: 1.001 (0.997 to 1.006) <u>Gender for Age (men <35 vs men >35):</u> OR: 0.4642 (0.59 to 3.73) NNE: 526 for <35; 239 for >35 Diagnostic surrender: 87.5% (24.6 to 75.3) Sensitivity: 0.37% (0.16 to 0.74) Specificity: 99.4% (98.9 to 99.7) LR +: 2.15 (0.34 to 13.38) LR-: 0.997 (0.992 to 1.007) <u>Gender for Age (women <57 vs women >57):</u> OR: 0.1347 (0.034 to 0.736)	

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				NNE: 555 for <57; 77 for >57 Diagnostic surrender: 75% (34.9 to 96.8) Sensitivity: 1.34% (0.49 to 2.89) Specificity: 99.8% (99.3 to 99.9) LR+: 7.343 (1.701 to 31.705) LR-: 0.9888 (0.972 to 0.996)	
Rossi 2002	Prospective case series	n=1777 Mean age: 60 yrs, range 16-92 Men: 52% Inclusion: Referral for upper GI endoscopy Exclusion: None	Association of ASGE indications with endoscopic findings	Pts underwent endoscopy primarily for dyspepsia (53.5%) associated with age >45 yrs (27%), failure of therapy (15.6%), or alarm symptoms (13%). Indication for endoscopy was appropriate by American Society for Gastrointestinal Endoscopy (ASGE) criteria in 84.4% of cases. *% patients with endoscopi diagnosis (ASGE indications present; non-ASGE):* Total: 47.4%; 28.8% (OR: 2.23; 99% CI: 1.55, 3.22; *P*<0.01) Erosive gastritis: 24.3%; 14.7% (OR: 1.86; 99% CI: 1.17, 2.95; *P*<0.01) Erosive esophagitis: 15.2%; 10.9% (OR: 1.48; 99% CI: 0.87, 2.52; *P*<0.05) Barrett's esophagus: 3.4; 0.4 (OR: 9.76; 99% CI; 0.72, 132; *P*<0.05)	Fair Conflicts of interest not reported Similarity in duration of symptoms unknown
Veldhuyzen Van Zanten 2006	Cross sectional study	1040 pts who underwent endoscopy Gastric biopsies were obtained from all pts for histological diagnosis of *Helicobacter pylori* infection 95% of pts were Caucasian	Relationship between prevalence of Barrett's Esophagus and prevalence of potential risk factors for disease.	*Prevalence of Barrett's Esophagus suspected on endoscopy:* 5% (53/1040) Of 53 suspected cases: 30 pts >50 yrs; 14 pts >60 yrs; 9pts >65 *Prevalence of Barrett's Esophagus confirmed*	Poor Financially supported by AztraZeneca Canada Potential confounding factors not controlled for when identifying

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
		Inclusion criteria: >18 yrs of age; primary complaint of ≥3 mos of either continuous or intermittent dyspepsia of any severity Exclusion criteria: Documented history of upper GI pathology or surgery; clinical endoscopic or radiological evaluation of dyspepsia in past 6 months or on > 2 occasions in past 10 years; use of proton pump inhibitors w/in 30 days or H_{-2} receptor antagonists w/in 14 days of study enrollment.		*histologically:* n=25; 2.4% [mean age, 53 yrs; M/F, 17/8, *P*=0.068). Mean duration of dyspeptic symptoms in 25 confirmed pts: 10 yrs Pts w/ symptoms <5 yrs duration: n=11(44%) Pts w/ symptoms <1 yr duration: n=4 (16%) Of 25 confirmed pts, 16 (64%) reported either heartburn or acid regurgitation as dominant dyspepsia symptom compared w/ 377/1015 (37%) of pts w/o Barrett's Esophagus (*P*=0.0062). NS differences in BMI between pts w/ confirmed Barrett's Esophagus and population as a whole. *Prevalence of confirmed Barrett's Esophagus by age*: >50 yrs: 15/379; 4% Of these 15 pts, 5 pts >60 yrs (3%); 5 pts >65 yrs (5%) 2 pts >70 yrs (5.7%) Disease significantly more common in pts >50 yrs (4%; 15/379) compared with younger pts (1.5%; 10/661) (*P*=0.013) *Prevalence of hiatus hernia:* 235/1040; 23%	identify associations between various factors and disease outcomes; missing data; according to authors, study was not specifically designed to assess prevalence for Barrett's Esophagus and prevalence of disease may have been underestimated

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
				Confirmed Barrett's Esophagus: 3% (7/235) of pts also diagnosed w/ hiatus hernia compared w/ 2% (18/805) of pts w/o hiatus hernia (NS) *Prevalence of reflux esophagitis:* 17/25 (68%) confirmed Barrett's Esophagus pts compared w/ 434/1015 (43%) of pts w/o Barrett's Esophagus *Prevalence of Helicobacter Pylori:* *Helicobacter pylori* present in 7/25 (28%) confirmed cases and absent in 18/25 (72%) (*P*=0.012) Overall prevalence of Helicobacter Pylori: 30% in 1013 histologically confirmed pts Confirmed Barrett's Esophagus observed in pts w/ dominant reflux-like (4%), ulcer-like (1%), and dysmotility-like symptoms (2%).	
Westbrook 2005	Retrospective cohort study (chart review and telephone interview)	n=302 Mean age: Men, 48 yrs; Women, 52 yrs Endoscopic diagnosis: esophagitis, 126; esophagitis and peptic ulcer, 26; normal findings with reflux symptoms, 53; normal findings without reflux symptoms, 66; peptic ulcer,	Change in symptom status and medication at long-term follow-up after endoscopic diagnosis Initial assessment: 18 mos following	399/495 patients (81%) eligible for initial assessment; there were no differences between eligible and ineligible groups. 302/399 patients (76%) were available for long-term follow-up, there were no differences between completers and dropouts in age, sex, or diagnosis. No association between diagnosis and age or diagnosis and sex.	Good Financial disclosure was not reported, but study funding was noncommercial Follow-up data obtained by telephone interview

Reference	Study Design	Sample size; patient Characteristics	Type of Relationship Follow-up	Factors Assessed Main Findings	Quality Comments
		31 Inclusion: >16 yrs of age; dyspeptic symptoms, initial upper GI endoscopy; at least 1 of 10 upper GI symptoms (epigastric pain, nausea, vomiting, heartburn, acid regurgitation, anorexia, dysphagia, bloating, early satiety, belching) Exclusion: Inpatient; GI bleed; history of peptic ulcer disease or cancer; previous endoscopy; history of gastric surgery	endoscopy Follow-up: 8-9 yrs following endoscopy	62/119 patients (52%) with normal endoscopic results and 116/183 patients (63%) with abnormal endoscopic results were still symptomatic long-term follow-up; no significant global association between endoscopic diagnosis and symptom outcome. However, the proportion of patients taking H2RA and receiving a normal endoscopic diagnosis diminished from 40% to 20%. No change in use of PPIs with respect to diagnosis was observed. (Proportions calculated from data supplied by study authors.)	

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments

Appendix E. Summary of Findings Table for Economic Evaluation Studies

Barkun 2010 (Economic Evaluation - Canada)	1.Symptom-free mos 2.QALYs 3.Dir.costs ($C) 4.ICER 5.CEACurve	4 CADET studies n=2236	Adults pres to PCP with 3-mo uninvestigated dyspepsia (CanDys def'n)	1.CanDysOmeprazole 2. CanDysRanitidine 3. Emp. Omeprazole 4. Emp. Ranitidine 5. Endoscopy+PPI 6. Endoscopy+H2RA	12 mo	1. **217** (139-448) 2. **252** (128-635) 3. **213** (73-777) 4. **255** (59-1,276) 5. **1,560** (647-4,533) 6. **1,225** (756-2,108)	**QALYs** 1.**0.9444** (0.9401-0.9490) 2. **0.9419** (0.9378-0.9462) 3. **0.9425** (0.9386-0.9465) 4. **0.9401** (0.9364-0.9438) 5. **0.9577** (0.9533-0.9621) 6. **0.9557** (0.9595-0.9610)	**C$/iQALY** **1v3. +26,321** (-519,155 to +492,323) **2v3. -121,104** (-742,429 to +727,877) **4v3. +58,448** (-746,485 to +703,044) **6v3. +82,497** (+20,709 to +190,546) **5v3. +92,690** (+18,133 to +306,405) **5v1. +109,163** (+27,607 to +355,615) **6v1. +108,415** (+37,555 to +253,817) **6v5. +372,704** (-2.25M to +2.54M)	CanDys Omeprazole most cost-effective at WTP C$30K-70K/QALY	Good	Individual pt data from a series of Canadian studies. Concludes that no strategy is the overwhelming cost-effective choice.

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments
Barton 2008 (2nd-Order Simulation Model – US)	1. QALYs 2. Dir. Costs ($US) 3.ICER 4. CEA Curve	n=10,000 hypothetical patients	Hypothetical adults with uninvestigated dyspepsia	1. Antacid (base) 2. H2RA 3. PPI then scope (no bx) 4. PPI 5. Scope (no bx) 6. ELISA and treat 7. UBT-treat-PPI-scope 8. Scope (biopsy all) 9. UBT and treat 10. PPI then scope (biopsy all)	5 years	**US$-60 yo** 1. 2842 2. 4103 3. 4298 4. 4070 5. 4557 6. 4087 7. 4315 8. 4486 9. 4087 10. 4334 **US$-30 yo** 1. 1976 2. 2897 3. 3591 4. 3986 5. 3340 6. 3842 7. 4008 8. 3581 9. 3598 10. 3656	**QALY-60yo** 1. 4.2031 2. 4.2281 3. 4.3665 4. 4.3680 5. 4.3712 6. 4.3852 7. 4.3852 8. 4.3860 9. 4.3876 10. 4.3942 **QALY-30yo** 1. 4.2004 2. 4.2203 3. 4.3381 4. 4.3387 5. 4.3404 6. 4.3488 7. 4.3496 8. 4.3497 9. 4.3511 10. 4.3541	**US$/QALY-60yo** 2v1. Domin. 3v1. Domin. 4v1. 7,440 5v1. Domin. 6v1. 6,830 7v1. Domin. 8v1. Domin 9v1. 6740 10v1. 7800 3v9. 37,500 **US$/QALY-30yo** 2v1. 46,300 3v1. Domin. 4v1. 9,740 5v1. Domin. 6v1. 10,800 7v1. Domin. 8v1. Domin. 9v1. 10,800 10v1. 10,900 3v5. 23,100	For 30yo, neither T&T nor EGD likely to be CE (slowly rising CEAC). PPI flat curve vs. H2RA For 60yo, T&T is flat & shallow CE across WTP	Good	Empirical PPI is the choice in 30yo In pts >55yo, T&T is most CE, early endoscopy is reasonable

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments
Duggan 2008 (RCT – UK)	1. Symptom &Satisfaction Questionnaire 2. GP consult for dyspepsia 3. Dyspepsia prescribing 4. Hospital referral for dyspepsia 5. Endoscopy	762 recruited; 753 completed	Adults presenting to a GP between 1995-1998 with uninvestigated dyspeptic symtoms	1. Early EGD 2. Test&Refer 3. Test&Treat 4. Empiric PPI	12mo	**£/12mo** 1. 265 2. 199 3. 159 4. 174	**% symptom-free/12 mo** 1. 55% 2. 53% 3. 52% 4. 50%	NA	T&T dominates at low WTP; EGD overcomes but point of intersection sensitive to EGD costs	Fair	Empiric PPI pts had high rates of subsequent EGD; T&T cheapest due to lowest # of EGDs overall
García-Altés 2005 (Decision analysis – Spain)	% asymptomatic patients	NA	Adults presenting to GP with uninvestigated dyspepsia	1. Endoscopy 2. Score & Scope (*locally validated instrument*) 3. Test & Scope 4. Test & Treat 5. Empiric PPI	NA	**€/patient** 1. 157.53 2. 105.85 3. 202.82 4. 152.91 5. 75.89	**% symptom-free** 1. 38.4 2. 34.7 3. 35.5 4. 35.3 5. 28.5	**€/asymptomatic patient** 1v5. 1396.85 2v5. 483.17 3v5. Dominated 4v5. Dominated	NA	Fair	Sensitivity analysis shows values of ICER vary with age but order does not

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments
Ginannini 2008 (RCT – Italy)	1. Symptom score 2. Direct medical cost 3. QOLRAD	612	Patients 18-70yo at GI centers w/3mo typical GERD symptoms, no alarm symptoms	1. Empiric Omeprazole 2. Endoscopy	24wk	**€/patient** 1. 88.34 2. 127.06	**% Responders** 1. 71.8% 2. 68.3% **QOLRAD** No sig difference, either group	NA	NA	Poor	Empiric tx and positive endoscopy got same 40mg PPI; negative endoscopy got 20mg PPI.
Kjeldsen 2007 (CE analysis of RCT data – Denmark)	1. Days free of dyspepsia 2. % symptom-free at 1 yr	368	Dyspeptic patients ≥18yo at PC practice	1. Empiric PPI x 2 weeks 2. Endoscopy	12 mo	**€/Patient (including indirect)** 1. 488 (407-569) 2. 887 (775-998) **€/Patient (Direct only)** 1. 321 (241-400) 2. 570 (462-688)	**Days w/o dyspepsia (pt report)** 1. 205.0 2. 207.6 **% symptom-free @12 mo (pt report)** 1. 21 2. 24 **% symptom-free @12 mo (GP report)** 1. 55 2. 61	**€/symptom-free day (pt report)** 154 (-989 to 1012) **€/pt symptom-free at 12 mo (pt report)** 13,905 (-99,077 to 117,661) **€/pt symptom-free at 12 mo (GP report)** 5,990 (-46,986 to 61,147)	Flattens out near 80% at WTP ~€300 (favors PPI) Sensitive to age; ICER higher for EGT in pts <45 yo	Poor	EGD slightly more effective but much more expensive; when predominant symptom was reflux, PPI was both cheaper and more effective

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments
Klok 2005 (RCT – Netherlands)	1. QALY (RAND-36)	281	Dyspeptic patients ≥18yo at PC practice	1. Test & Treat 2. Prompt EGD	12 mo	**€/patient** 1. 511.02 2. 748.08	**QALY/pt** 1. 0.037 2. 0.032	**€/QALY** 47,412	NA	Poor	Suggests test-and-treat is slightly more effective while being less costly
Makris 2003 (Decision model – Canada)	1. Symptomatic cure	NA	Adults 18-45yo(group A) and >45yo (group B) with uninvestigated dyspepsia	1. Empirical antisecretory 2. Barium meal test 3. Endoscopy 4. Sequential test 5. Serology 6. Empirical eradication 7. Urea breath test	12 mo	**C$/pt (Grp A)** 1. 629.04 2. 748.71 3. 791.13 4. 807.56 5. 775.48 6. 802.41 7. 838.91 **Grp B not reported**	**% cured (Grp A)** 1. 27.14 2. 29.86 3. 30.58 4. 32.00 5. 32.07 6. 32.49 7. 32.84 **Grp B not reported**	**C$/Cure (A)** 2v1. Dominated 3v1. Dominated 4v1. Dominated 5v1. 2,970 6v1. 6,412 7v1. 10,429 **C$/Cure (B)** 7v1. 10,835 7v2. 4,114	NA	Good	
Spiegel 2002 (Decision Analysis – US)	1. Symptomatic cure 2. QALYs	NA	Patients < 45 yo presenting to PCP with upper abd pain, no alarm symptoms, reflux/regurg not dominant	1. T&T→EGD 2. T&T→PPI→EGD 3. PPI → EGD 4. PPI→ T&T→EGD	12 mo	**US$/pt** 1. 1902 2. 1680 3. 1628 4. 1788	**% cured** 1. 75 2. 84 3. 78 4. 84 **QALY** 1. 0.92 2. 0.98 3. 0.97 4. 0.98	**US$/Cure** 1. 2535 2.1996 3. 2078 4. 2124 **US$/QALY** 1. 2067 2. 1714 3. 1678 4. 1824	NA	Good	Sensitivity analysis confirmed results of base-case scenario. CoI not reported

Reference (type of evidence*)	Outcomes	No of Participants (No of trials)	Participant characteristics	Intervention	Median follow-up	Costs (Range)	Effectiveness (Range)	ICER (95% CI)	CEA Curve	Quality‡	Comments
You 2006 (Markov analysis – China)	1. Healed ulcer	NA	Pts presenting w/weekly attacks of heartburn, regurgitation	1. No therapy 2. Empirical PPI 3. Test & Treat 4. Endoscopy	12 mo	**US$/pt** 1. 14 2. 1548 3. 1742 4. 1784	**% Healed** 1. 1.5 2. 72.6 3. 98.7 4. 100	**US$/Healed** 2v1. 2158 3v1. 1778 4v1. 1797	NA	Good	Conclusion that T&T most CE is sensitive to prevalence of *H. pylori*

Appendix F. Quality Assessment of Selected Guidelines

Key Criteria	Guideline Developer, Year				
	AGA, 2008 (GERD)	**ASGE, 2007 (Dyspepsia)**	**ASGE, 2006 (Endoscopic practice for the elderly)**	**ASGE, 2007 (Mgmt of GERD)**	**UMHS, 2007 (GERD)**
Section 1: Primary Criteria					
Rigor of Development: Evidence	Good	Good	Poor	Good	Poor
Rigor of Development: Recommendations	Good	Fair	Poor	Fair	Fair
Editorial Independence	Fair	Poor	Poor	Poor	Good
Section 2: Secondary Criteria					
Scope and Purpose	Good	Good	Good	Good	Good
Stakeholder Involvement	Good	Fair	Fair	Fair	Poor
Clarity and Presentation	Good	Good	Good	Good	Good
Applicability	Fair	Fair	Fair	Fair	Fair
Section 3: Overall Assessment of the Guideline					
How well done is this guideline?	**Good**	**Poor**	**Poor**	**Poor**	**Poor**

Appendix G. Quality Assessment Tools

MED PROJECT	**Methodology Checklist: Systematic Reviews and Meta-analyses**
Study citation (*Include last name of first author, title, year of publication, journal title, pages*)	
MED Topic:	Key Question No.(s):
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY					
In a well conducted systematic review		***In this study the criterion is met:***			
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	UNCLEAR	N/A
1.2	An adequate description of the methodology used is included, and the methods used are appropriate to the question.	YES	NO	UNCLEAR	N/A
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	YES	NO	UNCLEAR	N/A
1.4	The criteria used to select articles for inclusion is appropriate.	YES	NO	UNCLEAR	N/A
1.5	Study quality is assessed and taken into account.	YES	NO	UNCLEAR	N/A
1.6	There are enough similarities between the studies selected to make combining them reasonable.	YES	NO	UNCLEAR	N/A
1.7	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.8	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY					
2.1	How well was the study done to minimize bias? *Code: Good, Fair or Poor*	GOOD	FAIR	POOR	

2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this key question?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	**Methodology Checklist: Randomized Controlled Trials**

Study identification (*Include author, title, year of publication, journal title, pages*)

MED topic: | Key Question No(s):

Checklist completed by: | Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***In this study this criterion is met:***
RANDOM ALLOCATION OF SUBJECTS		
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.	YES NO UNCLEAR N/A
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.	YES NO UNCLEAR N/A
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP		
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.	YES NO UNCLEAR N/A
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.	YES NO UNCLEAR N/A
1.6	The study had an appropriate length of follow-up.	YES NO UNCLEAR N/A
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).	YES NO UNCLEAR N/A

1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out before the study was completed? What percentage did not complete the intervention(s)?	
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP, Cont.		
1.10	All relevant outcomes are measured in a standard, valid and reliable way.	YES NO UNCLEAR N/A
1.11	The study reported only on surrogate outcomes. (If so, please comment on the strength of the evidence associating the surrogate with the important clinical outcome for this topic.)	YES NO UNCLEAR N/A
1.12	The study uses a composite (vs. single) outcome as the primary outcome. If so, please comment on the appropriateness of the composite and whether any single outcome strongly influenced the composite.	YES NO UNCLEAR N/A
CONFLICT OF INTEREST		
1.13	Competing interests of members have been recorded and addressed.	YES NO UNCLEAR N/A
1.14	Views of funding body have not influenced the content of the study.	YES NO UNCLEAR N/A
Section 2: Overall Study Assessment		
2.1	How well was the study done to minimize bias? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	**Methodology Checklist: Cohort Studies**

Study identification (*Include author, title, year of publication, journal title, pages*)

Review topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted cohort study:	***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	YES NO N/A
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	YES NO N/A
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	YES NO N/A
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis.	YES NO N/A
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	
1.6	Comparison is made between full participants and those who dropped out or were lost to follow up, by exposure status.	YES NO N/A
ASSESSMENT AND FOLLOW-UP		
1.7	The study employed a precise definition of outcome(s) appropriate to the key question(s).	YES NO N/A
1.8	The assessment of outcome(s) is made blind to exposure status.	YES NO N/A
1.9	Where outcome assessment blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	YES NO N/A
1.10	The measure of assessment of exposure is reliable.	YES NO N/A

1.11	Exposure level or prognostic factor is assessed more than once.	YES NO N/A
1.12	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	YES NO N/A
1.13	The study had an appropriate length of follow-up.	YES NO N/A
1.14	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	YES NO N/A
CONFOUNDING		
1.15	The main potential confounders are identified and taken into account in the design and analysis.	YES NO N/A
STATISTICAL ANALYSIS		
1.16	Have confidence intervals been provided?	YES NO N/A
CONFLICT OF INTEREST		
1.17	Competing interests of members have been recorded and addressed.	YES NO N/A
1.18	Views of funding body have not influenced the content of the study.	YES NO N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair, or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO N/A
2.4	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	YES NO N/A
2.5	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	**Methodology Checklist: Case Series**

Study identification (*Include author, title, year of publication, journal title, pages*)

Review topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

Section 1: Internal validity				
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	N/A
SELECTION OF SUBJECTS				
1.2	Were the patient characteristics clearly described?	YES	NO	N/A
1.3	Was the likelihood that some eligible subjects might have the outcome at the time of enrollment assessed and taken into account in the analysis (pertinent for screening and diagnostic topics)?	YES	NO	N/A
1.4	Was the study based on a consecutive sample or other clearly defined relevant population?	YES	NO	N/A
1.5	Did all of the individuals enter the study at a similar point in their disease progression?	YES	NO	N/A
ASSESSMENT AND FOLLOW-UP				
1.6	Were outcomes assessed using objective criteria (i.e. medical records) or was blinding used?	YES	NO	N/A
1.7	Was follow-up long enough for important events to occur?	YES	NO	N/A
1.8	Was there a low dropout or withdrawal rate (<20%)?	YES	NO	N/A
CONFOUNDING				
1.9	Were the main potential confounders identified and taken into account in the design and analysis?	YES	NO	N/A
CONFLICT OF INTEREST				
1.10	Competing interests of members have been recorded and addressed.	YES	NO	N/A
1.11	Views of funding body have not influenced the content of the study.	YES	NO	N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY				
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect?	GOOD	FAIR	POOR

	Code: Good, Fair, or Poor	
2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO N/A
2.4	Other reviewer comments:	

MED PROJECT	**Methodology Checklist: Economic Evaluation**

Study citation (*Include last name of first author, title, year of publication, journal title, pages*)

MED Topic:	Key Question No.(s):
Checklist completed by:	Date:

Cost
Cost analysis (no measure of benefits)

Economic Evaluations (please circle):

Study Type	*Measurement of Benefits*
Cost minimization	Benefits found to be equivalent
Cost effectiveness analysis	Natural units (e.g., life years gained)
Cost utility analysis	Healthy years (e.g. quality adjusted life years, health years equivalent)
Cost-benefit analysis	Monetary terms

Section 1: Applicability

	In a well conducted economic study…	**In this study the criterion is met:**
1.1	The results of this study are directly applicable to the patient group targeted by this key question.	YES NO UNCLEAR N/A
If criterion 1.1 is rated no, the study should be excluded.		
1.2	The healthcare system in which the study was conducted is sufficiently similar to the system of interest in the topic key question(s).	YES NO UNCLEAR N/A

SECTION 2: Study Design, Data Collection, and Analysis

	In a well conducted economic study…	**In this study the criterion is met:**
2.1	The research question is well described.	YES NO UNCLEAR N/A
2.2	The economic importance of the research question is stated.	YES NO UNCLEAR N/A

2.3	The perspective(s) of the analysis are clearly stated and justified (e.g. healthcare system, society, provider institution, professional organization, patient group).	YES	NO	UNCLEAR	N/A
2.4	The form of economic evaluation is stated and justified in relation to the questions addressed.	YES	NO	UNCLEAR	N/A
Methods to estimate the effectiveness of the intervention					
2.5	*Circle one* a. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies). b. Details of the design and results of effectiveness study are given (if based on a single study).	YES	NO	UNCLEAR	N/A
2.6	Estimates of effectiveness are used appropriately.	YES	NO	UNCLEAR	N/A
2.7	Methods to value health states and other benefits are stated.	YES	NO	UNCLEAR	N/A
2.8	Outcomes are used appropriately.	YES	NO	UNCLEAR	N/A
2.9	The primary outcome measure for the economic evaluation is clearly stated.	YES	NO	UNCLEAR	N/A
2.10	Details of the subjects from whom valuations were obtained are given.	YES	NO	UNCLEAR	N/A
2.11	Competing alternatives are clearly described.	YES	NO	UNCLEAR	N/A
Methods to estimate the costs of the intervention					
2.12	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
2.13	Methods for the estimation of quantities and unit costs are described.	YES	NO	UNCLEAR	N/A
2.14	Quantities of resource use are reported separately from their unit costs.	YES	NO	UNCLEAR	N/A

2.15	Productivity changes (if included) are reported separately.	YES	NO	UNCLEAR	N/A
2.16	The choice of model used and the key parameters on which it is based are justified.	YES	NO	UNCLEAR	N/A
2.17	All costs are measured appropriately in physical units.	YES	NO	UNCLEAR	N/A
2.18	Costs are valued appropriately.	YES	NO	UNCLEAR	N/A
2.19	Outcomes are valued appropriately.	YES	NO	UNCLEAR	N/A
2.20	The time horizon is sufficiently long enough to reflect all important differences in costs and outcomes.	YES	NO	UNCLEAR	N/A
2.21	The discount rate(s) is stated.	YES	NO	UNCLEAR	N/A
2.22	An explanation is given if costs and benefits are not discounted.	YES	NO	UNCLEAR	N/A
2.23	The choice of discount rate(s) is justified.	YES	NO	UNCLEAR	N/A
2.24	All future costs and outcomes are discounted appropriately.	YES	NO	UNCLEAR	N/A
2.25	Details of currency of price adjustments for inflation or currency conversion are given.	YES	NO	UNCLEAR	N/A
2.26	Incremental analysis is reported or it can be calculated from the data.	YES	NO	UNCLEAR	N/A
2.27	Details of the statistical tests and confidence intervals are given for stochastic data.	YES	NO	UNCLEAR	N/A
2.28	Major outcomes are presented in a disaggregated as well as aggregated form.	YES	NO	UNCLEAR	N/A
2.29	Conclusions follow from the data reported.	YES	NO	UNCLEAR	N/A
2.30	Conclusions are accompanied by the appropriate caveats.	YES	NO	UNCLEAR	N/A
SECTION 3: sensitivity Analysis					

	In a well conducted economic study…	**In this study the criterion is met:**
3.1	The approach to sensitivity analysis is given.	YES NO UNCLEAR N/A
3.2	All important and relevant costs for each alternative are identified.	YES NO UNCLEAR N/A
3.3	An incremental analysis of costs and outcomes of alternatives is performed.	YES NO UNCLEAR N/A
3.4	The choice of variables for sensitivity analysis is justified.	YES NO UNCLEAR N/A
3.5	All important variables, whose values are uncertain, are appropriately subjected to sensitivity analysis.	YES NO UNCLEAR N/A
3.6	The ranges over which the variables are varied are justified.	YES NO UNCLEAR N/A
SECTION 4: CONFLICT OF INTEREST		
	In a well conducted economic study…	**In this study the criterion is met:**
4.1	Competing interests of members have been recorded and addressed.	YES NO UNCLEAR N/A
4.2	Views of funding body have not influenced the content of the study.	YES NO UNCLEAR N/A
SECTION 5: OVERALL ASSESSMENT		
5.1	**How well was the study done to minimize bias?** **Code: Good, Fair or Poor**	GOOD FAIR POOR
5.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?	
5.3	Other reviewer comments:	

MED Project 2011. Adapted from BMJ, NICE, and the Consensus on Health Economic Criteria (CHEC).

MED PROJECT	**Methodology Checklist: Guidelines**

Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*

MED Topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: PRIMARY CRITERIA

To what extent is there		***Assessment/Comments:***
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[1] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD FAIR POOR

If any of three primary criteria are rated poor, the entire guideline should be rated poor.

SECTION 2: SECONDARY CRITERIA

2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD FAIR POOR

SECTION 2: SECONDARY CRITERIA, CONT.

1 Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD	FAIR	POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available Updating procedure specified	GOOD	FAIR	POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered Monitoring/audit/review criteria presented	GOOD	FAIR	POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE				
3.1	How well done is this guideline?	GOOD	FAIR	POOR
3.2	Other reviewer comments:			

[This tool is adapted from the Appraisal of Guidelines Research & Evaluation (AGREE) II tool. The full AGREE II tool is available from http://www.agreetrust.org/resource-centre/agree-ii/]

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix H. Payer Policy Summary Table

Payer	Coverage Summary
Medicare NCD Manual (2012), Endoscopy, Section 100.2 (Revised: 10/3/2003)	**Medicare National Coverage Determination, Endoscopy** Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool, endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct. *Indications and Limitations of Coverage* Endoscopic procedures are covered when reasonable and necessary for the individual patient. ***CMS Region X LCDs (Washington, Oregon, Idaho, Alaska):*** No LCDs identified addressing upper endoscopy.
Aetna CPB number: 0736 (Last review: 11/18/2011)	**Aetna Clinical Policy Bulletin (CPB): Upper Gastrointestinal Endoscopy** I. Aetna considers esophagogastroduodenoscopy (EGD)/upper endoscopy medically necessary for *high-risk screening* in any of the following: A. Persons with chronic (5 years or more) gastroesophageal reflux disease (GERD) at risk for Barrett's esophagus. (Note: After a negative screening EGD, further screening EGD is not indicated). B. Persons with symptomatic pernicious anemia (e.g., anemia, fatigue, pallor, Red tongue, shortness of breath, as well as tingling and numbness in the hands and feet) to identify prevalent lesions (e.g., carcinoid tumors, gastric cancer). C. Persons with cirrhosis and portal hypertension but no prior variceal hemorrhage, especially those with platelet counts less than 140,000/mm^3, or Child's class B or C disease.

Payer	Coverage Summary

II. Aetna considers *diagnostic* EGD medically necessary in any of the following:
   A. Evaluation of upper abdominal symptoms that persist despite an appropriate trial of therapy.
   B. Evaluation of upper abdominal symptoms associated with other symptoms or signs suggesting serious organic disease (e.g., anorexia and weight loss) or in persons over 45 years of age.
   C. Evaluation of dysphagia or odynophagia.
   D. Evaluation of esophageal reflux symptoms that are persistent or recurrent despite appropriate therapy.
   E. Evaluation of esophageal masses and for directing biopsies for diagnosing esophageal cancer.
   F. Evaluation of persons with signs or symptoms of loco-regional recurrence after resection of esophageal cancer.
   G. Evaluation of persistent vomiting of unknown cause.
   H. Evaluation of other diseases in which the presence of upper gastrointestinal (GI) pathological conditions might modify other planned management (e.g., persons who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anti-coagulation, or long-term non-steroidal anti-inflammatory drug therapy for arthritis, and those with cancer of the head and neck).
   I. Evaluation of familial adenomatous polyposis syndromes.
   J. Confirmation and specific histological diagnosis of radiologically demonstrated lesions:
      1. Gastric or esophageal ulcer
      2. Suspected neoplastic lesion
      3. Upper tract stricture or obstruction
   K. Evaluation of GI bleeding:
      1. For persons with active or recent bleeding
      2. For presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source or when colonoscopy results are negative
   L. Sampling of upper GI tissue or fluid.
   M. Evaluation of persons with suspected portal hypertension to document or treat esophageal varices.
   N. Evaluation of acute injury after caustic ingestion.

Payer	Coverage Summary

O. Evaluation of dyspepsia when any of the following is present:
   1. Chronic GI bleeding
   2. Epigastric mass
   3. Iron deficiency anemia
   4. Persistent vomiting
   5. Progressive difficulty swallowing
   6. Progressive unintentional weight loss
   7. Suspicious barium meal (upper GI series)

P. Diagnosis of irritable bowel syndrome when other studies (e.g., colonoscopy, enterosocpy, ileoscopy, capsule endoscopy, and flexible sigmoidoscopy) have negative results.

Q. Differentiation of Crohn's disease from ulcerative colitis in indeterminate colitis.

III. Aetna considers ***therapeutic*** EGD medically necessary in any of the following:

A. Banding or sclerotherapy of varices.

B. Dilation of stenotic lesions (e.g., with trans-endoscopic balloon dilators or dilation systems using guide wires).

C. Management of achalasia by means of botulinum toxin, balloon dilation

D. Palliative treatment of stenosing neoplasms by means of laser, multi-polar electrocoagulation, stent placement.

E. Placement of feeding or drainage tubes (peroral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy).

F. Removal of foreign bodies or selected polypoid lesions.

G. Treatment of bleeding lesions such as ulcers, tumors, and vascular abnormalities by means of electrocoagulation, heater probe, laser photocoagulation, or injection therapy.

IV. Aetna considers ***sequential or periodic*** EGD medically necessary in any of the following:

A. Surveillance of persons with Barrett's esophagus (BE) without dysplasia. For persons with established BE of any length and with no dysplasia, after 2 consecutive examinations within 1 year, an acceptable interval for additional surveillance is every 3 years.

B. Surveillance of persons with BE and low-grade dysplasia at 6 months. If low-grade dysplasia is confirmed, then surveillance at 12 months and yearly thereafter as long as dysplasia persists.

Payer	Coverage Summary

C. Surveillance of persons with BE and high-grade dysplasia every 3 months for at least 1 year. After 1 year of no cancer detection, the interval of surveillance may be lengthened if there are no dysplastic changes on 2 subsequent endoscopies performed at 3-month intervals.
D. Surveillance of persons with a severe caustic esophageal injury every 1 to 3 years beginning 15 to 20 years after the injury.
E. Surveillance of persons with tylosis every 1 to 3 years beginning at 30 years of age.
F. Surveillance of recurrence of adenomatous polyps in synchronous and metachronous sites at 3- to 5-year intervals.
G. Surveillance of persons with familial adenomatous polyposis starting around the time of colectomy or after age of 30 years.
H. Surveillance of persons with hereditary non-polyposis colorectal cancer.

V. Aetna considers EGD (screening, diagnostic, therapeutic, or sequential/periodic) experimental and investigational for any of the following because its effectiveness for these indications has not been established:
A. EGD for routine screening.
B. Evaluation of symptoms that are considered functional in origin. (There are exceptions in which an EGD may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy).
C. Evaluation of metastatic adenocarcinoma of unknown primary site when the results will not alter management.
D. Repeat EGD for persons with a prior normal EGD if symptoms remain unchanged.
E. Routine evaluation of abdominal pain in children (i.e., without other signs and symptoms suggestive of serious organic disease).
F. Evaluation of radiographical findings of:
1. Asymptomatic or uncomplicated sliding hiatal hernia
2. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy
3. Uncomplicated duodenal ulcer that has responded to therapy
G. Surveillance for malignancy in persons with gastric atrophy, pernicious anemia, or prior gastric

Payer	Coverage Summary
	operations for benign disease (e.g., partial gastrectomy for peptic ulcer disease). H. Surveillance of healed benign disease (e.g., esophagitis or duodenal/gastric ulcer). I. Surveillance during repeated dilations of benign strictures unless there is a change in status. J. Surveillance of persons with achalasia. K. Surveillance of persons with previous aerodigestive squamous cell cancer. L. Surveillance of persons with gastric intestinal metaplasia. M. Surveillance of persons following adequate sampling or removal of non-dysplastic gastric polyps.
GroupHealth	No policies identified addressing upper endoscopy for people with symptoms of GERD
Regence BCBS Washington	No policies identified addressing upper endoscopy for people with symptoms of GERD

Appendix I. Draft Key Question Public Comments – Overview and CEbP Response

Submitted By	*Cited Evidence*	*Overview of Public Comment*	*CEbP Response*
Karen Anderson, MD, MPH	No	▪ Recommended eliminating key question #1 and #2 ▪ Recommended changing key question #3 from "…Does repeat endoscopy change treatment and outcome?" to "…Does endoscopy (initial or repeat) change treatment and outcome?" ▪ For key question 5, recommended adding under (d) individuals known to ingest alcohol chronically	▪ Thank you for your comments. The Key Questions address specific items of interest to the HTA clinical committee as outlined. ▪ Key Question #3 is focused specifically on repeat endoscopy. ▪ We have amended Key Question #5 item *e* as follows: e. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes, high BMI, and chronic ingestion of alcohol.

Note: No public comments were received on the draft report.

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