**Name of Policy:**
Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Policy #: 326  
Category: Surgery  
Latest Review Date: April 2015  
Policy Grade: B

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an emerging area of gastrointestinal 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 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:
The Natural Orifice Transluminal Endoscopic Surgery (NOTES) procedures do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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.

Practice Guidelines and Position Statements
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.

Key Words:
Natural orifice, transluminal endoscopic surgery, hollow viscus, target cavity, NOTES

Approved by Governing Bodies:
Not applicable

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 are no specific codes for Natural Orifice Transluminal Endoscopic Surgery.

References:

Policy History:
Medical Policy Group, January 2009
Medical Policy Administration Committee, February 2009
Available for comment February 6-March 23, 2009
Medical Policy Group, April 2015 (4): Update to Description, Key Points, and References. No policy statement change.

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.