Washington State Health Care Authority, HTA Program
FINAL Key Questions and Background
Upper Endoscopy for gastroesophageal reflux disease (GERD) and upper gastrointestinal (GI) symptoms

Introduction

Upper endoscopy for gastroesophageal reflux disease (GERD) was selected for review by the HTA program. Acid reflux is a condition where the acidic juices (digestive acids) regurgitate or reflux up into the esophagus. GERD is a more serious form of acid reflux. Occasional acid reflux is a common condition and does not necessarily mean a person has GERD. GERD can lead to more serious health problems due to the effect of digestive acid on the lining of the esophagus. Causes of GERD are varied, but may include anatomical abnormalities, obesity, pregnancy, and smoking. GERD may occur in children and adults. Persistent acid reflux may indicate GERD.

Upper endoscopy is a diagnostic procedure. Upper endoscopy involves the insertion of a thin flexible tube down a patient's throat and esophagus. The endoscope has a light and camera attached allowing a doctor to visually inspect the esophagus for abnormalities and to take small pieces of tissue (biopsy) if needed.

Policy Context

Upper GI symptoms, acid reflux and GERD are very common. Upper endoscopy is an invasive diagnostic procedure that may be indicated for persons with upper GI symptoms and/or a diagnosis of GERD. State agencies concerns: safety- Low, efficacy- Medium-High, cost- Medium-High.

Population: Adults with an initial presenting complaint of upper gastrointestinal symptoms and/or GERD

Intervention: Upper gastrointestinal endoscopy

Comparator: Medical management without endoscopy – including screening questionnaires, noninvasive H. pylori testing, empiric acid-suppression therapy

Outcomes: Clinical symptom resolution (e.g. as measured by symptom scoring tools), health care resource utilization, development of serious gastrointestinal pathology (e.g. malignancy, Barrett's esophagus, esophageal stricture), quality of life indicators

Key Questions

KQ1: What is the evidence of effectiveness for early treatment strategies that include upper endoscopy compared with empiric medical management?

KQ2: Are there clinical signs and symptoms useful to identify patients for whom early endoscopy is effective to improve health outcomes and/or disease management?

KQ3: For what diagnoses and within what time frames, is repeat endoscopy indicated versus other tests or no follow-up tests for surveillance of disease progression and/or treatment response? Does repeat endoscopy change treatment and outcome?

KQ4: What are the potential harms of performing upper endoscopy in the diagnostic or treatment planning workup of adults with upper GI symptoms? What is the incidence of these harms? Include consideration of progression of treatment in unnecessary or inappropriate ways.

KQ5: What is the evidence that upper endoscopy has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender
b. Age
c. Psychological or psychosocial co-morbidities
d. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes, high BMI, and chronic ingestion of alcohol
e. Provider type, setting or other provider characteristics
f. Payer / beneficiary type: including worker's compensation, Medicaid, state employees?

KQ6: What is the evidence of cost and cost-effectiveness of endoscopy compared to other treatment strategies when used in diagnostic or treatment planning workups of adults with upper GI symptoms?

Public comment and Response

HTA received 1 public comment. The comment was forwarded to the technology assessment center for consideration and was reviewed by HTA program staff.

The commenter 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?"; and for key question 5, recommended adding under (d) individuals known to ingest alcohol chronically.

Response: No changes to key questions 1, 2 and 3. Added "and chronic ingestion of alcohol" to KQ5 sub bullet (d).

For additional information on key questions and public comments

Washington State Health Care Authority
Health Technology Assessment

Upper Endoscopy for GERD and GI Symptoms

Clinical Expert

Drew Blackham Schembre, MD

Swedish Medical Center
Chief and co-founder, Swedish Gastroenterology/Swedish Center for Digestive Health
2446 1st Ave N
Seattle, WA 98109

Curriculum Vitae

Drew Blackham Schembre, MD **September 15, 2011**

2446 1st Ave N.
Seattle, WA 98109

Phone: 206-341-0931
Fax: 206-223-6379
Mobile: 206-612-2391

Vital Statistics:

DOB: September 16, 1961
Citizenship: United States
New York License # 206730
Utah License # 89-181661-1205
Washington State License # MD0006475

Positions:

2010-Present

Chief and co-founder, Swedish Gastroenterology/Swedish Center for Digestive Health, Swedish Medical Center, Seattle, Washington. Establishing new, tertiary care/advanced GI group at leading medical center in Pacific Northwest.

2006-2010

Chief, Division of Gastroenterology, Virginia Mason Medical Center, Seattle, Washington. Medical Director of a 15 physician GI/6 mid-level/80 employee division within a 450+ physician multi-specialty group and tertiary referral center

Deputy Chief of Medicine, Virginia Mason Medical Center

Clinical Associate Professor of Medicine, University of Washington

1998-2006

Staff Gastroenterologist, Virginia Mason Medical Center, Seattle, Washington. Areas of special interest: diagnostic and therapeutic endoscopic ultrasound, photodynamic therapy, endotherapy for esophageal cancer, emerging endoscopic techniques

	Clinical Associate Professor of Medicine, University of Washington
1997-1998	Clinical Instructor, Division of Gastroenterology, Columbia College of Physicians and Surgeons, New York
1995-1997	Co-director, Division of Gastroenterology, Talbert Medical Group, Salt Lake City, Utah
1995	Mountain West Gastroenterology Salt Lake City, Utah
Winters, 1993-95	Emergency Physician, Snowbird Medical Clinic Snowbird Ski Resort, Alta, Utah
1991-1992	Internist, Salt Lake Community Health Centers, Salt Lake City, Utah

Education

1997-1998	Third Tier Fellowship in Advanced Endoscopic Techniques, Columbia-Presbyterian Medical Center, New York, Charles Lightdale, director. Emphasis on endoscopic ultrasound, photodynamic therapy and clinical research
1992-1994	Fellowship in Gastroenterology University of Utah Health Sciences Center Salt Lake City, Utah
1988-1991	Internship/Residency in Internal Medicine University of Utah Health Sciences Center Salt Lake City, Utah
1984-1988	University of Medicine and Dentistry of New Jersey, New Jersey Medical School Newark, New Jersey
1979-1983	Middlebury College, Bachelor of Arts, Cum Laude Biology/Literature

Certifications:	Board Certified, Gastroenterology, 1995, 2005 Board Certified, Internal Medicine, 1991, 2001
Awards:	Charles Flood Award for Clinical Research, 1998

New Jersey Medical Society Essay Award, 1986

Societies:

President, Pacific Northwest Gastroenterology Society, 2007

American Society of Gastroenterologic Endoscopy
Chair, Special Interest Group: Endotherapy for Esophageal Diseases, 2010
Fellow, 2008
Member Practice Management Committee 2004-2007
Alternate, CPT Representative 2006-2008
Member ad hoc subcommittee on endoscopic ultrasound 2001-2002
American Gastroenterological Association
American College of Gastroenterology
Fellow, 2008
American Medical Association
King County Medical Society

Reviewer:

Gastrointestinal Endoscopy
American Journal of Gastroenterology
Digestive and Liver Disease
Journal of Clinical Gastroenterology
Journal of the Esophagus

Current Clinical Research/Patents:

1. New device development. Responsible for design of Cook Echotip ProCore EUS biopsy needle, launched 2010, patent pending.
2. On-going development of a variety of devices to facilitate endoscopic procedures and to improve endoscopic safety efficiency.

Presentations:

1. Update on Capsule and Deep Enteroscopy, Pacific Northwest Gastrointesinal Society full day meeting, Seattle, WA 9/17/11
2. Tertiary Gastroenterology, Fairbanks AK, 7/19/11
3. Emil Jobb GI Conference, Swedish Medical Center, Seattle WA (Course organizer and director), 4/15/11
4. Advanced Imaging Facilitates Mucosal Resection, ASGE Hands-On Course, Advanced Endoscopic Techniques, Oak Brook, IL 6/5/10
5. Esophageal Stenting in 2010, BSCI-sponsored DDW symposium, New Orleans, LA, 5/3/10

6. Small Bowel Enteroscopy: From Bench to Bedside, DDW 2010, New Orleans, LA, 5/5/10
7. Advances in the use of removable esophageal stents, Internal Medicine Grand Rounds, Madigan Army Base, Tacoma, WA, 4/7/10
8. Rendezvous Endoscopy for Obstructed Esophagus and Colon, Society of Gastrointestinal Intervention, Seoul, Korea, 10/10/09
9. Advances in Tertiary Gastroenterology, Fifth Annual Current Issues in Cancer Care: A Symposium for Primary Care Providers, October 3, 2009, Campbell's Resort at Lake Chelan, WA.
10. Endotherapy for Early Esophageal Cancer, John Muir Cancer Center, Walnut Creek, CA 9/17/09.
11. Deep Enteroscopy, Meet the Professor, DDW 2009, Chicago, IL. 5/26/09
12. Advanced Small Bowel Imaging Hands on Course, DDW 2009 Chicago, IL 5/23/09
13. Deep Entersoscopy: The long and winding road. GI Potpourri, Virginia Mason Medical Center, Seattle, 3/14/09
14. Narrow-Band Imaging in the Esophagus and Colon. Vancouver, BC, 1/20/09
15. Endotherapy for Early Esophageal Neoplasia: Change we can believe in. Annual Midwestern Oncology Conference, Nov. 4, 2008, Omaha NE
16. Narrow-Band Imaging in the Esophagus and Colon. Olympus University, Anchorage AK, 7/9/08
17. Endotherapy versus Esophagectomy: Don't throw the esophagus out with the bathwater, Society for Surgery of the Alimentary Tract, Digestive Disease Week, San Diego, CA, 5/20/08
18. Deep Enteroscopy, Meet the Professors, Digestive Disease Week, San Diego, CA, 5/19/08
19. Deep Enteroscopy Coding, An inconvenient truth. ASGE Deep Enteroscopy Training Course, Chicago IL, 3/2008 and 11/2007
20. Double Balloon Enteroscopy and Competing Technologies, Symposium Co-Chair, Digestive Disease Week, Washington, DC, 5/07
21. Small Bowel Enteroscopy, the ShapeLock experience, Digestive Disease Week, Washington, DC, 5/07
22. Coding for Endoscopic Ultrasoud, EUS special interest group, Digestive Disease Week, Washington, DC, 5/07
23. Photodynamic Therapy for Cholangiocarcinoma—the Virginia Mason Experience, Congress of the International Photodynamic Therapy Association, Shanghai, China, 3/29/07
24. Endotherapy versus Surgery for Barrett's Esophagus with High-Grade Dysplasia, Virginia Mason Medical Center, Grand Rounds, 11/3/06
25. The Evolution of Esophageal Stenting: From Sandelwood to Silicone, Portland, OR, 6/06
26. Endotherapy versus Surgery for Barrett's Esophagus with High-Grade Dysplasia, Digestive Disease Week, Los Angeles, 5/06
27. Oncogel Injection for Unresectable Esophageal Cancer (video presentation), World Congress of Gastroenterology, Montreal, Canada, 9/05
28. Photodynamic Therapy for Cholangiocarcinoma, MD Anderson

Pancreaticobiliary Conference, Hyanis, MA, 6/05

29. Comparison of endoscopic therapy versus esophagectomy for Barrett's
30. esophagus with dysplasia or early cancer. Western States Thoracic Surgery Society, Vancouver, BC, 6/05
31. Advances in gastrointestinal endoscopy: the fantastic voyage, GI NursingUpdate, Virginia Mason Medical Center, 3/12/05
32. Double Balloon Enterosocpy, Univ. of Washington GI Grand Rounds, 3/05
33. Endoscopic therapies for esophageal cancer, Virginia Mason Medical Center,Cancer Update, 2/05
34. Colon Cancer Update, Seattle Rotary, 1/05
35. Endoscopic ablative therapies for early esophageal and biliary malignancies,Salt Lake Gut Club, Salt Lake City, Utah, 1/20/05
36. Endoscopic ablative therapies for early esophageal and biliary malignancies, VMMC, 10/04
37. Endoscopic ablative therapies for early esophageal and biliary malignancies, Bellingham, Washington, 10/04
38. Establishing Standards for Endoscopic Ultrasound, Frontiers in Endoscopy, Sante Fe, New Mexico, 9/04
39. Potential and Pitfalls of EUS in Private Practice, Digestive Disease Week ASGE endoscopic ultrasound special interest group, New Orleans, 5/18/04
40. Standard Work for Ulcerative Colitis, VMMC Grand Rounds, 4/23/04
41. Ablative therapy of esophageal and biliary neoplasms, Spokane, WA 4/04
42. Ultra-Jumbo biopsy forceps for Barrett's esophagus, Univ. Washington GI Grand Rounds, 3/04
43. Endoscopic therapy for early esophageal and biliary malignancies, Vancouver Gut Club, Vancouver, BC 1/04
44. "Smart Endoscopes" Frontiers in Endoscopy, Santa Fe New Mexico, 9/03
45. Endoscopic therapy for early esophageal malignancies and dysplasia, Anchorage, AK 3/03
46. Endoscopic therapy for early esophageal malignancies and dysplasia, Tacoma, Washington, 3/03
47. Photodynamic therapy for pre-malignant conditions of the esophagus: a review of the first 32 cases, GI Grand Rounds, University of Washington, Seattle, WA 3/03
48. Barrett's Esophagus and adenocarcinoma of the esophagus, Idaho Gut Club, Sun Valley Idaho, 3/03
49. Endoscopic therapy for early esophageal malignancies and dysplasia, Idaho Gut Club, Sun Valley Idaho, 3/03
50. Endoscopic therapy for early esophageal malignancies and dysplasia, Tacoma, Washington, 3/03
51. Photodynamic therapy for early esophageal neoplasms, Gastroenterology Grand Rounds, University of Colorado Health Sciences Center, Denver, CO 1/03
52. Photodynamic therapy for gastrointestinal malignancies. Quebec Gut Club, Mont Ste. Michelle, Quebec, 9/02
53. Photodynamic therapy for gastrointestinal malignancies. Everett Gut Club, Everett, Washington, 3/02
54. Endoscopic therapies for esophageal cancer and pre-malignant conditions: What

we can, should and should not do. Esophageal Cancer 2001: Managing the epidemic. Virginia Mason Medical Center, Seattle, 2001

55. Photodynamic therapy for esophageal lesions, American Society for Laser Medicine and Surgery, New Orleans, 2001
56. Photodynamic therapy for esophageal lesions, American Society for Laser Medicine and Surgery, Reno, 2000.
57. Endoscopic ultrasound for gastrointestinal malignancies, Virginia Mason Medical Center Grand Rounds, Seattle, 9/98

Posters/Abstracts:

1. Schembre D, Ross A, Kozarek R, Yield of Double Balloon Enterosocopy versus Spirus Enteroscopy in Occult Small Bowel Bleeding (Poster) DDW Chicgao, IL 2009
2. Schembre D, Arai A, Levy S, Farrell-Ross M, Low D. Quality of Life after Esophagectomy and Endoscopic Therapy for Barrett's Esophagus with High-Grade Dysplasia or Intra-Mucosal Carcinoma, (Poster) DDW San Diego, CA 2008
3. Schembre D, Ayub K, Gibbons E, Simmons S, Hampson NB. Noninvasive monitoring for methemoglobinemia after topical application of benzocaine during upper endoscopy and trans-esophageal echocardiography, (Poster) DDW Washington DC, 2007
4. Schembre, D, Ayub K, Jiranek, G. Endoscopic Mucosal Resection (EMR) Changes Staging for Early-stage Neoplasia in Barrett's Esophagus Compared to Pinch Biopsies and EUS (poster) DDW, Los Angeles, 2006
5. Schembre D, Kozarek R, Use of a Self-Expanding, Removable, Plastic Stent (Polyflex®) for Esophageal Fistulae, Perforations and Benign and Malignant Strictures: Early Experience at a Single Institution. (poster) DDW, Chicago, 2005
6. Schembre D, Fotoohi M, Gluck M, Picozzi V, Kozarek R. Photodynamic Therapy (PDT) for Unresectable Cholangiocarcinoma: A Single Center Experience. (poster) DDW, Chicago, 2005
7. Schembre D, Lin O, Brandabur J, et al. Creation of a colonoscopy screening clinic for improving endoscopy unit efficiency (poster) DDW, New Orleans, LA, 2004
8. Schembre D, Wilbur P, Kozarek R, et al. Introducing manufacturing efficiency tools to the endoscopy suite: how the Toyota model helps drive endoscopes. (poster) DDW, New Orleans, LA, 2004
9. Schembre D, Fenske M. "Ultra-jumbo" biopsies for sampling Barrett's mucosa in surveillance and post-ablation therapy patients. (poster) DDW, New Orleans, LA, 2004
10. Breitinger A, Schembre D, Mergener K, et al. Can non-endoscopists screen capsule endoscopy findings? (poster) American College of Gastroenterology, Seattle, 10/02
11. Schembre D, Robinson D, Guinee D. EUS guided injection of cyanoacrylate glue into a disconnected pancreatic duct. (poster) 2002, EUS 2002, New York
12. Schembre D, Belz M, Larson L. EUS diagnosis of swallow-induced tachycardia:

A unique approach to an unusual problem. (poster) 2002, Digestive Disease Week, San Francisco

13. Schembre D. Photodynamic therapy for pre-malignant conditions of the esophagus: a review of the first 26 cases. (poster) 2002, Digestive Disease Week, San Francisco
14. Schembre D, Chak A, Lightdale C, Stevens P, Sivak M. Prospective evaluation of balloon sheath for ultrasound catheter system. (poster) 1998, Digestive Disease Week, New Orleans.
15. Schembre D, Lightdale C, Ligresti R, Stevens P. Photodynamic therapy for high grade dysplasia and early adenocarcinoma of the esophago-gastric junction and gastric cardia in elderly patients with short segment Barrett's esophagus. (poster) 1998, Digestive Disease Week, New Orleans.
16. Sahai A, Schembre D, Lightdale C, Hawes R, Sivak M. EUS-guided fine-needle aspiration with the Olympus GFUM30P echoendoscope and the Olympus MAJ363 FNA-needle system safely and effectively obtains diagnostic cytological specimens in patients with suspected malignancy. (poster) 1998, Digestive Disease Week, New Orleans.
17. Schembre D, Cannon-Albright L, Burt R, Do Age and Subsite Location Increase Familial Risk of Colon Cancer? (Poster), Digestive Disease Week, New Orleans, May 18, 1994

Book Chapters

1. Coding Primer: A guide for gastroenterologists. Editor Glenn Littenberg, co-editor, Drew Schembre 2009, ASGE Press.
2. Schembre D. Recent Advances in the Use of Stents for Esophageal Disease. Gastrointestinal Endoscopy Clinics of North America, 2009;20:103-21.
3. Schembre D. Photodynamic therapy of the gastrointestinal tract beyond the esophagus. Advances in photodynamic therapy: Basic, translational and clinical. Chapt 24. Ed Michael R. Hamblin, Pawel Mroz. Artech House, Boston, 2008
4. Schembre D. Role of endoscopic ultrasound for diagnosis and differential diagnosis of neoplastic lesions. The Pancreas: An integrated textbook of basic science, medicine and surgery, Second edition. Chapt 62. Ed. Hans Beger, Andrew Warshaw Markus Buchler, Richard Kozarek et al. Blackwell Publishing, Malden, MA, 2008.
5. Schembre D. Dilation and stenting of the gastrointestinal tract. Gastroenterology and Hepatology: the Modern Clinician's Guide. Chapt 154. Ed. Wildred Weinstein, C.J. Hawkey, Jamie Bosch. Elsevier Science, London, 2004

Reviews, Letters and Editorials:

1. Schembre DB, Ross AS. Spiral Enteroscopy: A new twist on overtube-assisted endoscopy. Gastrointestinal Endoscopy, 2009;69:333-336.
2. Lin O, Schembre D. Are split bowel preparation regimens practical for morning colonoscopies? Implications of the new american college of gastroenterology colon cancer screening guidelines for real-world clinical practice. Am J

Gastroenterol. 2009;104:2627-8

3. Schembre D, Ayub K, Jiranek G. High-frequency mini-probe ultrasoundL the Rodney Dangerfield of endoscopy? J Clin Gastroenterol, 2005;39:555-6.

Articles:

1. Schembre D, Gluck M, Lin O, et al. Use of a threaded overtube to complete colonoscopy in the redundant colon. Gastrointest Endososc 2011;73:515-519.
2. Schembre D. Multi-focal Metastatic Renal Cell Cancer Presenting as GI Bleeding with Resolution by Endoscopic Resection. 2011, Swedish Medical Center Bulletin.
3. Kuppusamy MK, Felisky C, Kozarek RA, Schembre D, et al. Impact of endoscopic assessment and treatment on operative and non-operative management of acute oesophageal perforation. Br J Surg 2011;98:818-824.
4. Schembre D, Dever J, Glenn M, et al. Esophageal Reconstitution by Simultaneous Antegrade-Retrograde Endoscopy: Reestablishing patency of the completely obstructed esophagus. Endoscopy 2011;43:434-437.
5. Story B, Thirlby R, Schembre D. Diagnosis of ileal dysplasia in a patient with Crohn's disease by using retrograde enteroscopy with an overtube: a case report. Gastrointest Endosc 2011;73:178-179.
6. Schembre D. Advances in Esophageal Stenting. Advan Therapy 2010;27:413-425.
7. Schembre D, Arai A, Farrel-Ross M, Low D. Quality of life after esophagectomy and endoscopic therapy for Barrett's esophagus with dysplasia. Dis Esoph 2010;23:458-464.
8. Schembre D. Endotherapy for Barrett's Esophagus with High-Grade Dysplasia and Intramucosal Carcinoma. Journal of Gastrointestinal Surgery 2009;13:1172-8.
9. Schembre DB, Huang J, Lin OS, Cantone N, Low D. Endotherapy versus Esophagectomy for Barrett's Esophagus with High-Grade Dysplasia or Intra-mucosal Carcinoma. Gastrointest Endosc 2008; 67:595-601.
10. Ross A, Mehdizadeh S, Tokar J, Leighton J, Kamal A, Chen A, Schembre D, Chen G, Binmoeller K, Kozarek R, Waxman I, Dye C, Gerson L, Harrison ME, Haluszka O, Lo S, Semrad C. Double Balloon Enteroscopy Detects Small Bowel Mass Lesions Missed by Capsule Endoscopy. Dig Dis Sci 2008;53: 2140-3.
11. Schembre D, Brill JV, Littenberg G, Cameron RB. Coding for "deep ennteroscopy" procedures in an era of emerging technology. Gastrointest Endosc 2008;67:391-393.
12. Karbowski M, Schembre D, Kozarek R, Ayub K, Low D. Polyflex sef-expanding, removable plastic stents: Assessment of treatment efficacy. Surgical Endoscopy 2008;22:1326-33.
13. Low D, Kunz S, Schembre D, et al. Esophagectomy—It's Not Just About Mortality Anymore: Standardized Perioperative Clinical Pathways Improve Outcomes in Patients with Esophageal Cancer. J Gastrointest Surg 2007;11;1873.
14. Lin O, Schembre D, Ayub K, et al. Patient satisfaction scores for endoscopic procedures: impact of a survey-collection method. Gastrointestinal Endoscopy

2007;65:775-81.
15. Lin OS. Brandabur JJ. Schembre DB. Soon MS. Kozarek RA. Acute symptomatic small bowel obstruction due to capsule impaction. Gastrointestinal Endoscopy. 2007;65:725-8.
16. Lin OS, Schembre DB, Mergener K, Spaulding W, Lomah N, Ayub K, Brandabur JJ, Bredfeldt J, Drennan F, Gluck M, Jiranek GC, McCormick SE, Patterson D, Kozarek RA. Blinded comparison of esophageal capsule endoscopy versus conventional endocsopy for a diagnosis of Barrett's esophagus in patients with chronic gastroesophageal reflux. Gastrointest Endosc 2007;65:577-583.
17. Lin O, Brandabur J, Schembre D. Acute symptomatic small bowel obstruction due to capsule impaction . Gastrointest Endosc, 2007;65:725-728
18. Mehdizadeh S, Ross A, Gerson L, Leighton J, Chen A, Schembre D, Chen G, Semrad C, Kamal A, Harrison EM, Binmoeller K, Waxman I, Kozarek R, Lo SK. What is the learning curve associated with double-balloon enteroscopy? Technical details and early experience in 6 U.S. tertiary care centers. Gastrointest Endosc, 2006;64:740-50.
19. Lin OS, Kozarek RA, Schembre DB, Ayub K, Gluck M, Cantone N, Soon MS, Dominitz JA. Risk stratification for colon neoplasia: screening strategies using colonoscopy and computerized tomographic colonography. Gastroenterology, 2006;131:1011-9.
20. Clark CJ, Thirlby RC, Picozzi V, Schembre DB, Cummings FP, Lin E. Current Problems in surgery: gastric cancer. Curr Probl Surg, 2006;43:566-670.
21. Wolfsen H, Canto M, Etemad B, Greenwald B, Gress F, Schembre D, Bare fiber photodynamic therapy using porfimer sodium for esophageal disease. Photodiagnosis and photodynamitc therapy 2006;3:87-92.
22. Lin OS, Kozarek RA, Schembre DB, Ayub K, Gluck M, Drennan F, Soon MS, Rabeneck L. Screening colonoscopy in very elderly patients: prevalence of neoplasia and estimated impact on life expectancy. JAMA, 2006;295:2357-65.
23. Cotton PB, Hawes RH, Barkum A, Ginsberg GG, Amman S, Cohen J, Ponsky J, Rex DK, Schembre D, Wilcox CM. Excellence in endoscopy: toward practical metrics. Gastrointest Endosc, 2006;63:286-91.
24. Lin OS, Schembre DB, McCormick SE, Gluck M Patterson DJ, Jiranek GC Soon MS, Kozarek RA. Risk of proximal colorectal neoplasia among asymptomatic patients with distal hyperplastic polyps. Am J Med, 2005;118:1113-9.
25. Lin OS Gerson LB, Soon MS, Schembre DB, Kozarek RA. Risk of proximal neoplasia with distal hyperplastic polyps: a meta-analysis. Arch Intern Med, 2005;165:382-90.
26. Mosler P, Mergener K, Brandabur J, Schembre D, Kozarek R. Paliation of gastric outlet obstruction and proximal small bowel obstruction with self-expanable metal stents: a single center series. 2005;39:124-128.
27. Soon MS, Soon A, Schembre D, Lin O. Prospective evaluation of a jelly-like conducting medium for catheter endosonographic imaging of the esophagus. Gastrointest Endosc, 2005;61:133-139.
28. Schembre D. Smart Endsocopes. Gastrointestinal Endosc Clinics of North America, 2004;14:709-716.
29. Schembre D. Photodynamic therapy for esophageal cancer. Visible human journal

of endoscopy. (on-line journal www.vhjoe.com), Vol 3(1).
30. Schembre D, Lin O. The Frequency and Costs of Echoendoscope Repairs: Results of a survey of endosonographers: results of a survey of endosonographers. Endosocopy, 2004;36:982-986.
31. Schembre D, Endoscopic therapeutic esophageal interventions: old, new, borrowed and …methylene blue? Current Opinion in Gastroenterology, 2003, 19:394-399.
32. Schembre D, Endoscopic therapeutic esophageal interventions, Current Opinion in Gastroenterology, 2002;18:479-485.
33. Mergener K, Brandabur J, Schembre D. Capsule endoscopy—A new procedure for evaluation patients with obscure gastointestinal bleeding. Virginia Mason Medical Center Bulletin, 2002;56:30-33.
34. Schembre D. Endoscopic ablative therapies for malignant esophageal strictures. Techniques in Gastrointestinal Endoscopy, 2001;3:159-165.
35. Schembre D, Endoscopic therapeutic esophageal interventions, Current Opinion in Gastroenterology, 2001;17:387-92.
36. Gluck M, Schembre D, Kozarek R, A concern with use of the "push technique" in patients with multiple esophageal rings, (letter), Gastrointestinal Endoscopy, 2001;54:543-4.
37. Schembre D, Infectious Complications Associated with Gastrointestinal Endoscopy, Gastrointestinal Endoscopy Clinics of North America, 2000;10:215-232.
38. Schembre D, Chak A, Lightdale C, Stevens P, Sivak M. Prospective evaluation of balloon sheath for ultrasound catheter system. Gastrointestinal Endoscopy, 2001;53:758-61.
39. Kozarek R, Attia F, Schembre D, et al, Reusable biopsy forceps: a prospective evaluation of cleaning, function, adequacy of tissue specimen, and durability. Gastrointestinal Endoscopy, 2001;53:747-50.
40. Schembre D, Kozarek R, Endoscopic therapeutic esophageal interventions, Current Opinion in Gastroenterology, 2000;16:380-5.
41. Schembre D, Gluck M, Neuzil, D. Endoscopic Ultrasound findings of linitis plastica. Virginia Mason medical center bulletin 2000, 54:29-32
42. Sahai A, Schembre D, Lightdale C, Hawes R, Sivak M. EUS-guided fine-needle aspiration with the Olympus GFUM30P echoendoscope and the Olympus MAJ363 FNA-needle system safely and effectively obtains diagnostic cytological specimens in patients with suspected malignancy. Gastrointestinal Endoscopy 1999;50:792-6.
43. Schembre D, Picozzi V, Cha C, Esophageal cancer: New diagnostic and therapeutic approaches, Virginia Mason Bulletin 1999;53:1-16.
44. Schembre D, Boynton, K. Ischemic colitis caused by diet medications. (letter) New England J Med, 1997;336:510-11.
45. Schembre D, Bjorkman D. A rational approach to giving antibioptic prophylaxis before endoscopy. Who needs it?. Journal of Critical Illness 1995;10:259-61.
46. Burt RW, Schembre D. Advancements in the Genetics of Colorectal Cancer. Implications for diagnosis and therapy. Practical Gastroenterology. 1994;18:12C-12O.

47. Schembre D, Bjorkman DJ. Endoscopy Related Infections. Alimentary Pharmacology and Therapeutics, 1993;7:347-55.
48. Schembre D, Bjorkman DJ. Post-Sclerotherapy Bacterial Peritonitis. Am J Gastroenterol. 1991;86:481-486.
49. Schembre D, Lazaro EJ. Dermatobia hominis Myiasis Masquerading as an Infected Sebaceous Cyst. Canadian J Surg. 1990;33:145-6.
50. Schembre D. Scut is a Four Letter Word. *Pulse* (in JAMA, medical student editions) 1987;257:iv.
51. Schembre D. License to Practice. *Pulse* (JAMA) 1986;256:iv.
52. Schembre D. The Best Medicine. *Pulse* (JAMA) 1986;256:iv.

Washington State Health Care Authority

Participant Conflict of Interest Guideline

Introduction

The HTCC Workgroup is a public service workgroup established to safeguard the public interest by identifying medical tests and treatments where evidence shows they are safe, effective, and cost-effective. Balance, independence, objectivity and scientific rigor are a basis for public trust and crucial to the credibility and integrity of decisions.

Guiding Principle

Conflict of interest decisions must be disclosed and balanced to ensure the integrity of decisions while acknowledging the reality that interests, and sometimes even conflicting interests, do exist. Individuals that stand to gain or lose financially or professionally, or have a strong intellectual bias need to disclose such conflicts.

> *For example,* the fact that a member or stakeholder is a health care provider that may use a service under review creates a potential conflict. However, clinical and practical knowledge about a service is also useful, and may be needed in the decision making.

Procedure

Declaration of real or potential conflicts of interest, professional, intellectual, or financial is required prior to membership or provision of written or verbal commentary. Participants must sign a conflict of interest form; stakeholders providing comment must disclose conflicts.

The HTCC Chair or HCA Administrator shall make a decision, in his/her sole discretion, as to whether a conflict of interest rises to the level that participation by the conflicted participant could result in a loss of public trust or would significantly damage the integrity of the decision.

HCA defines conflict of interest as any situation in which a voting member or anyone who provides written or verbal testimony regarding products, services, or technologies discussed or voted on during the workgroup meeting, has a relationship with a manufacturer of any commercial products and / or provider of services discussed or voted on during the meeting. Relationship extends to include immediate family member(s) and / or any entity in which the member or person testifying may have an interest.

A relationship is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $10,000.
2. Equity interests such as stocks, stock options or other ownership interests in excess of $10,000 or 5% ownership, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: If representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).
8. Travel: If an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000	x	
2.	Equity interests such as stocks, stock options or other ownership interests		
3.	Status of position as an officer, board member, trustee, owner		
4.	Loan or intellectual property rights		
5.	Research funding		
6.	Any other relationship		

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Cook Medical. Royalties associated with patented endoscopic ultrasound biopsy needle and limited educational speaking involving proper use of device.

	Potential Conflict Type	Yes	No
7.	Representation: If representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		x

7. If yes, Provide Name and Funding Sources: _____

	Potential Conflict Type	Yes	No
8.	Travel: If an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).		x

8. If yes, Provide Name of Organization / Company and Disclose Travel Accommodations:

Washington State Health Care Authority

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 5/9/12 Drew Schembre, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Overview of Public Comments and Response

Upper Endoscopy for GERD

April 2012

Center for Evidence-based Policy
Oregon Health & Science University
3455 SW US Veterans Hospital Road
Mailstop SN-4N, Portland, OR 97239-2941
Phone: 503.494.2182
Fax: 503.494.3807
http://www.ohsu.edu/ohsuedu/research/policycenter/med/index.cfm

Draft Key Questions

Overview of Public Comments 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.

Draft Report

No public comments were received on the draft report.

Washington State Health Care Authority

Agency Medical Director Comments
Health Technology Clinical Committee
Upper Endoscopy(EGD) for GERD and GI Symptoms

G. Steven Hammond PhD, MD, MHA
Chief Medical Officer
Department of Corrections
May 18, 2012

Upper Endoscopy for GERD Background

- GERD and GI Symptoms are extremely common in the primary care setting (estimated prevalence 10-58%)
- Upper endoscopy (esophagogastroduodenoscopy or EGD) is a moderately expensive and invasive procedure.
  - Coverage policy and guidelines are helpful to direct rational utilization management procedures

Upper Endoscopy for GERD Background

AMDG Perspective

Evidence review upon which to base coverage policy and utilization management is sought

Upper Endoscopy for GERD
Current State Agency Policy

L&I allows Upper Endoscopy for GERD

UMP allows Upper Endoscopy for GERD

Medicaid Policies allow Upper Endoscopy for GERD

State Agencies Questions

- **Safety:** Concern level low
  - However:
    - Overly aggressive management may expose patients to risk of harm from unnecessary diagnostic procedures and treatment
  - Yet:
    - What is the risk of overly conservative management?
      - » Missed diagnosis leading to worse health outcomes?

State Agencies Questions

- **Effectiveness:** Concern level medium-high
  - What is the benefit of early and/or repeated upper endoscopies on health outcomes?

- **Cost:** Concern level medium-high
  - Given the high prevalence of GERD/dyspepsia, potential utilization of upper endoscopy is high
  - An evidence-based approach to control of utilization would aim at avoiding wasted healthcare resources while optimizing health outcomes

Upper Endoscopy for GERD Billing Codes

Diagnosis (Dx) Codes Likely to Indicate GERD (Sample Diagnoses)			
Objective Findings Based Dx		**General Symptoms Based Dx**	
530.1	Esophagitis	536.8	Dyspepsia and other specified disorders of function of stomach
530.11	Reflux esophagitis	787.1	Heartburn
530.81	Esophageal reflux	787.2	Dysphagia, NOS
530.85	Barrett's esophagus	787.21	Dysphagia, oral
535.0	Acute gastritis, without mention of hemorrhage	789.06	Abdominal pain, epigastric

Upper Endoscopy for GERD
State Agency Utilization

	2007	2008	2009	2010
PEB Total Population	**172,009**	**204,804**	**210,501**	**213,487**
% of Total Population w/ GERD Dx	14.0%	13.9%	14.0%	13.6%
% of Total Population w/ EGD	2.7%	2.7%	2.9%	2.8%
% of Total Pop. w/ UE for GERD	1.5%	1.5%	1.5%	1.4%
Medicaid Total FFS Population	**378,915**	**392,808**	**416,871**	**424,230**
% of Total Population w/ GERD Dx	15.1%	15.1%	15.3%	15.1%
% of Total Population w/EGD	2.1%	2.0%	2.3%	2.7%
% of Total Pop. w/UE for GERD	1.1%	1.1%	1.2%	1.4%

Note: Figures not available for L&I

Upper Endoscopy for GERD
State Agency Utilization

PEB Member counts	2007	2008	2009	2010
All members w GERD Diagnosis (Dx)	24035	28529	29546	29050
All GERD Dx Upper Endoscopies	2531	2997	3196	3077
%	10.5%	10.5%	10.8%	10.6%

Medicaid Patient counts	2007	2008	2009	2010
All patients w GERD	57332	59268	63851	63994
All GERD Dx Upper Endoscopies	4093	4199	5016	6031
%	7.1%	7.1%	7.9%	9.4%

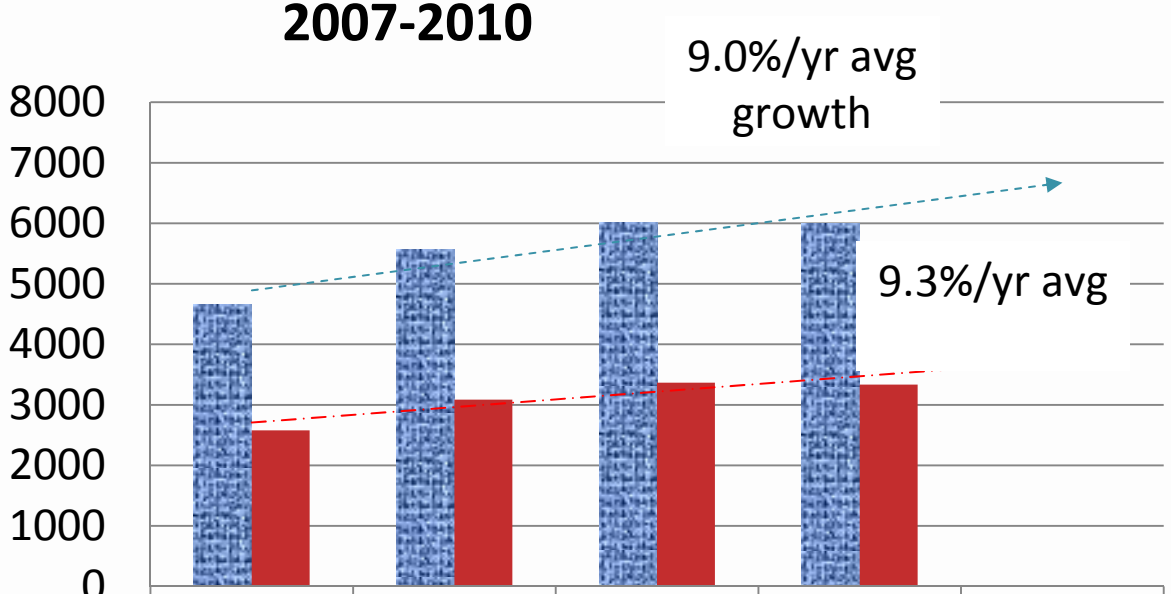
L&I Claimant counts	2007	2008	2009	2010
All claimants w GERD	1234	1163	1099	1039
All GERD Dx Upper Endoscopies	46	46	51	32
%	3.73%	3.96%	4.64%	3.08%

Upper Endoscopy for GERD
State Agency Utilization

Upper Endoscopies w/ GERD Diagnoses	2007	2008	2009	2010	4 year overall
PEB: Total Paid	**$1.6M**	**$2.0M**	**$2.4M**	**$2.3M**	**$8.3M**
Patient Count	2578	3087	3366	3335	12366
Max paid /proc	$4,896	$4,677	$4,964	$6,030	$6,030
Avg/ proc	$611	$667	$702	$683	$669
Avg/ proc (primary payer only)	$872	$912	$978	$953	$933
Medicaid: Total Paid	**$1.2M**	**$1.3M**	**$1.6M**	**$1.8M**	**$5.9M**
Patient Ct	4093	4199	5016	6031	19339
Max/proc	$3,221	$4,896	$3,469	$3,604	$4,896
Avg/ proc	$297	$309	$327	$294	$306
L&I: Total Payments	**$34,577**	**$33,466**	**$36,548**	**$20,837**	**$125,429**
Patient Count	46	46	51	32	175
Max/procedure	$3,407	$1,606	$3,139	$1,679	$3,407
Avg/procedure	$752	$728	$717	$651	$717

Upper Endoscopy for GERD
State Agency Utilization

PEB Patient Counts for Upper Endoscopy (UE), 2007-2010

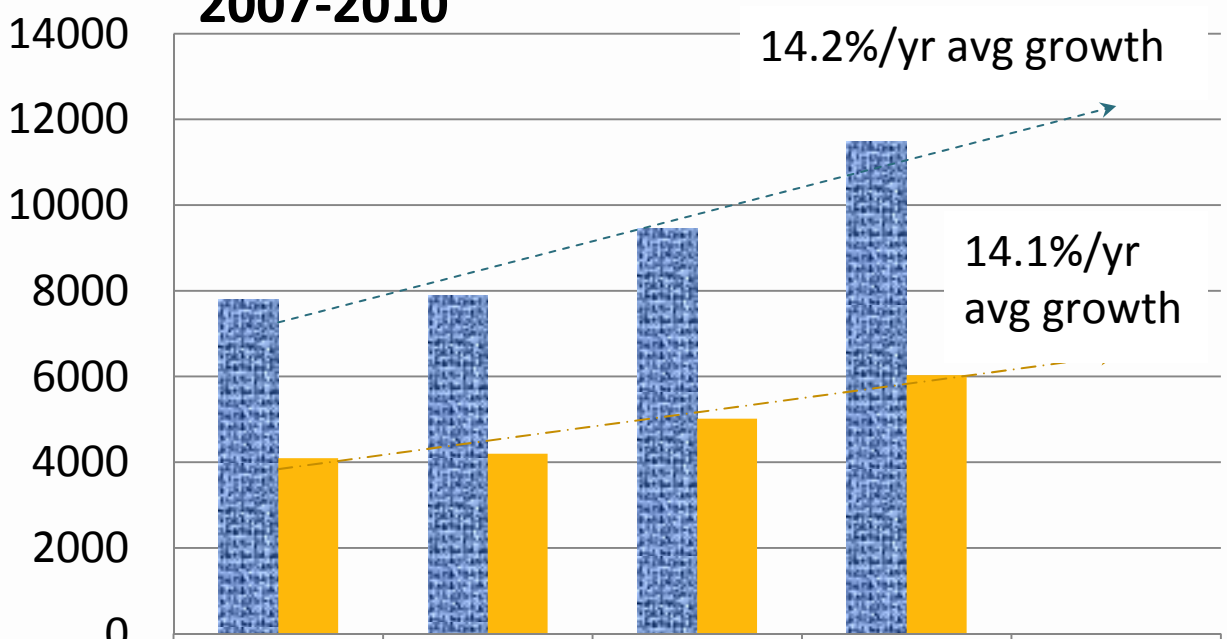


	2007	2008	2009	2010	2011
All Upper Endoscopies (UE)	4662	5569	6010	5998	
All GERD Diagnosis UE	2578	3087	3366	3335	
GERD % of all UE	55.3%	55.4%	56.0%	55.6%	

Washington State Health Care Authority

Upper Endoscopy for GERD
State Agency Utilization

Medicaid Patient Counts for Upper Endoscopy, 2007-2010

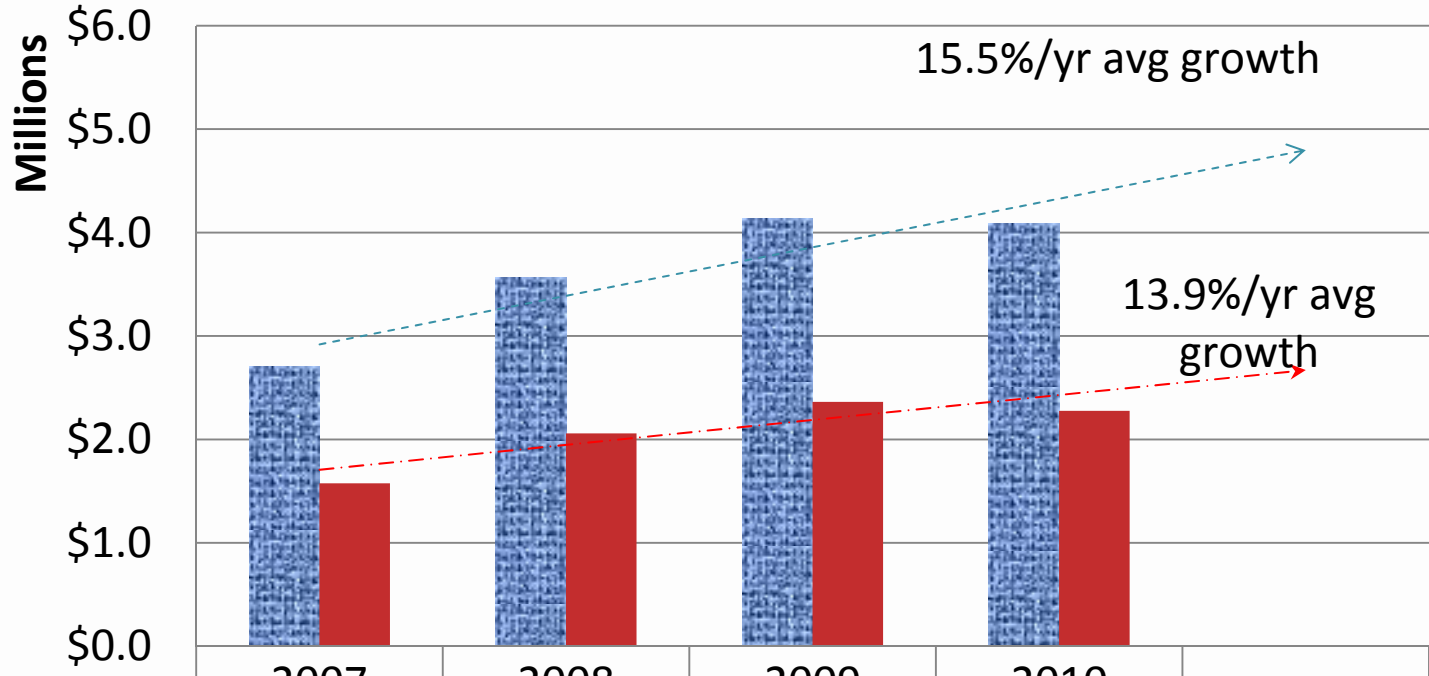


	2007	2008	2009	2010	2011
All Upper Endoscopies (UE)	7794	7899	9457	11481	
All GERD Diagnosis UE	4093	4199	5016	6031	
GERD % of all UE	52.5%	53.2%	53.0%	52.5%	

Washington State Health Care Authority

Upper Endoscopy for GERD
State Agency Utilization

PEB Payments for Upper Endoscopy, 2007-2010

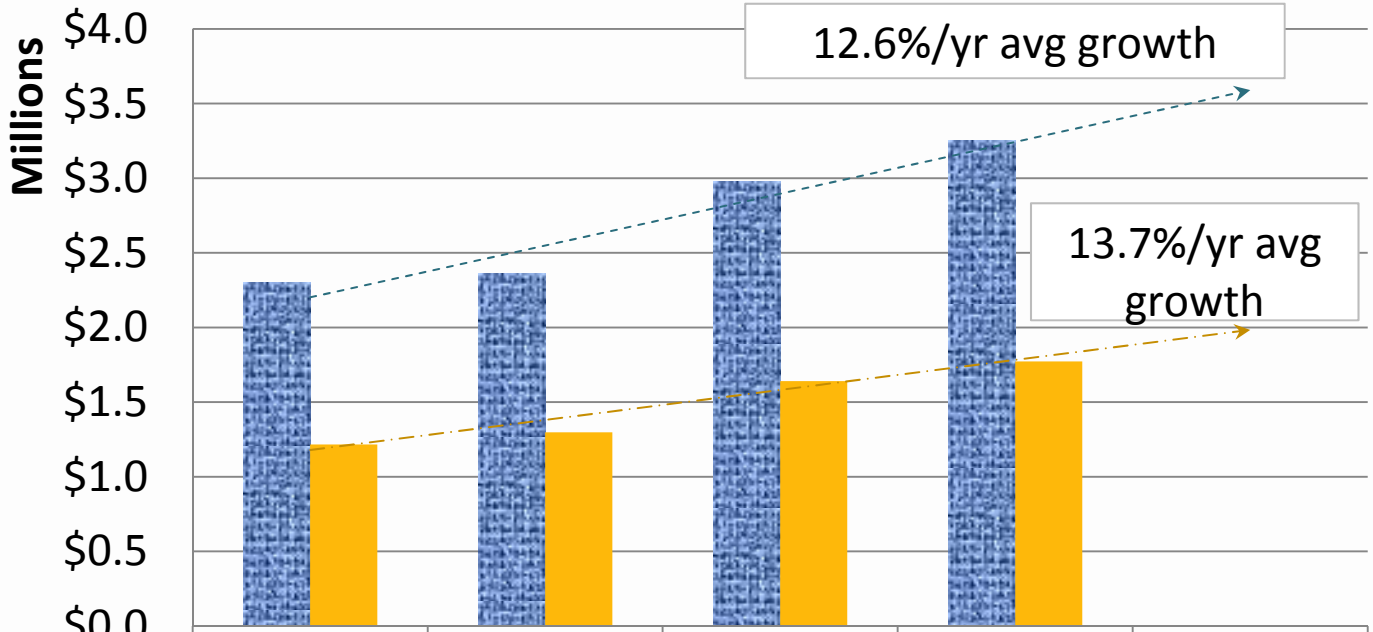


	2007	2008	2009	2010	
All Upper Endoscopies (UE)	$2,707,776	$3,568,862	$4,135,016	$4,083,934	
All GERD Dx endoscopies	$1,576,355	$2,058,633	$2,363,815	$2,277,442	
% GERD in all UE	58.2%	57.7%	57.2%	55.8%	

Washington State Health Care Authority

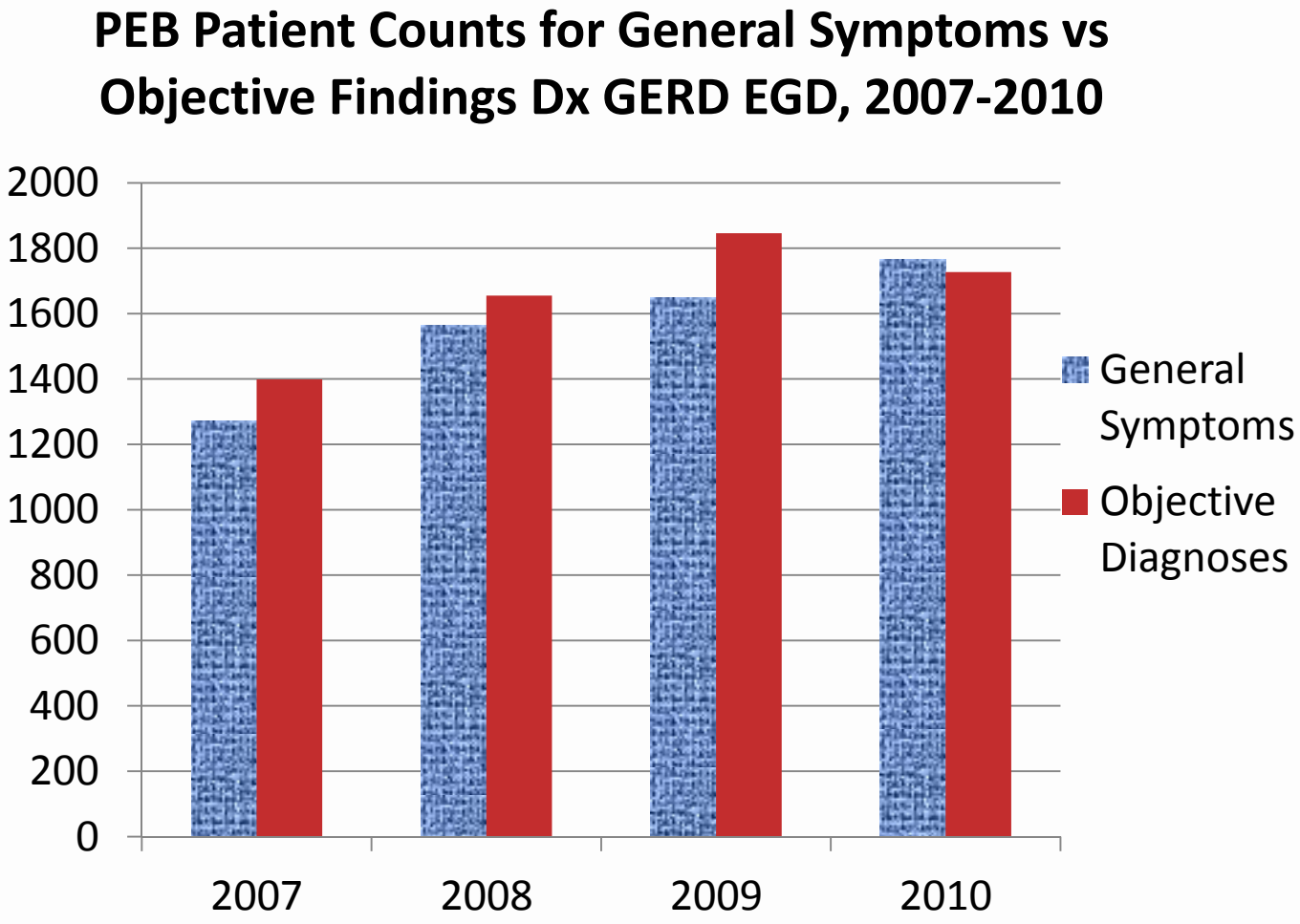
Upper Endoscopy for GERD
State Agency Utilization

Medicaid Payments for Upper Endoscopy, 2007-2010



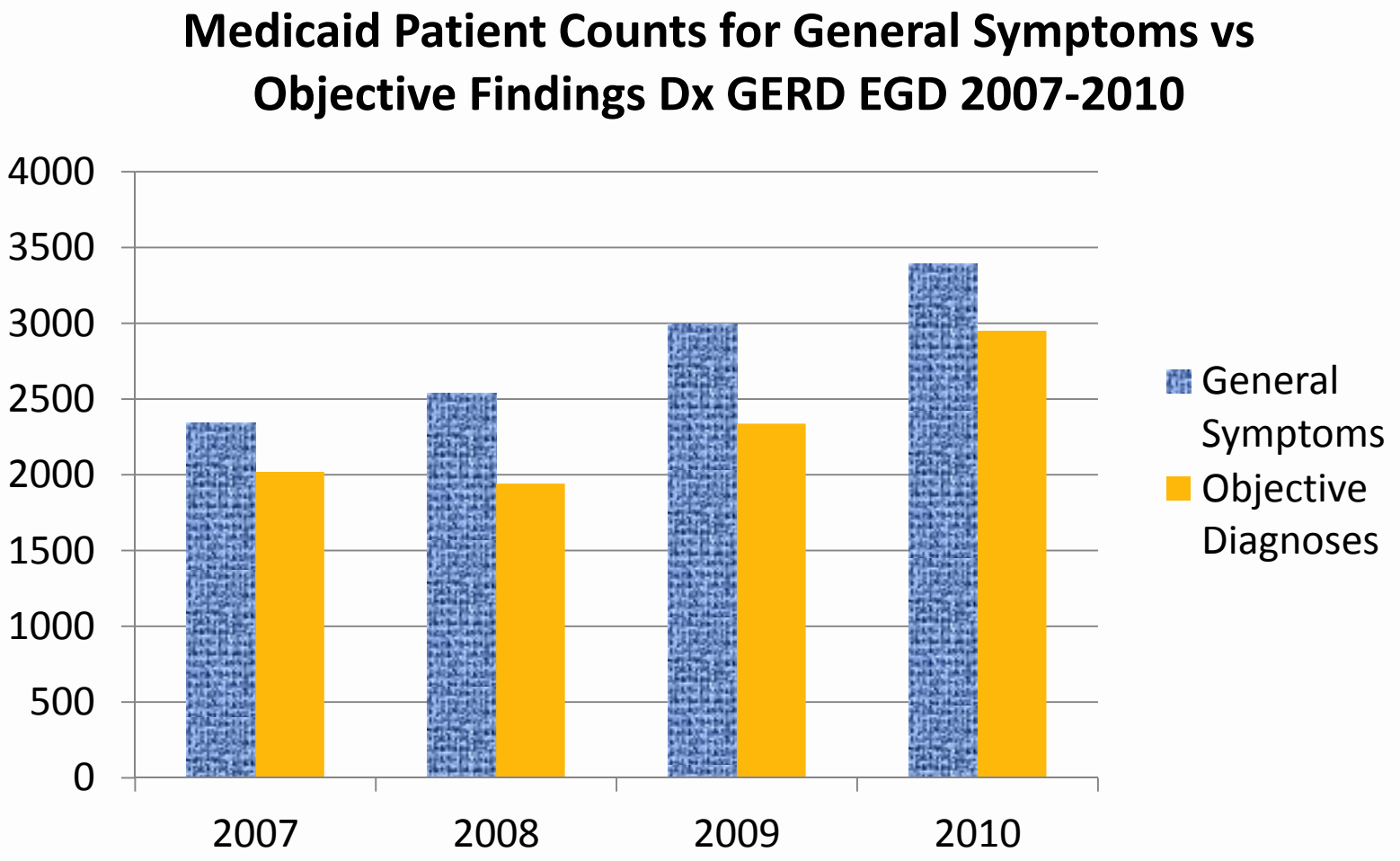
	2007	2008	2009	2010	2011
All Upper Endoscopies (UE)	$2,299,776	$2,361,653	$2,980,410	$3,250,317	
All GERD Diagnosis UE	$1,215,982	$1,297,634	$1,640,671	$1,772,311	
GERD % of all UE	52.9%	54.9%	55.0%	54.5%	

Upper Endoscopy for GERD
State Agency Utilization



Washington State Health Care Authority

Upper Endoscopy for GERD
State Agency Utilization



Washington State Health Care Authority

Upper Endoscopy for GERD
State Agency Utilization

PEB Patients with Repeated Endoscopies with GERD Diagnoses (4 years data, 12366 total patients)

Procedures	Patients
16	1
12	1
10	2
9	1
8	4
7	8
6	9
5	19
4	62
3	231
2	1156
1 (no rpt)	8809 (71%)

Medicaid Patients with Repeated Endoscopies with GERD Diagnoses (4 years data, 19339 total patients)

Procedures	Patients
17	1
16	1
15	1
14	4
10	8
9	4
8	6
7	13
6	15
5	10
4	42
3	83
2	350
1 (no rpt)	18,801 (97%)

Upper Endoscopy for GERD: Other Centers, Agencies and HTAs

Medicare – NCD

Covered "when reasonable and necessary for the individual patient" – note this is an old coverage decision [per CMS website "longstanding… effective date… not posted"] and not evidence based

Aetna –

Covered for specified indications

BCBS –

Covered, no restrictions

Upper Endoscopy for GERD: Risks & Benefits

- **Possible benefit**
  - Objective evaluation of condition diagnosed on basis of symptom report
  - Possible early detection of condition with serious health outcome sequelae that can be mitigated by early detection
- **Risk**
  - Wasted healthcare resources with little if any potential benefit

Upper Endoscopy for GERD: Evidence Summary

The evidence shows:

- Early endoscopy for general upper GI symptoms compared to trial of treatment does not appear to improve outcomes
- Certain factors, such as “alarm symptoms”, (e.g., anemia, unintentional weight loss, intractable vomiting, dysphagia) and more advanced age, while not strongly predictive of more serious pathology, may be a reasonable indication for endoscopy
- In absence of objective findings, there is little evidence to support repeat endoscopy
- Risk of foregoing endoscopy in presence of alarm symptoms or advanced age uncertain

State Agencies Summary View

- GERD and related upper GI symptoms are very common
  - Benefit of early endoscopy for upper GI symptoms, in absence of alarm symptoms or advanced age, not evident
  - Repeat endoscopy in absence of objective findings not supported
  - Endoscopy in presence of advanced age or alarm symptoms may be prudent in absence of strong evidence otherwise

State Agencies Recommendation

- Cover with Conditions
  - Failure of trial of treatment to improve or resolve symptoms OR
  - Presence of alarm symptoms or advanced age (>55 years) OR
  - Objective findings of serious upper GI pathology (e.g., ulceration, stricture, dysplasia)

Questions?

More Information:

http://hta.hca.wa.gov

OREGON HEALTH & SCIENCE UNIVERSITY

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

Presented by : Robyn Liu, MD, MPH
Center for Evidence-based Policy
Date: May 18, 2012

Introduction

- Background
- Methods
- Key Questions
- Findings
- Guidelines
- Coverage Policies
- Summary

Background – *Clinical Overview*

- Dyspepsia--encompasses one or more of:
  - Epigastric pain or burning
  - Postprandial fullness and/or early satiety
  - Nausea and vomiting
  - Upper abdominal bloating
  - Heartburn and/or regurgitation

- GERD: “a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications” (Montreal Consensus Panel definition, cited in Vakil 2006)

Background – *Clinical Overview*

Image: digestivediseaseny.com

- Esophagogastroduodenoscopy (EGD or Upper GI Endoscopy) is used to distinguish GERD and dyspepsia from more serious pathology (adenocarcinoma, Barrett's Esophagus, etc)

- Other diagnostic tools include symptom questionnaires, empiric therapeutic trials, pH monitoring

PICO

- **Population:** Adults with an initial presenting complaint of upper gastrointestinal symptoms and/or GERD
- **Intervention:** Upper gastrointestinal endoscopy
- **Comparator:** Medical management without endoscopy – including screening questionnaires, noninvasive *H. pylori* testing, empiric acid-suppression therapy
- **Outcome:** Clinical symptom resolution (e.g., as measured by symptom scoring tools), health care resource utilization, development of serious gastrointestinal pathology (e.g. malignancy, Barrett's esophagus, esophageal stricture), quality of life indicators

Key Questions

- **KQ#1:**

  What is the evidence of effectiveness for early treatment strategies that include upper endoscopy compared with empiric medical management?

- **KQ #2:**

  Are there clinical signs and symptoms useful to identify patients for whom early endoscopy is effective to improve health outcomes and/or disease management?

Key Questions

- **KQ#3:**
  For what diagnoses and within what time frames, is repeat endoscopy indicated versus other tests or no follow-up tests for surveillance of disease progression and/or treatment response? Does repeat endoscopy change treatment and outcome?

- **KQ#4:**
  What are the potential harms of performing upper endoscopy in the diagnostic or treatment planning workup of adults with upper GI symptoms? What is the incidence of these harms? Include consideration of progression of treatment in unnecessary or inappropriate ways.

Key Questions

- **KQ#5:**
  What is the evidence that upper endoscopy has differential efficacy or safety issues in sub-populations? Including consideration of:
  - a. Gender
  - b. Age
  - c. Psychological or psychosocial co-morbidities
  - d. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes, high BMI, and chronic ingestion of alcohol
  - e. Provider type, setting or other provider characteristics
  - f. Payer / beneficiary type including worker's compensation, Medicaid, state employees

Key Questions

- **KQ#6:**

  What is the evidence of cost and cost-effectiveness of endoscopy compared to other treatment strategies when used in diagnostic or treatment planning workups of adults with upper GI symptoms?

Methods – Search Strategy

- Systematic reviews (SRs) and technology assessments (TAs) identified using a "best evidence" SR methodology
- The most recent and comprehensive, high-quality SR/TA identified was updated by a MEDLINE literature search for individual studies
- If SR/TAs were not identified, a 10 year search for individual studies was completed (January 2002 to January 2012)
- A 5 year search for guidelines used CEbP core sources
- Relevant policies were identified on CMS, Aetna, BCBS, and Group Health websites

Methods – Search Strategy (cont)

- For Key Question #6, all relevant economic evaluations, cost-effectiveness analyses, and economic simulation models were included.

- Exclusion criteria for all KQ's:
  - Long-term treatment of GERD
  - Confirmed Barrett's esophagus (BE) diagnosis
  - Wireless capsule endoscopy
  - Prior GI and anti-reflux surgeries
  - Studies of exclusively Asian populations

Methods – Quality Assessment

- Methodological quality of the studies were assessed with instruments adapted by CEbP based on those used by NICE and SIGN
  - Studies were rated as good, fair, or poor for minimization of bias
- Methodological quality of the guidelines were assessed using an instrument adapted and developed by CEbP from the AGREE Collaboration
  - Guidelines rated as good, fair, or poor based on methodology and potential for bias

Methods – Quality Assessment (cont)

- Methodological quality of the economic studies was rated using an instrument adapted by CEbP that incorporates modifications of the BMJ, CHEC, and NICE economic evaluation checklists
  - Studies were rated as good, fair, or poor based on methodology and potential for bias
- The modified GRADE system was used to rate the overall strength of evidence
  - Evidence was rated as high, moderate, low, and very low for each key question and outcome

Results – Literature Search

- ~ 1400 citations were reviewed
- Most studies were retrospective observational cohort studies
- 3 SRs and 7 articles met inclusion criteria
- 4 relevant guidelines

KQ #1: Effectiveness of EGD

- Good-quality SR (Delaney 2005) with MA (5 RCTs) of PPI vs. early endoscopy
  - No difference in symptomatic cure at 12 months
- Same SR with MA (5 RCTs) of early endoscopy vs. test-and-treat (T&T) for *H. pylori*
  - Trial-level data: No difference in effect but high heterogeneity
  - Individual Patient Data (IPD) analysis: small, statistically significant benefit to early endoscopy (RR 0.95, 95% CI 0.92 to 0.99)

KQ #1: Effectiveness of EGD (cont)

- Fair-quality cohort study of 6 tests for GERD (Madan 2005)
  - 24-hour pH monitoring most sensitive single test
  - Sequential PPI challenge, endoscopy, biopsy → 100% sensitive
- Overall, evidence indicates that endoscopy is not superior to non-invasive strategies for diagnosis and management of upper GI symptoms
- *Strength of evidence: High*

KQ #2: Identifying EGD candidates

- Good quality SR, including 17 cohort studies (fair to good quality) (Vakil 2006)
  - Alarm symptoms, clinical opinion, computer modeling programs are all poor predictors of malignancy
  - Cutoff age >55 “most logical alternative strategy”
- Good quality prospective cohort study, n=4,329 (Marmo 2005)
  - Diagnostic yield (malignancy) of endoscopy increased for males >35 and females >57 years old
  - 69.8% of cancer patients have alarm symptom
  - 0.9% of pts without alarm symptoms have cancer

KQ #2: Identifying EGD candidates (cont)

- Fair quality prospective cohort study (Rossi 2002)
  - Endoscopy pre-test probability of "relevant endoscopic diagnosis" including malignancy, BE, erosions; 47% if ASGE GL criteria present, 29% if absent
- Fair quality prospective cohort (Bowrey 2005)
  - 15% of patients with carcinoma had no alarm symptoms
- Fair quality prospective cohort (V. van Zanten 2006)
  - BE most likely in males, >50 years old, reflux-predominant, >5 yr symptom duration
- *Strength of evidence: Moderate*

KQ #3: Indications for repeat endoscopy

- Good quality prospective cohort study (n=302) (Westbrook 2005)
  - Dyspeptic patients with non-malignant findings on index endoscopy
  - 1/3 had repeat endoscopy within 9 years
  - No difference in symptoms based on repeat endoscopy

- *Strength of evidence: Low*

KQ #4: Harms of endoscopy

- Most SRs, MAs and EEs failed to report harms
- One good quality EE (Spiegel 2002) used a 0.02% incidence of severe harms
  - Cost modeled on surgical repair of perforation

- *Strength of evidence: Low*

KQ #5: Differential efficacy or safety

- Good-quality SR (Ford 2005) with IPD MA (5 RCTs, n=1924) looked at age, gender, dominant symptom, and *H. pylori* status
  - Small, significant benefit of endoscopy for symptom relief in >50 year old patients; no other associations
- Good-quality cohort study (Marmo 2005)
  - On average, patients with malignancy are 20 years older
- Fair-quality cohort study (Bowrey 2005)
  - Prevalence of malignancy rises with age

KQ #5: Differential efficacy or safety (cont)

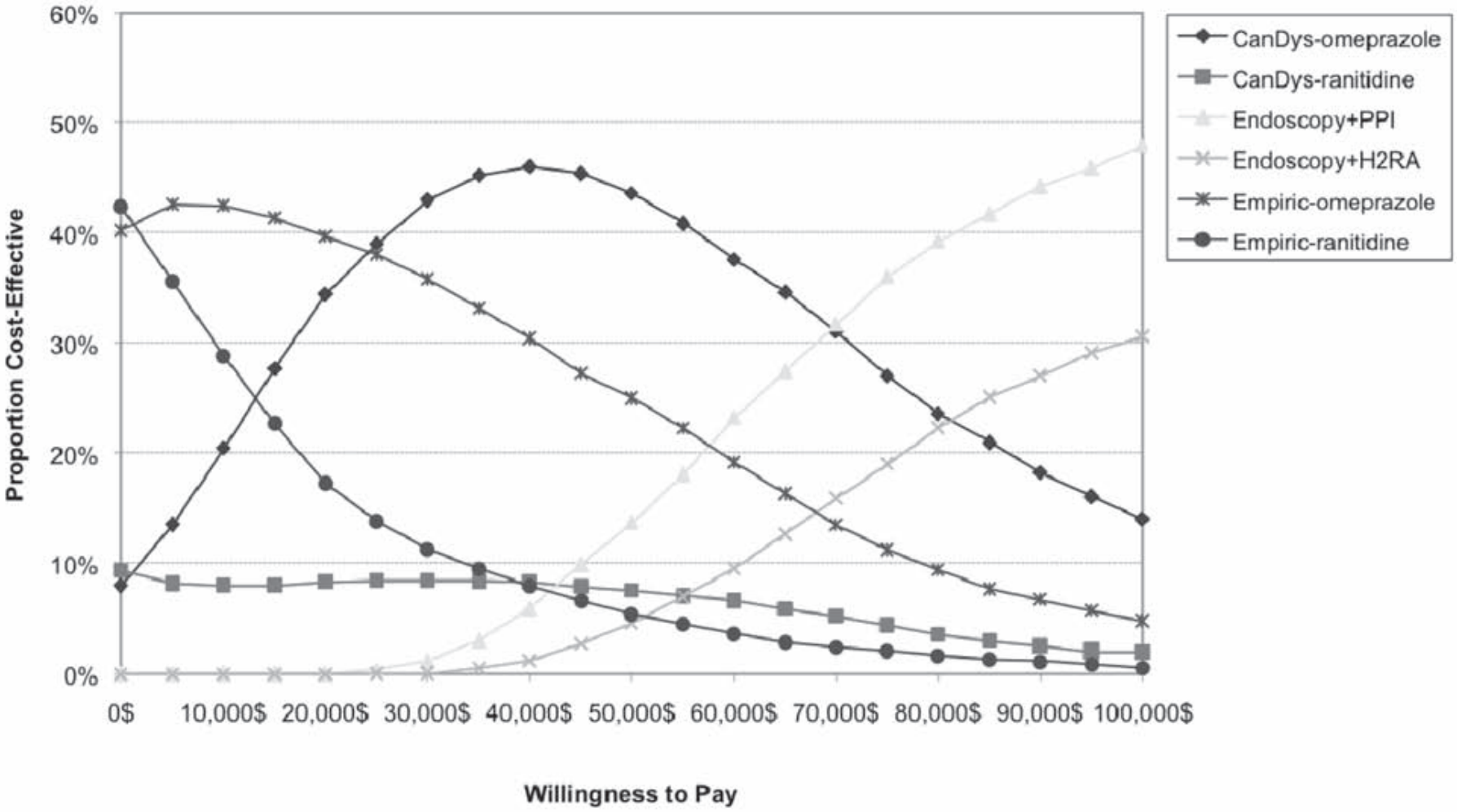
- Good-quality EE model (Barton 2008)
  - Relative effectiveness same in 30-year-olds as 60-year-olds
- Poor-quality retrospective chart review (Connor 2004)
  - No correlation between all significant endoscopic findings and age, gender, race, or NSAID use
- *Strength of evidence: Moderate (Age); Very Low (others)*

KQ #6: Cost and cost-effectiveness

- *H. pylori* test-and-treat (T&T) favored by 7 of 10 studies
- One good quality economic evaluation (Barton 2008) favored empiric PPI for US 30-year-olds but T&T for 60-year-olds
- Good quality economic evaluation of Canadian data found no one strategy clearly cost effective, but "CanDys" protocol best at WTP CAN$30,000 to CAN$70,000/QALY
  - Protocol incorporates empiric PPI for heartburn/reflux predominant patients, test-and-treat for others

- *Strength of evidence: Moderate*

Acceptability Curve (Barkun 2008)



KQ #6: Cost and cost-effectiveness (cont)

Empiric PPI	*H. pylori* Test & Treat	Questionnaire
Good Quality		
• Barton 2008, US (*preferred strategy for hypothetical 30yo pop.*)	• Barton 2008, US (*preferred strategy for hypothetical 60yo pop.*) • Makris 2003, Canada (*preferred strategy for both hypothetical 18-45yo and ≥45yo pops.*) • You 2006, Hong Kong (*hypothetical ≥18yo pop.*) • Barkun 2010, Canada (*individual data from 2,236 Canadians ≥18yo*) • Spiegel 2002 (*T&T→PPI→EGD is the preferred strategy in US patients < 45 yo*) • Ford 2005 (IPD *meta-analysis of Cochrane data*)	
Fair Quality		
	• Duggan 2008, UK (*762 adults ≥18yo presenting to primary care with dyspepsia*)	• Garcia-Altes 2005, Spain (*hypothetical ≥18yo pop.*)
Poor Quality		
• Giannini 2008, Italy (*612 adults ≥18yo presenting to GI centers with ≥3mo of symptoms*) • Kjeldsen 2007, Denmark (*368 adults ≥18yo presenting to primary care with dyspepsia*) **Note:** Neither study included a comparison with *H. pylori* test-and-treat	• Klok 2005, Netherlands (*281 adults ≥18yo presenting to primary care with dyspepsia*)	

Guidelines

- AGA, 2008, good quality
  - Endoscopy recommended for GERD unresponsive to treatment
  - Recommends against routine endoscopy for surveillance of GERD
- ASGE, 2007a, fair quality
  - Endoscopy recommended for screening of BE, recurrent reflux after surgery, suspected extraesophageal manifestations of GERD
- ASGE, 2007b, fair quality
  - Recommends endoscopy for patients 45-55 years with new onset dyspepsia and alarm symptoms; endoscopy *or* PPI for patients <50 with negative *H. pylori* testing
- ASGE, 2006, poor quality
  - Only perform endoscopy in elderly patients when results will influence clinical management

Policy Summary

- Medicare
  - NCD for “endoscopy” allows coverage “when reasonable and necessary for the individual patient”
  - No applicable LCDs for Washington or CMS Region X
- Aetna
  - Clinical Policy Bulletin Criteria (2011)
    - Diagnostic (e.g., failed therapy, alarm symptoms, dysphagia, bleed)
    - High-risk screening (e.g., >5 yrs GERD, pernicious anemia, cirrhosis and portal hypertension)
    - Surveillance (e.g., BE, adenomatous polyps, h/o caustic injury)
- GroupHealth, Regence BCBS Washington – *no policies*

Summary

- High level of evidence that upper endoscopy is not more effective for symptom relief than non-invasive strategies for uncomplicated dyspepsia
- Moderate level of evidence that endoscopy is more beneficial for symptom relief and for detection of malignancy with rising patient age
- Moderate level of evidence that "alarm symptoms," clinical opinion, and computer-based models are poor predictors of malignancy

Summary (cont)

- Low level of evidence that repeat endoscopy for patients with nonmalignant findings does not improve symptom outcome
- Few data exist on harms of endoscopy
- Moderate level of evidence that *H. pylori* test-and-treat is most cost-effective strategy for symptom relief
  - Empiric PPI may be more cost-effective in younger patients
- Guidelines and policies are permissive and rely on clinical judgment

Questions or comments?

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage

Organization	Date	Outcome	Evidence Base	Grade / Rating
Centers for Medicare and Medicaid Services CMS National Policy Decisions – Publication Number 100-3 **WA HTA Page 52**	"The effective date of this version has not been posted."	**Item/Service Description** 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 http://go.cms.gov/K7tksU		

Guidelines (Page 50 of WA HTA Report)

Guideline	Recommended Use of Endoscopy	Not Recommended / Insufficient Evidence	Quality
AGA (2008) [GERD]	• Endoscopy with biopsy for patients with an esophageal GERD syndrome with troublesome dysphagia • Evaluation of patients who have not responded to an empirical trial of twice-daily PPI therapy and who have suspected esophageal GERD symptoms	• Routine endoscopy for patients with erosive or nonerosive reflux disease to assess for disease progression (Recommends Against) • Routine upper endoscopy for chronic GERD symptoms to diminish the risk of death from esophageal cancer (Insufficient Evidence) • Screening of "Barrett's esophagus and dysplasia in adults 50 years or older with greater than 5 to 10 years of heartburn to reduce mortality from esophageal adenocarcinoma (Insufficient Evidence)	Good
ASGE (2007a) [GERD]	• Patients who have alarm symptoms • Evaluation of patients with suspected extra-esophageal manifestations of GERD • Evaluation of patients with recurrent symptoms after endoscopic or surgical antireflux procedures • Screening for Barrett's Esophagus in selected patients as clinically indicated	• GERD can be diagnosed based on typical symptoms without the need for endoscopy	Fair
ASGE (2007b)	• Patients between 45 to 55 years	n/a	Fair

Guideline	Recommended Use of Endoscopy	Not Recommended / Insufficient Evidence	Quality
[Dyspepsia]	with new onset dyspepsia • Patients with alarm features • Patients without alarm features for whom there is clinical suspicion of malignancy • Patients younger than 50 years and who are *H pylori* negative, endoscopy or short trial of PPI acid suppression • Patients with dyspepsia who do not respond to empiric PPI therapy or have recurrent symptoms after an adequate trial		
ASGE (2006) [Considerations for older population]	• If results will influence clinical management or outcomes • Intensified monitoring may be appropriate for many elderly patients	n/a	Poor

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	Upper Endoscopy for GERD and Upper GI Symptoms
Safety Outcomes	**Safety Evidence**
Perforation	
	Efficacy / Effectiveness Evidence
Sensitivity	
Specificity	
Treatment planning	
Diagnostic yield	
Cancer detection	
Cancer prevention	
Special Population / Considerations Outcomes	**Special Population Evidence**
Gender	
Age	
Comorbidities (including smoking, alcohol use, psychological)	
BMI	
Other characteristics	
Provider type, setting, other	

Payer or Beneficiary Type	
Cost	**Cost Evidence**
Total Health Care Costs / Societal Costs	
Direct and indirect	
Cost Effectiveness	

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered. _____ Covered Unconditionally. _____ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?