



AMERICAN SOCIETY OF GENERAL SURGEONS

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Date: April 1, 2011

TO: Medical Directors

FROM: Guy Nicastri, M.D., ASGS President

RE: Coverage of Transoral Fundoplication

The ASGS represents the scientific, educational, socioeconomic, ethical, and professional interests of General Surgeon Specialists. With over 3,000 members, we are the only national organization that represents exclusively practicing general surgeons. We are dedicated to maintaining the highest standards of practice for the specialty of General Surgery and the highest quality of care for those patients who require surgery. As a result, we seek to serve as a knowledgeable resource for patients and payers in matters related to new technology used in General Surgery.

The introduction of new technology is a constant in modern medicine. While the U.S. Food and Drug Administration (FDA) provides regulatory clearance on safety and effectiveness, practicing general surgeons require scientific evidence on net health outcomes before offering new procedures to their patients. In addition, to meet the clinical expectations of practicing general surgeons, new technology must stay consistent with fundamental surgical principles. If not, it quickly becomes apparent that the new technology will be ineffective.

In the surgical treatment of gastroesophageal reflux disease (GERD), the ASGS believes that transoral fundoplication adheres to fundamental surgical principles. We also believe that there is a sufficient body of peer-reviewed literature that establishes transoral fundoplication as reasonable and medically necessary for a subset of patients who are candidates for surgical fundoplication; specifically, patients who either can not obtain satisfactory relief from standard PPI therapy or who wish to avoid a lifetime of dependence on such medications, and present with a 2 centimeter or smaller hiatal hernia.

The ASGS has developed the attached position statement in support of transoral fundoplication as an educational tool for payers. As you update your 2011 medical policy on the surgical treatment of GERD, we encourage you to include transoral fundoplication as an acceptable technique used by trained General Surgeons to create a surgical fundoplication.

American Society of General Surgeons (ASGS) Position Statement Transoral Fundoplication

The ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who fail to achieve satisfactory response to a standard dose of Proton Pump Inhibitor (PPI) therapy or for those who wish to avoid the need for a lifetime of medication dependence. The purpose of surgical fundoplication is to reconstruct the biomechanics and physiology of the esophagogastric junction in order to prevent stomach contents from refluxing into the patient's esophagus. The General Surgeon has a choice on how to achieve a surgical fundoplication – open incisional, laparoscopic or transoral. Transoral fundoplication adheres to the same fundamental surgical principles, which have guided surgical care of GERD for more than 50 years. Specifically, a trained General Surgeon can create a full thickness esophagogastric fundoplication to correct an incompetent lower esophageal sphincter with a transoral approach.

During transoral fundoplication, a General Surgeon constructs an anterior partial fundoplication of 270-300 degrees by attaching the fundus to the anterior and left lateral wall of the distal esophagus slightly above the esophagogastric junction through fullthickness plications using multiple fasteners around the gastroesophageal junction. In clinical studies, the transoral fundoplication procedure has been shown to offer comparable results to traditional open and laparoscopic approaches. Transoral fundoplication is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia < 2cm in patients with chronic GERD.

The ASGS continues to supports the adoption of this procedure by trained General Surgeons as a less invasive alternative to more conventional surgical techniques. However, ASGS believes that in patients who are candidates for fundoplication, the preferred surgical technique for creating the fundoplication should be left to the discretion of the General Surgeon and should be based on the surgeon's independent medical judgment and the individual patient's clinical circumstances. The ASGS position on transoral fundoplication is based in part upon the following peer-reviewed.

Supporting Publications:

-Barnes WE, Hoddinott KM, et al. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surgical Innov* 2011 Feb;[Epub ahead of print].

-Bell RCW, Freeman KD. Clinical pH-metric outcomes of transoral esophagogastric fundoplication for the treatment of gastroesophageal reflux disease. *Surgical Endoscopy*. 2010 December 8;[Epub ahead of print].

-Cadiere G-B, Van Sante N, et al. Two-year results of a feasibility study on Antireflux Transoral incisionless fundoplication (TIF) using EsophyX. *Surgical Endoscopy*. 2009; 23 (5): 957-64.