



BlueCross BlueShield
of Alabama

Name of Policy:

Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Policy #: 326
Category: Surgery

Latest Review Date: January 2009
Policy Grade: B

Background:

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.*

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 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.

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 members' 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:

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.

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 NOSCART, to provide consensus and guidelines for this procedure. Currently, NOSCART 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.

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

AT&T contracts: No special consideration

FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification requirements: Not applicable

Pre-determination requirements: Pre-determinations will be performed as a courtesy review at the request of the physician and/or subscriber.

Coding:

CPT Codes: There are no specific codes for Natural Orifice Transluminal Endoscopic Surgery.

References:

1. Bergman S, et al. *Natural orifice transluminal endoscopic surgery*. Surgical Clinics of North America 2008; 88: 1131-1148.
2. Hawes RH. *ASGE/SAGES Working Group on Natural Orifice Transluminal Endoscopic Surgery, White Paper*. Gastrointestinal Endoscopy 2006, vol. 63, No. 2, pp. 199-203.
3. Pasricha PJ, et al. *Natural orifice transluminal endoscopic surgery (NOTES)*. August 2008. <http://www.uptodate.com>.
4. Pasricha PJ. *The future of therapeutic endoscopy*. Clinical Gastroenterology Hepatology 2004; 2: 286.
5. Sodergren MH, et al. *Natural orifice transluminal endoscopic surgery: Critical appraisal of applications in clinical practice*. Surgical Endoscopy, January 2009.
6. Swain PA. *A justification for NOTES-natural orifice transluminal endosurgery*. Gastrointestinal Endoscopy 2007; 65: 514.
7. Wagh MS, et al. *Endoscopic transgastric abdominal exploration and organ resection: Initial experience in a porcine model*. Clinical Gastroenterology and Hepatology 2005; 3: 892-896.
8. Zorron R, et al. *NOTES transvaginal for cancer diagnostic staging: Preliminary clinical application*. Surgical Innovations 2008.

Policy History:

Medical Policy Group, January 2009

Medical Policy Administration Committee, February 2009

Available for comment February 6-March 23, 2009

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 plans contracts.