For dates of service October 11, 2020, and after, refer to L38551, A58000.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transanal Endoscopic Microsurgery (TEMS)

Policy #: 313
Category: Surgery

Latest Review Date: September 2020
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).*

POLICY:

Effective for dates of service October 11, 2020, and after, refer to LCD L38551, A58000.

Effective for dates of service on or after March 24, 2020 and prior to October 11, 2020:
Blue Advantage will treat **transanal endoscopic microsurgery (TEMS)** as a **covered benefit** for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision.

Blue Advantage will treat **transanal endoscopic microsurgery (TEMS)** as a **covered benefit for treatment of T1 rectal adenocarcinomas** that cannot be removed using other means of local excision and that meet **all** of the following criteria;

- Located in the middle or upper part of the rectum, **AND**
- Well or moderately differentiated (G1 or G2) by biopsy, **AND**
- Without lymphadenopathy or microscopic angiolymphatic invasion, **AND**
- Less than 1/3 the circumference of the rectum

Blue Advantage will treat **transanal endoscopic microsurgery** as a **non-covered benefit** and as **investigational** for the treatment of rectal tumors that do not meet the previously listed criteria.

Effective for dates of service on or after February 26, 2018 and prior to March 24, 2020, refer to LCD L34555.

Effective for dates of service on or after November 6, 2009 and prior to February 26, 2018:
Blue Advantage will treat **transanal endoscopic microsurgery (TEMS)** as a **covered** benefit for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision.

Blue Advantage will treat **transanal endoscopic microsurgery (TEMS)** as a **covered** benefit for **coverage for treatment of T1 rectal adenocarcinomas** that cannot be removed using other means of local excision and that meet **all** of the following criteria;

- Located in the middle or upper part of the rectum **AND**
- Well or moderately differentiated (G1 or G2) by biopsy, **AND**
- Without lymphadenopathy or microscopic angiolymphatic invasion **AND**
- Less than 1/3 the circumference of the rectum.

Blue Advantage will treat **transanal endoscopic microsurgery** as a non-covered benefit and as **investigational** for the treatment of rectal tumors that do not meet the previously listed criteria.

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:

Transanal endoscopic microsurgery (TEMS) is a minimally invasive surgical approach to local excision of rectal lesions that cannot be directly visualized. It is an alternative to open or laparoscopic excision and has been studied in the treatment of both benign and malignant conditions of the rectum.

Transanal Endoscopic Microsurgery

Transanal Endoscopic Microsurgery (TEMS) has been used in benign conditions such as large rectal polyps (that cannot be removed through a colonoscope), retrorectal masses, rectal strictures, rectal fistulae, rectal pelvic abscesses, and in malignant conditions such as malignant polyps. Use of TEMS for resection of rectal cancers is more controversial. TEMS can avoid morbidity and mortality associated with major rectal surgery including fecal incontinence related to stretching of the anal sphincter, and can be performed under general or regional anesthesia.

The TEMS system has a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. This procedure has been available in Europe but has not been used widely in the United States. Two reasons for this slow diffusion are the steep learning curve for the procedure and the limited indications. For example, most rectal polyps can be removed endoscopically and many rectal cancers need a wide excision and are thus not amenable to local resection.

Other Treatment Options

The most common treatment for rectal cancer is surgery; the technique chosen will depend on several factors. The size and location of the tumor, evidence of local or distal spread, and patient characteristics and goals are all attributes that will affect the treatment approach. Open, wide resections have the highest cure rate but may also have significant adverse effects. Most patients find the potential adverse effects of lifelong colostomy, bowel; bladder; or sexual dysfunction, acceptable in the face of a terminal illness. Laparoscopic-assisted surgery, with lymph node dissection as indicated, is technically difficult in the pelvic region but is being investigated as a less invasive alternative to open resection.

Local excision (LE) alone does not offer the opportunity for lymph node biopsy and therefore has been reserved for patients in whom the likelihood of cancerous extension is small. LE can occur under direct visualization in rectal tumors within 10cm of the anal verge. TEMS extends LE ability to the proximal rectosigmoid junction. Adenomas, small carcinoid tumors, and nonmalignant conditions; such as strictures or abscesses; are amenable to LE by either method.

The use of LE in rectal adenocarcinoma is an area of much interest and may be most appropriate in small tumors (<4 cm) confined to the submucosa (T1, as defined by the TNM staging system). Presurgical clinical staging, however, may miss up to 15% of regional lymph node spread. During an LE, the excised specimen should be examined by a pathologist; if adverse features such as high-grade pathology or unclear margins are observed, the procedure can be converted to a wider resection. Despite this increased risk of local recurrence, LE may be an informed alternative for patients. TEMS permits LE beyond the reach of direct visualization equipment.

KEY POINTS:

The most recent update with literature review covers through September 09, 2019.

Summary of Evidence

For individuals who have rectal adenomas who receive TEMS, the evidence includes a few nonrandomized comparative studies, and numerous single-arm case series. The relevant outcomes are OS, functional outcomes, health status measures, QOL, and treatment-related morbidity. The evidence supports conclusions that the removal of polyps by TEMS is associated with low postoperative complications low-risk of recurrence.

For individuals with early rectal adenocarcinoma who receive TEMS, the evidence includes two small RCTs, a few nonrandomized comparative studies, and many single-arm case series. The relevant outcomes are OS, functional outcomes, health status measures, QOL, and treatment-related morbidity. The evidence supports the conclusions that TEMS is associated with fewer postoperative complication but higher local recurrence rates and possibly higher rates of metastatic disease. There is no demonstrated difference in long-term OS in the available studies.

Based on clinical input supplemented by the outcomes of single-arm series that have shown low complication rates and low recurrence rates of lesions supporting use of TEMS when lesions are not amenable to standard excision, TEMS may be considered medically necessary for excision of rectal adenomas and early carcinomas that cannot be removed by standard approaches when specific criteria are met. These criteria are clinical stage T1 cancers that are located in the middle or upper part of the rectum, are well- or moderately differentiated (G1 or G2) by biopsy, are without lymphadenopathy, and involve less than one-third of the circumference of the rectum.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (v.2.2019) in its updated guidelines on the treatment of rectal cancer), altered a statement on transanal local excision to exclude transanal endoscopic microsurgery (TEM). It now states, “When the lesion can be adequately localized to the rectum, local excision of more proximal lesions may be technically feasible using advanced techniques, such as transanal microscopic surgery or transanal minimally invasive surgery (TAMIS).”

However, under discussion is the statement, “TEM can facilitate excision of small tumors through the anus when lesions can be adequately identified in the rectum. TEM may be technically feasible for more proximal lesions.”

National Cancer Institute
The NCI (2019) guidelines on treatment of rectal cancer indicate the management of rectal cancer is multimodal and involves a multidisciplinary team of cancer specialists with expertise in gastroenterology, medical oncology, surgical oncology, radiation oncology, and radiology. Based on the increased risk of local recurrence and poor overall prognosis, management of rectal cancer diverges from colon cancer. The differences include surgical technique, use of radiation therapy and method of chemotherapy administration. Additional issues are maintenance or restoration of normal anal sphincter and genitourinary function. The NCI recommends as a primary treatment for patients with rectal cancer surgical resection of the primary tumor. The NCI guidance specific to this policy includes, "…Transanal local excision and transanal endoscopic microsurgery for select clinically staged T1/T2 N0 rectal cancers."

American Society of Colon and Rectal Surgeons
The American Society of colon and Rectal Surgeons have published a 2013 update of its 2010 practice parameters for the management of rectal cancer. The 2013 guidelines state that curative local excision is an appropriate treatment modality for carefully selected well to moderately differentiated T1 rectal cancers. Tumor size must be less than 3cm in diameter and less than one third of the bowel lumen circumference. Additionally, patients must have a lymphovascular or perineural invasion. The guidelines note visualization with transanal endoscopic microsurgery appears to be superior to the transanal approach, but randomized controlled trials on the issue are lacking. T2 lesions should be treated with radical mesenteric excision unless the patient is a poor candidate for a more extensive surgical procedure.

American College of Radiology
The ACR;(2015) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer in 2015. The ACR notes TEMS is an appropriate operative procedure for locally complete excision of distal rectal lesions and has been "evaluated for curative treatment of invasive cancer." TEMS is noted to have "been shown to be as effective and associated with less morbidity than conventional transanal excision" and is considered safe after treatment with chemoradiation. These ACR guidelines are based on expert consensus and analysis of current literature.

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:
Transanal endoscopic microsurgery, TEMS, TEM, rectal cancer, adenocarcinoma, adenoma

APPROVED BY GOVERNING BODIES:
In March 2001, the Transanal Endoscopic Microsurgery (TEMS) Combination System and Instrument Set (Richard Wolf Medical Instruments, Vernon Hills, IL) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA

determined that this device was substantially equivalent to existing devices for use in inflating the rectal cavity, endoscopically visualizing the surgical site, and accommodating up to three surgical instruments. The Covidien SILS™ Port subsequently received 510(k) approval in 2011. The SILS port is a similar instrument that can be used for rectal procedures including TEMS. Another device determined by the FDA to be substantially equivalent to these devices is the GelPOINT® Path (Applied Medical Resources).

Device	Manufacturer	Date Cleared	510(k) No.	Indication
AP50/30 Insufflator with Insuflow Port	Lexion Medical LLC	8/28/2019	K191780	For use in transanal endoscopic microsurgery
AirSeal	ConMed Corporation	3/28/2019	K190303	For use in transanal endoscopic microsurgery
GRI-Alleset Veress Needle	GRI Medical and Electronic Technology Co. Ltd.	6/11/2018	K172835	For use in transanal endoscopic microsurgery
SurgiQuest AIRSEAL iFS System	ConMed Corporation	3/16/2018	K172516	For use in transanal endoscopic microsurgery
TEMED Gas Diffuser	TEMED	2/14/2018	K173545	For use in transanal endoscopic microsurgery
AP 50/30 Insufflator with Insuflow Port	LEXION Medical LLC	11/14/2017	K170799	For use in transanal endoscopic microsurgery
Veress Needle	WickiMed (Huizhou) Medical Equipment Manufacturing Co.Ltd.	9/14/2017	K172120	For use in transanal endoscopic microsurgery
GelPOINT Path Transanal Access Platform	Applied Medical Resources Corp.	7/20/2017	K171701	For use in transanal endoscopic microsurgery
HumiGard Surgical Humidification System HumiGard Humidified	FISHER & PAYKEL HEALTHCARE	6/23/2017	K162582	For use in transanal endoscopic microsurgery

Insufflation Kit				
LaparoLight Veress Needle	Buffalo Filter LLC	5/18/2017	K171139	For use in transanal endoscopic microsurgery
PNEUMOCLEAR	W.O.M World Of Medicine GmbH	5/15/2017	K170784	For use in transanal endoscopic microsurgery
ENDOFLATOR 40 ENDOFLATOR 50	KARL STORZ ENDOSCOPYAMERICA INC.	3/2/2017	K161554	For use in transanal endoscopic microsurgery
U-Blade Veress Needle	TIANJIN UWELL MEDICAL DEVICE MANUFACTURING CO.LTD.	12/12/2016	K162648	For use in transanal endoscopic microsurgery
S698 Symbioz flow	SOPRO - ACTEON GROUP	6/17/2016	K153367	For use in transanal endoscopic microsurgery
Insufflator 50L FM134	W.O.M WORLD OF MEDICINE GMBH	3/4/2016	K153513	For use in transanal endoscopic microsurgery
Unimicro Veress Needle	Unimicro Medical Systems (ShenZhen) Co.Ltd.	7/31/2015	K150068	For use in transanal endoscopic microsurgery
SurgiQuest AirSeal iFS System	SURGIQUEST INC.	3/20/2015	K143404	For use in transanal endoscopic microsurgery
GELPOINT PATH TRANSANAL ACCESS PLATFORM	APPLIED MEDICAL RESOURCES CORP.	1/2/2014	K133393	For use in transanal endoscopic microsurgery

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT Codes:

0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS), including muscularis propria (i.e., full thickness)

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POLICY HISTORY:

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Medical Policy Group, November 2010

Medical Policy Group, April 2012
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Medical Policy Group, October 2013
Medical Policy Group, September 2015
Medical Policy Group, November 2016
Medical Policy Group, November 2017
Medical Policy Group, February 2018
Medical Policy Group, September 2020: Reinstated policy effective March 24, 2020. For dates of service before March 24, 2020, and on or after February 26, 2018, refer to LCD L34555. L34555 (Non-Covered Category III CPT Codes) retired effective March 23, 2020.
