



INLAND EMPIRE HEALTH PLAN

**IEHP UM Subcommittee Approved Authorization Guidelines**  
***Natural Orifice Transluminal Endoscopic Surgery (NOTES)®***

**Policy:**

IEHP does not cover Natural Orifice Transluminal Endoscopic Surgery (NOTES)® as a benefit because it is investigational and experimental.

**Background:**

NOTES® may offer advantages in the future, over laparoscopic surgery, but it continues to be an investigational procedure with yet to be proven advantages, such as decreased post-surgical infection rates or decreased hospital length of stay.

In general, NOTES® is an incision-less, or scarless, surgical procedure in that no incisions are made on the external body surface. The endoscope is always introduced through an orifice, like the mouth, vagina, urethra or anus. 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<sup>1</sup>. Hybrid-NOTES® procedures involve laparoscopic assistance.

As NOTES® may be the next major advancement in minimally invasive surgery, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) joined together to create the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR)® Working Group on NOTES®. NOSCAR® has the goals of setting standards, promoting and guiding research, organizing NOTES® practitioners, and supporting NOTES® specific research. They outline the following priorities for research: safe peritoneal access and secure gastric closure, intraperitoneal contamination, image display and maintenance of spatial orientation, development of stable working platforms, physiologic perturbations, and tissue approximation methods<sup>2</sup>. The majority of the research thus far has been conducted on animal models<sup>3</sup>. Human clinical trials are currently underway to investigate transgastric and transvaginal approaches<sup>4</sup>.

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

Neither national Coverage Determination (NCD) nor Local Coverage Articles are currently available for NOTES® procedures<sup>5,6</sup>.

### **Medi-cal:**

There are no specific coverage details offered for NOTES®. Medi-cal requires Treatment Authorization Requests (TAR) for “unlisted procedures, stomach”, “unlisted procedures, biliary tract”, and “will not pay for assistant surgeon services” for “esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete”<sup>7</sup>.

### **Health Plans**

#### **Aetna (2016):**

NOTES® authorization guidelines are considered in relation to the type of surgical treatment it might be used in lieu of. It is considered experimental and investigational in the treatment of obesity (i.e. transoral gastroplasty, Restorative Obesity Surgery Endoluminal [ROSE] ®, etc.) and gastroesophageal reflux disease (i.e. StomaphyX® or EsophyX®)<sup>8,9</sup>.

#### **Blue Cross/ Blue Shield (2016):**

“Natural orifice transluminal endoscopic surgery (NOTES)® for the treatment of all conditions/diseases, including, but not limited to, the following: appendectomy, gastroplasty (e.g., Restorative Obesity Surgery Endoluminal [ROSE] ®, StomaphyX®), fundoplication (e.g., EsophyX™), cholecystectomy, cystogastrostomy, nephrectomy and peroral endoscopic myotomy (POEM) for treatment of esophageal achalasia is considered *investigational*”<sup>10,11</sup>.

#### **Cigna (2016):**

NOTES® procedures are not covered for treatment of morbid obesity or gastroesophageal reflux disease<sup>12, 13</sup>.

#### **Health Net (2016):**

NOTES® is considered investigational for morbid obesity<sup>14</sup>.

### **Additional Sources:**

#### **Apollo:**

A query run on 11/1/16 failed to produce guidance on this experimental surgical procedure.

#### **ECRI (2009):**

ECRI determined that NOTES® would be limited to academic research medical centers. One of the main reasons for the limited utilization is the lack of clinical evidence supporting the safety and efficacy of NOTES® over conventional techniques. Additionally, no human trials have demonstrated a minimized risk of peritoneal infection from the intentional GI tract perforation approach of NOTES®.

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ECRI also reports that no devices have yet received FDA marketing clearance or marketing approval specifically for NOTES®. ECRI suggest that for NOTES® to move from research to regular clinical practice, NOTES® procedures will need to prove comparable to conventional laparoscopic techniques in procedural time, procedural costs, safety, efficacy and technical difficulty.

NOTES® credentialing is another issue that will need to be resolved if NOTES® is to be a regularly performed procedure. There is a possibility that when a complication arises during a NOTES® procedure, it will require conversion to an open case. In this case, should the performing physician also be a trained and credentialed surgeon? The issue arises as both surgeons and non-surgeon gastroenterologists are interested and involved in this developing field<sup>15</sup>.

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**Reviewed Annually:**

<b>Revised:</b>

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