BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

# Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Policy #: 326
Category: Surgery

Latest Review Date: March 2018
Policy Grade: B

## Background:

***Blue Advantage*** *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

**Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare*** *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*



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## Description of Procedure or Service:

Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an emerging area of surgery in which the surgeon accesses the peritoneal cavity via a hollow viscus and performs diagnostic and therapeutic procedures. The surgeon passes a flexible scope through a natural orifice (oral, vaginal, urethral, nasal or rectal) and transects through that lumen into the open peritoneum where the actual surgery is performed. The NOTES procedure may have the potential to be the "ideal scar-free" surgery and have a shorter postoperative recovery if the technological and practical issues are achieved.

The key technical elements in a NOTES procedure are access via a hollow viscus, performance of the desired maneuver once in the target cavity, and closure of the port upon exit.

The specific surgical or diagnostic procedure will dictate which orifice should be used. For example, rectal entry provides easy access to the gall bladder and upper abdominal structures and is simpler than a gastric entry. However, it requires colon cleansing and has an increased infection risk and the concept is unpleasant to patients. An appendectomy, cholecystectomy, or sleeve gastrectomy can be performed via the vagina. The problem with vaginal access is that it requires a blind insertion into the peritoneum. Access through the bladder is sterile, but limits the size of instruments that can be used. One aspect of bladder entry is for transvesicular assistance for transoral procedures, or the use of two orifices for one procedure, where one orifice is used for viewing while the other is used for operating.

There are several limitations to these procedures. There will be some degree of bacterial contamination in the peritoneal cavity, with a risk of peritonitis and abscess formation. There may be effects on the immune system. It may be difficult to deal with major complications such as major bleeding, laceration, or perforation of other organs. Another concern with NOTES is the possibility of over-insufflation of the peritoneal cavity and subsequent decreased venous return to the heart.

## Policy:

**Effective for dates of service on or after March 16, 2009:**

Blue Advantage will treat **Natural Orifice Transluminal Endoscopic Surgery (NOTES)** procedures as a **non-covered** benefit and as **investigational**.

**Blue Advantage** will treat **endoscopic suturing devices** (e.g. Overstich, Over the Scope clips [OTSC]) **as non-covered** and as **investigational**.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most*

*appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## Key Points:

The first successful NOTES procedure performed in a human was in 2007, when a cholecystectomy through transgastric and transvaginal route was completed. There are several case series in the literature of the NOTES procedures in humans. These include transvaginal appendectomy, transvaginal cholecystectomy, transgastric peritoneoscopy for evaluation for a pancreatic mass, and transvaginal exploration for cancer staging. More recently, literature, studies include transgastric appendectomy, and salpingo-oophorectomy.

A major concern of the NOTES procedure is regarding the sufficient closing of the gastric wall in the transgastric approach. In prospective clinical studies between April 2010 and March 2014 by Magdeburg and Kaehler, 43 patients underwent the transgastric NOTES procedure. This study focused on the feasibility and safety of gastric closure. In all 43 of the procedures performed, the incision to the gastric wall was successfully closed. There were three adverse events postoperatively, which comprised of one major event and two minor events. The major event included a patient that began showing symptoms of acute peritonitis and subsequently had a diagnostic laparoscopy. Findings were "an insufficiency of the gastric closure with a local peritonitis; thus, the gastrotomy was closed with laparoscopic suturing and the abdominal cavity was cleaned with liquid solution." This patient was discharged a week later. Postoperatively in two cases there were clinical signs of acute gastrointestinal bleeding causing an urgent gastroscopy to be performed. One case showed no signs of bleeding and the second case had four clips placed at a Forrest IIb ulcer at the closure site. According to this publication, the NOTES procedure "requires a well-trained physician in flexible endoscopy as well as in visceral surgery." While this procedure appears promising based on the very limited data, further investigation must be completed before clear indications and guidelines can be established for the transgastric approach.

In another article published by Lehmann, et al in 2010, NOTES is still considered experimental and far from routine clinical practice. There have been no large or multicenter studies available. Lehmann reports from The German Registry for Natural Orifice Transluminal Endoscopic Surgery registry (GNR). The GNR was a voluntary database which physicians performing NOTES procedures were requested to enter data. More than 550 patients and 572 target organs were entered into the database as having a NOTES procedure. Eighty-five percent of the procedures done were cholecystectomies in female patients using the transvaginal route. Of note, a hybrid approach using transvaginal access and one or more additional abdominal wall trocars was utilized in 99.3% of the patients. There were a total of 17 complications reported including injuries to the rectum, bladder, and small bowel intraoperatively; and postoperatively, infections, bleeding, and an abscess in the pouch of Douglas. Concerns for the transvaginal route include the late effects such as infertility and dyspareunia. Limitations of this study include a lack of a standardized follow-up and the concern of how complete and valid the data entered is due to the voluntary entries being anonymous.

In 2014, Yagci and Kayaalp published a systematic review on transvaginal appendectomy. A total of 58 articles were selected for review. After the elimination of studies with inadequate patient data, concomitant hysterectomy, experimental studies, and duplicated studies, 12 studies were analyzed with 112 transvaginal appendectomies. In the studies, complicated appendicitis (perforation, abscess, and mass) and morbidly obese patients were usually excluded. Most of the cases were of acute appendicitis. The mean hospital stay for the surgery was 1.25 days (excluding German studies due to their national health system). The surgical technique varied between transvaginal access only, or transvaginal access with abdominal assistance (hybrid procedure). The purely transvaginal access procedure was only performed in 22% of the cases. Only 2 of these studies compared transvaginal and conventional laparoscopic appendectomies with a limited number of patients. These 2 studies showed a trend toward shorter hospital stay and quicker recovery; however, operating time was longer for transvaginal group. Limitations reported were inadequate data of this technique for morbidly obese patients and cultural sensitivity of using the vagina as an access point. The authors also state that "technological difficulties limit the application of the pure transvaginal technique to highly selected cases." They conclude by states that potential advantages and disadvantages will become clearer in the future with comparative studies and more studies are necessary on the role of transvaginal appendectomy in subgroups like morbidly obese patients and perforated appendicitis.

Also in 2014, Xu et al published a prospective randomized study on 40 patients who were scheduled for salpingectomy due to a tubal ectopic pregnancy. The patients were randomized into transvaginal endoscopic surgery (n=18) versus laparoscopic approach (n=20). Two patients did not undergo surgery from the original 40. Patient data was recorded for estimated blood loss, time of anal exhaust, postoperative pain score, and length of stay. A single surgeon performed the surgeries on both groups. The results showed that there was no significant difference in blood loss, operative time, and time of anal exhaust after operation. The authors report that the transvaginal endoscopic approach is repeatable and a safe, minimally invasive surgery compared with the laparoscopic approach. The authors note that more sophisticated technologies and instruments need to be developed for NOTES. Due to the limited instruments, the patient population of this study was highly selected.

Endoscopic Closure Devices in NOTES Procedure

In 2014, Gonzaliz-Panizo-Tamargo et al published a study using the Overstitch endoscopic suturing system in NOTES procedures over a period of 6 months in 5 patients. The device was evaluated for endoscopic fixation of metallic stent to prevent migration in patients with GI non-neoformative pathology (n=3) and outlet reduction in patients with weight regain following Roux en Y gastric bypass (n=2). According to the authors, all stitches were successfully placed except 1 in whom the thread broke. Stents were adequately anchored in 3 cases. For the 2 outlet reduction procedures, significant gastric outlet reduction was achieved. Of the 2 patients that were treated for outlet reduction, 1 of the patients did not lose any weight, and the other lost 12 kg at the last follow up. The 3 patients treated for fixation of metallic stent, 2 patients had normal oral intake with no dysphagia after a follow up of 2 months. The third patient passed away related to complications of his basal disease. Complications were reported as minor bleeding which is comparable to other endoscopic non-complicated procedures, controlled vomiting during first 24 hours(bariatric patients), and stent related discomfort during first 24 hours. No other complications reported. The authors concluded by stating the Overstitch is a promising

endoscopic suturing system that needs new evidence with large and well-designed studies to confirm the promising results obtained.

**Summary of Evidence**

The evidence regarding the NOTES procedure and endoscopic suturing devices is still evolving. There are many studies still being conducted in animals. The literature available states pain and hospital stays are reduced after having the NOTES procedure vs laparoscopic procedures. There was no difference in morbidity, but cosmetic satisfaction was better for the NOTES group. However, there is no long term evidence for these procedures. Larger trials with long term follow up is needed to determine the efficacy of these procedures. The evidence is insufficient to determine the net health outcome of this procedure.

**Practice Guidelines and Position Statements**

National Orifice Surgery Consortium for Assessment and Research (NOSCAR)

In 2005, the American Society of Gastrointestinal Endoscopy (ASGE) and the Society of Gastrointestinal Endoscopic Surgeons (SAGES) came together in a consortium, the National Orifice Surgery Consortium for Assessment and Research, or NOSCAR, to provide consensus and guidelines for this procedure. Currently, NOSCAR requires that all NOTES procedures must be performed under an investigational research board protocol, and the laboratory rehearsal using NOTES procedures and techniques is first practiced on cadavers. The literature states that at present, NOTES should be considered experimental and should be performed only in a research setting.

In 2009, NOSCAR announced that they would be conducting a multicenter human trial on transoral and transvaginal cholecystectomies using NOTES, and enrolling patients to take part in this study. The study will compare NOTES cholecystectomy versus conventional laparoscopic cholecystectomy.

In 2012, NOSCAR stated that "while NOTES procedures are still considered experimental and require IRB approval, data regarding instrumentation are now sufficiently robust to make new recommendations." They conclude that the flexible endoscope should not be considered experimental when used to "traverse the wall of the GI tract or vagina"; however, the procedure itself is considered experimental.

**As of February 2018, there has not been an update.

## Key Words:

Natural orifice, transluminal endoscopic surgery, hollow viscus, target cavity, NOTES, endoscopic suturing device, endoscopic closure device, overstitch, OTSC

## Approved by Governing Bodies:

Not applicable



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## Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefits consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

## Coding:

CPT Codes:

There is no specific code for Natural Orifice Transluminal Endoscopic Surgery.

There is no specific code for endoscopic suturing devices. It would likely be submitted using the unlisted procedure, stomach code, 43999.

## References:


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## Policy History:

Adopted for Blue Advantage, January 2009
Available for comment January 30-March 15, 2009
Medical Policy Group, April 2015
Medical Policy Group, February 2018

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*