Transanal Endoscopic Microsurgery

Policy # 00821
Original Effective Date: 02/13/2023
Current Effective Date: 02/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transanal endoscopic microsurgery for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision to be **eligible for coverage.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transanal endoscopic microsurgery for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for transanal endoscopic microsurgery for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision may be considered when **ALL** of the following criteria are met:

- Located in the middle or upper part of the rectum; **AND**
- Well- or moderately differentiated (G1 or G2) by biopsy; **AND**
- Without lymphadenopathy; **AND**

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- Less than one-third of the circumference of the rectum.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of transanal endoscopic microsurgery for treatment rectal tumors when patient selection criteria are not met is considered to be **investigational.***

Policy Guidelines

The clinical staging of rectal cancers is determined from the physical examination, imaging, and biopsy results.

Background/Overview

Transanal Endoscopic Microsurgery

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

The TEM system has a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. This procedure has been available in Europe but has not been widely used in the U.S. Two reasons for this slow adoption 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 an individual's

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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 events. Most Individuals find the potential adverse events of lifelong colostomy and/or 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 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. Local excision can occur under direct visualization in rectal tumors within 10 cm of the anal verge. TEM extends local excision ability to the proximal rectosigmoid junction. Adenomas, small carcinoid tumors, and nonmalignant conditions (eg, strictures, abscesses) are amenable to local excision by either method.

The use of local excision 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 tumor, node, and metastasis staging system). Presurgical clinical staging, however, may miss up to 15% of regional lymph node spread. During local excision, 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, local excision may be an informed alternative for patients. TEM permits local excision beyond the reach of direct visualization equipment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2001, the TEM Combination System and Instrument Set (Richard Wolf Medical Instruments) 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 3 surgical instruments. In 2011, the SILS™‡ Port (Covidien) was cleared for marketing by the FDA through the 510(k) process. The SILS Port is a similar instrument that can be used for rectal procedures including TEM. Another device determined by the FDA to be substantially equivalent to these devices is the GelPOINT®‡ Path (Applied Medical Resources). FDA product codes: HIF, GCJ, FER. Table 1 lists some of the TEM devices cleared by the FDA.

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Table 1. Transanal Endoscopic Microsurgery Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Applied Medical Anoscope	Applied Medical Resources	01/06/2021	K200021	For use in transanal endoscopic microsurgery
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
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 Insufflation Kit	FISHER & PAYKEL HEALTHCARE	6/23/2017	K162582	For use in transanal endoscopic microsurgery

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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 ENDOSCOPY-AMERICA 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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Description
Transanal endoscopic microsurgery (TEM) is a minimally invasive approach for 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.

Summary of Evidence
For individuals who have rectal adenoma(s) who receive transanal endoscopic microsurgery (TEM), the evidence includes a few nonrandomized comparative studies and numerous single-arm case series. Relevant outcomes are overall survival (OS), functional outcomes, health status measures, quality of life (QOL), and treatment-related morbidity. The evidence supports conclusions that the removal of polyps by TEM is associated with low postoperative complication rates and low-risk of recurrence. However, due to the low quality of the evidence base, no conclusions can be made on the comparative efficacy of TEM and standard procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have early rectal adenocarcinoma who receive TEM, the evidence includes 2 small randomized controlled trials (RCTs), a few nonrandomized comparative studies, numerous single-arm case series, and systematic reviews of these studies. Relevant outcomes are OS, functional outcomes, health status measures, QOL, and treatment-related morbidity. The evidence supports conclusions that TEM is associated with fewer postoperative complications but higher local recurrence rates and possibly higher rates of metastatic disease. One systematic review indicates improved OS with radical surgery compared with TEM; however, the majority of systematic reviews did not demonstrate significant differences in OS. However, due to the low quality of the evidence base, these conclusions lack certainty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Based on clinical input obtained in 2009, supplemented by the outcomes of single-arm series that have shown low complication rates and low recurrence rates of lesions supporting use of TEM when lesions are not amenable to standard excision, TEM 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.

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Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009 Input
In response to requests, input was received from 2 academic medical centers while this policy was under review in 2009. Input supported the policy statements adopted in 2009. One reviewer commented specifically that this technique should be limited to select T1 rectal cancers.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (v. 4.2023) in its updated guidelines on the treatment of rectal cancer 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 endoscopic microsurgery (TEM) or transanal minimally invasive surgery (TAMIS)."

However, under discussion is the statement, "TEM [transanal endoscopic microsurgery] 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
In 2021, the National Cancer Institute (NCI) guidelines on treatment of rectal cancer indicated the management of rectal cancer is multimodal and involves a multidisciplinary team of cancer specialists with expertise in gastroenterology, medical oncology, surgical oncology, radiation

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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 radiotherapy, and method of chemotherapy administration. Additional issues are maintenance or restoration of the normal anal sphincter and genitourinary function. The NCI recommends surgical resection of the primary tumor as a primary treatment for patients with rectal cancer. The NCI guidance specific to this medical 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 published updated guideline recommendations for the management of rectal cancer in 2020. The guidelines indicate 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 3 cm in diameter and less than 30% of the bowel lumen circumference. Additionally, patients must not have a lymphovascular or perineural invasion. The guidelines noted that visualization with TEM appears to be superior to the transanal approach, but randomized controlled trials are lacking. T2 lesions should be treated with radical resection unless the patient is a poor candidate for a more extensive surgical procedure.

American College of Radiology
In 2015, the American College of Radiology (ACR) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer. The ACR noted that TEM is an appropriate operative procedure for locally complete excision of distal rectal lesions and has been "evaluated for curative treatment of invasive cancer." ACR also noted that TEM has "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 were based on expert consensus and analysis of current literature.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Unpublished			
NCT03718351	Randomized Controlled Trial of Endoscopic Submucosal Dissection Versus Transanal Endoscopic Microsurgery For Early Rectal Neoplasms And Large Rectal Adenomas: Comparison of Treatment Efficacy And Safety	236	Sep 2021 (unknown)
NCT02945566	Can the Rectum be Saved by Watchful Waiting or TransAnal Surgery Following (Chemo)Radiotherapy Versus Total Mesorectal Excision for Early REctal Cancer? (STAR-TREC)	120	Oct 2021 (unknown)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 02/13/2023
Current Effective Date: 02/12/2024
01/05/2023 Medical Policy Committee review
01/11/2023 Medical Policy Implementation Committee approval. New policy.
01/04/2024 Medical Policy Committee review
01/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 01/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0184T
HCPCS	No Codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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