



IEHP UM Subcommittee Approved Authorization Guideline			
<b>Guideline</b>	Natural Orifice Transluminal Endoscopic Surgery (NOTES)	<b>Guideline #</b>	UM SUR 06
		<b>Original Effective Date</b>	02/8/2017
<b>Section</b>	Surgical Procedures	<b>Revision Date</b>	04/30/24

### COVERAGE POLICY

IEHP does not cover Natural Orifice Transluminal Endoscopic Surgery (NOTES) as a benefit. An exception is transoral incisionless fundoplication (TIF) which is covered for Medicare patients if done by a well-trained surgeon for the following indications:

1. Symptomatic chronic gastroesophageal reflux (chronic being defined as great than 6 months of symptoms), and
2. Symptoms must not be completely responsive to Proton Pump Inhibitors (PPIs) as judged by Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD HRQL) scores of less than or equal to 12 while on PPIs and greater than or equal to 20 when off for 14 days (also acceptable would be the difference of greater than or equal to 10 of the scores between off and on therapy), and
3. Hiatal hernia less than or equal to 2 cm, including where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on (FDA) approval).

Please refer to Appendix 1 for the GERD HRQL Questionnaire.

### COVERAGE LIMITATIONS AND EXCLUSIONS

All other indications for NOTES are not covered. This includes minimally invasive endoluminal gastric restrictive surgical techniques, such as use of the EndoGastric StomaphyX™ endoluminal fastener and delivery system or endoscopic sleeve gastropasty.

### ADDITIONAL INFORMATION

NOTES is an emerging technique within minimal access surgery in which the surgeon accesses the peritoneal cavity via a hollow viscus and performs diagnostic and therapeutic procedures (Pasricha, 2021). When utilized as the only surgical technique, the procedure is considered “pure-NOTES”. Pure-NOTES procedures can be further subdivided into “direct target” and “distant target” procedures. Distant target procedures require that a transluminal conduit be made in a hollow organ, like the stomach, to access another organ, like the appendix, whereas direct target procedures, like peroral endoscopic myotomy (POEM) for treatment of esophageal achalasia and, transanal total mesorectal excision, do not. Hybrid-NOTES procedures involve laparoscopic assistance (Atallah 2015).

## **CLINICAL/REGULATORY RESOURCE**

### **Centers for Medicare and Medicaid Services (CMS):**

There is no National Coverage Determination (NCD) regarding NOTES procedures. Local Coverage Determination (LCD) Peroral Endoscopic Myotomy (POEM) (L38747) provides criteria for use of POEM for primary idiopathic achalasia but is not applicable to California.

However, Local Coverage Determination (LCD): Endoscopic Treatment of GERD (L34659) is applicable to California and states there is coverage of TIF for treatment of patients in whom proton pump inhibitor therapy fails. An example of the device used in TIF is EsophyX™. TIF can use this device to reconstruct the valve at the top of the stomach to prevent acid reflux.

### **Medi-Cal:**

There are no medical criteria for the use of NOTES. The only mention of transoral endoscopic surgery relates to CPT code 43211 (esophagoscopy, flexible, transoral; with endoscopic mucosal resection). This code is not reimbursable with CPT code 43202 when biopsy is performed on the same lesion. Providers must document when the procedure is performed on a different lesion in the Remarks field (Box 80)/Additional Claim Information field (Box 19) on the claim or on an attachment.

### **MCG Health**

There are no guidelines available regarding this procedure.

### **Apollo Medical Review Criteria Guidelines**

There are no guidelines available regarding this procedure.

### **Health Plans**

#### **Aetna**

The EndoGastric StomaphyX™ or EsophyX™ endoluminal fastener and delivery system is considered experimental and investigational for the management of individuals with gastroesophageal reflux disease (GERD) and all other indications because there is insufficient published scientific evidence to support the effectiveness of this intervention, especially with respect to long-term outcomes.

NOTES is mentioned as a type of endoscopic surgery offering the advantage of being a less invasive procedure for the treatment of GERD. However, it is noted that longer follow-up of patients who have had this surgery is necessary to verify the efficacy .

#### **Cigna**

This Coverage Policy addresses minimally invasive anti-reflux procedures for the treatment of gastroesophageal reflux disease (GERD) and Peroral Endoscopic Myotomy (POEM) for the treatment of esophageal achalasia, gastroparesis or Zenker's diverticula.

#### **United Healthcare**

Various types of Natural Orifice Transluminal Endoscopic Surgery (NOTES), such as transoral endoscopic surgery, transoral restorative obesity surgery (ROSE), Transpyloric Shuttle (TPS) and Endoscopic Sleeve Gastroplasty (ESG) are being explored as options for bariatric surgery since

they eliminate the need for abdominal incisions. These forms of surgery are being investigated as alternatives to conventional surgery.

## REFERENCES

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