



IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Natural Orifice Transluminal Endoscopic Surgery (NOTES)	Guideline #	UM SUR 06
		Original Effective Date	02/8/2017
Section	Surgical Procedures	Revision Date	04/24/23

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

NOTES is considered primarily experimental and should be performed only in a research setting for bariatric surgery.

The EndoGastric StomaphyX™ or EsophyX™ endoluminal fastener and delivery system is also considered experimental and investigational for the management of individuals with gastro-esophageal 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.

Cigna

Peroral endoscopic myotomy (POEM) is considered medically necessary when ALL of the following criteria are met:

1. The individual is age 18 years or older
2. Achalasia type I, ii or iii is diagnosed using esophageal manometry
3. Eckhart symptom score is >3

Peroral endoscopic myotomy (POEM) for ANY other indication is considered experimental, investigational and unproven.

Diverticular peroral endoscopic myotomy (D-POEM), Gastric peroral endoscopic myotomy (G-POEM), and Zenker peroral endoscopic myotomy (Z-POEM) are peroral endoscopic myotomy (POEM) procedures that are considered experimental, investigational, and unproven.

The following endoscopic anti-reflux procedures for gastroesophageal reflux disease (GERD), or any other indication, is considered experimental, investigational or unproven: Stretta System, Muse System, GERDx, EsophyX, PMMA, Durasphere, LINX and Apollo Overstich.

NOTES/endoscopic oral-assisted bariatric surgery procedures are considered experimental, investigational or unproven. This includes: restorative obesity surgery, endoluminal (ROSE), StomaphyX™, duodenojejunal bypass line (e.g., Endobarrier™), transoral gastropasty (e.g., TOGA®) and endoscopic closure devices (e.g., Apollo OverStitch™).

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 Gastropasty (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

1. Aetna. 2021. Clinical Policy Bulletin 0213 Gastroesophageal Reflux Disease (GERD): Treatment Devices. http://www.aetna.com/cpb/medical/data/200_299/0213.html. Accessed April 13, 2023.
2. Apollo Medical Review Criteria Guidelines for Managing Care, 20th edition. 2021. Accessed April 13, 2023.
3. Atallah S, Martin-Perez B, Keller D, Burke J, Hunter L. Natural-orifice transluminal endoscopic surgery. *British Journal of Surgery*. 2015;102(2):e73–e92. doi:10.1002/bjs.9710.
4. Castelijns, PSS, JEH Ponten, MCG vd Poll, ND Bouvy, JF Smulders. 2018. Quality of Life after Nissen fundoplication in patients with gastroesophageal reflux disease: Comparison between long- and short-term follow-up. *J Minim Access Surg*. 2018 Jul-Sep; 14(3): 213-220.
5. Centers for Medicare and Medicaid Services. 2021. Local Coverage Determination (LCD): Endoscopic Treatment of GERD (L34659). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=34659&ver=26&keyword=GERD&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact>. Accessed April 13, 2023.
6. Cigna. 2020. Medical Coverage Policy 0019 Minimally Invasive Anti-Reflux Procedures and Peroral Endoscopic Myotomy (POEM) Procedures. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0019_coveragepositioncriteria_endoscopic_treatment_for_gerd.pdf. Accessed April 13, 2023.
7. Cigna. 2020. Medical Coverage Policy 0051 Bariatric Surgery and Procedures. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0051_coveragepositioncriteria_bariatric_surgery.pdf. Accessed April 13, 2023.
8. UpToDate has multiple articles concerning Natural Orifice Transluminal Endoscopic Surgery (NOTES) procedures. . <https://www.uptodate.com/contents/search>. Accessed April 13, 2023.

9. MCG Health, 25th edition. 2021. Accessed. April 13, 2023
10. Medi-Cal Provider Manual, 2020. Surgery: Digestive System, Endoscopy. September 2020.<https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/surgdigest.pdf>. Accessed April 13, 2023.
11. United Healthcare. 2022. Commercial Medical Policy. Bariatric Surgery. Policy #2022T0362GG.
<https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/bariatric-surgery.pdf>. Accessed April 13, 2023.

DISCLAIMER

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.

Appendix 1: Quality of life questionnaire

GERD-Health Related Quality of Life Questionnaire (GERD-HRQL)

Institution: _____ Patient ID: _____ Date ___/___/___

On PPIs Off PPIs If off, for how long? _____ days / months

Scale:

- 0 = No symptom
- 1 = Symptoms noticeable but not bothersome
- 2 = Symptoms noticeable and bothersome but not every day
- 3 = Symptoms bothersome every day
- 4 = Symptoms affect daily activity
- 5 = Symptoms are incapacitating to do daily activities

*Please check the box to the right of each question which best describes your experience over the past **2 weeks***

- | | | | | | | | |
|-----|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| 1. | How bad is the heartburn? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 2. | Heartburn when lying down? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 3. | Heartburn when standing up? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 4. | Heartburn after meals? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 5. | Does heartburn change your diet? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 6. | Does heartburn wake you from sleep? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 7. | Do you have difficulty swallowing? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 8. | Do you have pain with swallowing? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 9. | If you take medication, does this affect your daily life? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 10. | How bad is the regurgitation? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 11. | Regurgitation when lying down? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 12. | Regurgitation when standing up? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 13. | Regurgitation after meals? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 14. | Does regurgitation change your diet? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 15. | Does regurgitation wake you from sleep? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 16. | How satisfied are you with your present condition? | | | | | | |
| | <input type="checkbox"/> Satisfied <input type="checkbox"/> Neutral <input type="checkbox"/> Dissatisfied | | | | | | |

Administered by _____

Monitored by _____

Date (mm/dd/yy) _____

Date (mm/dd/yy) _____

GERD-HRQL Questionnaire –Instructions

The GERD-HRQL questionnaire was developed and validated to measure changes of typical GERD symptoms such as heartburn and regurgitation in response to surgical or medical treatment.¹

When comparing GERD-HRQL scores post-TIF to scores pre-TIF, it is important to take medication use into consideration. It is recommended to request patients take this questionnaire twice at screening (once off PPIs and the other time on PPIs) for fair comparison at follow-ups post-TIF

Total Score: Calculated by summing the individual scores to questions 1-15.

- Greatest possible score (worst symptoms) = 75
- Lowest possible score (no symptoms) = 0

Heartburn Score: Calculated by summing the individual scores to questions 1-6 .

- Worst heartburn symptoms = 30
- No heartburn symptoms = 0
- Scores of ≤ 12 with each individual question not exceeding 2 indicate heartburn elimination.²

Regurgitation Score: Calculated by summing the individual scores to questions 10-15.

- Worst regurgitation symptoms = 30
- No regurgitation symptoms = 0
- Scores of ≤ 12 with each individual question not exceeding 2 indicate regurgitation elimination.²

References Cited

¹ Velanovich V. The development of the GERD-HRQL symptom severity instrument. *Dis Esophagus* 2007;20:130-4.

² Hunter JG, Trus TL, Branum GD, Waring JP, Wood WC. A physiologic approach to laparoscopic fundoplication for gastroesophageal reflux disease. *Ann Surg* 1996;223:673-85.