Letter to Insurance carriers

Regarding: Insurance coverage for the EsophyX™ TIF 2.0 procedure for gastroesophageal reflux disease

Dear Medical Director,

Gastroesophageal reflux disease (GERD) is one of the most common medical conditions in the United States, affecting millions of patients. The impact of this disease burden is significant for patients, payors and the healthcare community. While the majority of patients are well treated with medication and lifestyle changes, they are inadequate for many patients. There are now a number of surgical and endoscopic options for patients suffering from GERD which have been proven to be safe and effective. EsophyX™ is a device for performing transoral incisionless fundoplication (TIF) for treating gastroesophageal reflux disease. The procedure reconstructs the valve at the entry to the stomach to help prevent acid reflux, analogous to what is done during laparoscopic fundoplication surgery.

The FDA approved the original EsophyX™ device for patients with chronic GERD in 2007 and the first published report of using the device was in 2008. A next-generation version EsophyX™ device received FDA approval in 2016, offering advantages of simplified use. The procedure itself was also updated from TIF 1.0 to the TIF 2.0; additional fasteners are placed on the far posterior and anterior sides of the lesser curvature as well as 1–3 cm proximal to the GE junction with version 2.0 to generate a more physiological valve. Company data report that more than 22,000 TIF procedures have been performed worldwide to date

Currently, the supportive literature for TIF includes more than 100 publications including 4 randomized controlled trials of TIF 2.0 [1-4] (one RCT was published twice). Meta-analysis of those 4 studies found that patients who underwent TIF were more likely to attain the standard of responsiveness at six months compared with the control group treated with PPIs/sham (66% vs 30.5%, respectively and the pooled relative risk of response rate was 2.44, 95% CI: 1.25–4.79, p = 0.009) in the intention-t-treat analysis.[5] Hence, the literature supports that TIF 2.0 is effective in controlling regurgitation, reducing GERD symptoms, and reducing PPI usage in GERD patients without a >2cm hiatal hernia.

The TIF 2.0 procedure was granted a Category 1 CPT code by the CPT Editorial Panel of AMA based on strong clinical data and with broad multi-specialty support including the Society of American Gastrointestinal and Endoscopic Surgeon (SAGES), the American College of Surgeons (ACS), the American Society of Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), and the American Gastroenterology Association (AGA). The TIF 2.0 procedure is a covered benefit for all Medicare beneficiaries across the country.

The American Foregut Society (AFS) Board has concluded that there are sufficient data supporting TIF 2.0 as a safe and effective treatment for GERD in properly selected patients. Furthermore, the body of evidence is such that the EsophyX™ device and TIF 2.0 procedure is not investigational and should be covered by all payor organizations as it is by Medicare.

www.americanforegutsociety.com
Info@americanforegutsociety.com
499 E Hampden Avenue Suite 400
Englewood CO 80113

Respectfully,

The AFS Board

Reginald Bell M.D.
Tripp Buckley M.D.
Marcia Canto M.D.
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Mike Smith M.D.
Lee Swanstrom M.D.
Rena Yadlapati M.D.

References

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   *Co-first authors
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