Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Policy #: 326
Latest Review Date: May 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

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).*

POLICY:

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.

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.

KEY POINTS:

This policy's most recent literature review was performed through May 5, 2023.

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.

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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT 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.

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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
Medical Policy Group, October 2019
Medical Policy Group, June 2021
Medical Policy Group, May 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, May 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
