
Medical Policy



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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Transanal Endoscopic Microsurgery (TEM)

Description/Background

TRANSANAL ENDOSCOPIC MICROSURGERY

Transanal endoscopic microsurgery (TEM) is a minimally invasive approach to local excision of rectal lesions that cannot be directly visualized. 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 such as malignant polyps. Use of TEM for resection of rectal cancers is more controversial. TEM can avoid 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 used as 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 individual 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 individuals 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 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 non-malignant conditions (e.g., strictures or 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 TNM staging system). Presurgical clinical staging, however, may miss up to 15% of regional lymph node spread. During a 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.

Regulatory Status

In 2001, 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 three surgical instruments. In 2011, the SILS™ Port (Covidien) was subsequently cleared 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.

Table 1. Transanal Endoscopic Microsurgery Devices Cleared by the US 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 Insufflow 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
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

Medical Policy Statement

The safety and effectiveness of transanal endoscopic microsurgery have been established. It may be considered a useful therapeutic procedure for individuals meeting selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions:

TEM is appropriate for those patients with:

- Rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision.
- Clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision and the tumors are **(must meet all)**:
 - Located in the middle or upper part of the rectum
 - Well- or moderately-differentiated (G1 or G2) by biopsy
 - Have no associated lymphadenopathy
 - Less than 1/3 the circumference of the rectum

Exclusions

Patients not meeting the above criteria.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

0184T

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

RECTAL ADENOMA(S)

The following PICO was used to select literature to inform this review.

Clinical Context and Therapy Purpose

The purpose of transanal endoscopic microsurgery (TEM) in patients who have rectal adenoma(s) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant populations of interest are individuals with rectal adenoma(s).

Interventions

The therapy being considered is TEM. TEM is a form of transanal endoscopic surgery (TES) performed with a rigid operating proctoscope. When a flexible multichannel laparoscopic port is utilized, the transanal endoscopic procedure is known as transanal minimally invasive surgery (TAMIS).

Comparators

The following practices are currently being used to treat both rectal adenoma(s) and with early rectal adenocarcinoma: standard transanal excision (TAE) and laparoscopic excision.

Outcomes

The general outcomes of interest are overall survival (OS), tumor recurrence, and treatment-related adverse events (e.g., incontinence, sexual dysfunction).

Follow-up after hospital discharge (24 to 48 hours) takes about 1 to 2 weeks.

Study Selection Criteria

- Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The endoscopic approach to benign or premalignant lesions is similar to that throughout the colon, and studies focus on the relative safety of the technique. The evidence presented in this section may include adenomas. However, the focus of this research is on safety of the procedure.

Systematic Reviews

Barendse et al (2011) reported on a systematic review to compare transanal endoscopic microsurgery (TEM) to endoscopic mucosal resection (EMR) for rectal adenomas larger than two cm.(1) Included in the review were 48 TEM and 20 EMR studies; all were treated as single-arm studies. No controlled trials were identified that compared TEM to EMR directly. Early adenoma recurrence rates, within three months of the procedure, were 5.4% (95% confidence interval [CI]: 4.0-7.3) with TEM and 11.2% (95% CI: 6.0–19.9) with EMR ($p=0.04$) in pooled estimates. After 3 months, late adenoma recurrence rates in pooled estimates were 3.0% (95% CI: 1.3-6.9) with TEM and 1.5% (95% CI: 0.6-3.9) for EMR ($p=0.29$). Lengths of hospitalization and readmission rates did not differ significantly between procedures. For TEM, the mean hospital length of stay of was 4.4 days and 2.2 days for EMR ($p=0.23$). Hospital readmission rates were 4.2% for TEM and 3.5% for EMR ($p=0.64$). Complication rates after TEM, for rectal adenomas only, were 13.0% (95% CI: 9.8-17.0) and 3.8% (95% CI: 2.8-5.3) after EMR, for colorectal adenomas ($p<0.001$). Postoperative complications were found to increase significantly with larger polyp size ($p=0.04$). However, postoperative complication rates remained higher for TEM after adjusting for a larger mean polyp size in the TEM studies (8.7% [95 % CI: 5.8–12.7]) than in EMR (4.2% [95 % CI: 2.9–6.3; $p=0.007$]). These results suggest that TEM may be associated with less early cancer recurrence than with EMR, but late cancer recurrence (after three months) may not differ significantly different between procedures. Complications were significantly higher with TEM for rectal adenomas larger than 2 cm. This systematic review was limited by the low quality of the available studies, particularly on the single-arm study evidence base.

Middleton et al (2005) conducted a systematic review of TEM based on published results through August 2002.(2) Three comparative studies, including a randomized controlled trial (RCT), and 55 case series were included. The first area of study was the safety and efficacy in removal of adenomas. In the RCT, no difference could be detected in the rate of early complications between TEM (10.3% of 98 patients) and direct local excision (17% of 90 patients) (relative risk, 0.61; 95%, CI, 0.29-1.29). Transanal endoscopic microsurgery resulted in less local recurrence (6% [6/98]) than direct local excision (22% [20/90]) (relative risk, 0.28; 95%, CI, 0.12-0.66). The 6% local recurrence rate for TEM in this trial is consistent with rates found in the TEM case series.

Case Series

Numerous case series of TEM have evaluated the treatment of rectal adenomas; many included mixed populations of patients with benign and malignant lesions.(3-15) Most were retrospective, and a few compared outcomes with other case series of standard excision. These case series offer useful information on completeness of resection, local recurrence, and complications, but they do not provide definitive evidence on the comparative efficacy of this

procedure because the comparisons were limited by potential selection bias leading to differences in the patient populations.

Al-Najami et al (2016) reported on longer-term follow-up for a prospective cohort study of 280 patients with advanced polyps and early rectal cancer treated with TEM.(16) Most patients (n=163, 63%) had benign disease. Postoperative complications were more frequent in malignant cases (24%) than in benign cases (10.8%, P=0.03). A standard follow-up protocol was followed by 83% and 85% of benign and malignant cases, respectively. Over a mean follow up of 16.4 and 15.2 months in the benign and malignant groups, recurrences occurred in 8.3% and 13.5%, respectively.

Long-Term Outcomes

Chan et al (2020) conducted a retrospective cohort study at a large, single-center institution in Canada to assess long-term recurrence rates following TEM.(17) Consecutive patients (N=297) with pathology-confirmed rectal adenoma treated by transanal endoscopic surgery between May 2007 and September 2016 who had at least 1 y of confirmed endoscopic follow-up were included. Median follow-up was 623 days. A total of 62 recurrences occurred in 41 patients (13.8%). Recurrences were addressed with repeat TEM or endoscopic resection in 67.7% and 25.8% of cases, respectively. Radical resection for adenocarcinoma was required in 4 patients. Recurrence-free survival rates were 93.4% at 1 year, 86.2% at 2 years, and 73.1% at 5 years. The authors conclude that rectal adenomas managed by TEM are at high risk for recurrence and surveillance should be performed within the first 2 years and continued through at least 5 years.

Section Summary: Rectal Adenoma(s)

There is a lack of high-quality trials comparing TEM with standard surgical approaches for the removal of rectal adenomas. The available evidence is primarily from single arm studies and has reported that TEM can be performed with relatively low complication rates and low recurrence rates. It is not possible to determine the comparative efficacy of TEM and other surgical approaches with certainty based on the available evidence. Systematic reviews of nonrandomized comparative studies have concluded that the local recurrence rate with TEM may be lower than for other procedures, but that the short-term complication rates may be higher. The 5-year recurrence-free survival rate for one single-center experience was 73.1%. These conclusions are limited by potential selection bias leading to differences in the patient populations; in particular, it is possible that patients undergoing TEM have lower disease severity than patients undergoing standard excision. Therefore, it is not possible to form conclusions about the comparative efficacy of TEM with alternative approaches.

EARLY RECTAL ADENOCARCINOMAS

Systematic Reviews

Motamedi et al (2023) conducted a Cochrane systematic review comparing local excision techniques including TEM, TAMIS, and transanal endoscopic operation (TEO) to radical surgery in patients with stage 1 rectal cancer.19, Four RCTs were included in the analysis. Disease-free survival was non-significantly improved with radical surgery compared with local excision (n=212; HR, 1.96; 95% CI, 0.91 to 4.24; p=.09). Cancer-related survival was similar between procedures (n=207; HR, 1.42; 95% CI, 0.60 to 3.33). Results for local recurrence were not pooled. The authors concluded that additional RCTs are needed to increase the certainty of evidence and obtain additional data on local or distant metastases.

Li et al (2023) conducted a meta-analysis of RCTs and cohort studies comparing TEM with radical surgery. 20, A total of 5 RCTs and 8 cohort studies were identified. There were no significant differences between groups in terms of distant metastases, overall recurrence, or disease-specific survival. However, overall survival was lower in patients treated with TEM compared with radical surgery (RR, 0.88; 95% CI, 0.74 to 1.00) but with high heterogeneity (I², 55%). Other outcomes such as operative time, blood loss, and time of hospitalization were improved in patients treated with TEM.

Xiong et al (2021) reported on a systematic review and meta-analysis comparing TEM with radical surgery in patients with T1 or T2 rectal cancer.(21) The meta-analysis included 12 studies (N=3526): 2 RCTs, 3 prospective cohort studies, and 7 retrospective cohort studies. Meta-analysis of outcomes from 8 studies found a reduced rate of postoperative complications among patients treated with TEM (risk ratio, 0.23; 95% CI, 0.11 to 0.45; p<.0001). Transanal endoscopic microsurgery was associated with a significantly increased risk for local (risk ratio, 2.63; 95% CI, 1.60-4.31; p=.0001) and overall recurrence (risk ratio, 1.60; 95% CI, 1.09-2.36;p=.02). Overall survival was similar between groups (hazard ratio, 1.51; 95% CI, 1.16 to 1.96; p=.19).

Sgourakis et al (2011) conducted a meta-analysis of T1 and T2 rectal cancer treatment that compared TEM with standard resection and transanal excision (TAE).(22) Eleven studies were selected for analysis and included 3 randomized controlled, one prospective, and 7 retrospective trials (n=1,191 patients; 514 TEM, 291 standard resection, 386 TAE). Numerous combined analyses were performed to measure mortality, complications, and recurrence rates. For postoperative complication rates, the combined analysis showed a significantly lower rate of major complications for TEM than for standard resection (OR: 0.24, 95% CI: 0.07-0.91). Minor complications did not differ significantly between groups. Overall postoperative complications did not differ significantly between TEM and TAE when stage T1 and T2 tumor data were pooled. Follow-up for all of the studies was a mean or median of more than 30 months (except for follow-up of more than 20 months in one treatment arm in 2 studies). For T1 tumors, local recurrence was significantly higher for the TEM group than for the standard resection group (OR: 4.92, 95% CI: 1.81-13.41), as was overall recurrence (OR: 2.03, 95% CI: 1.15-3.57). Distant metastasis (OR: 1.05, 95% CI: 0.47-2.39) and overall survival (OR: 1.14, 95% CI: 0.55-2.34) did not differ significantly between groups. Results were similar when data were analyzed with T1 and T2 tumors, except that disease-free survival was significantly longer with TEM than with TAE. There was less evidence for T2 tumors, and conclusions for that group of patients were less clear. The results of this review also supported conclusions that TEM is associated with fewer postoperative complications than standard resection, higher local and distant recurrence rate, and no difference in long-term overall survival.

Randomized Controlled Trials

Bach et al (2021) conducted an open-label trial (TREC) comparing TEM plus short-course radiotherapy to radical resection in patients with early-stage (≤2) rectal cancer.(23) The study included both a randomized cohort (N=55) as well as a nonrandomized cohort (N=68) who were deemed ineligible for one of the randomized treatment assignments. Eight patients (30%) randomized to TEM plus radiotherapy were converted to radical resection. Serious adverse events were reported in fewer patients treated with TEM than radical resection (15% vs. 39%; p=.04). Overall, organ preservation was achieved in 70% of randomized patients and 92% of nonrandomized patients. The authors concluded that short-course radiotherapy with TEM is

associated with high levels of organ preservation with low morbidity and is an option for patients unsuitable for total resection.

E. Lezoche et al (2012) published a report on a similar RCT of 100 patients with T2 rectal cancers without evidence of lymph node or distant metastasis randomized to TEM or laparoscopic total mesorectal excision.(24) All patients received neoadjuvant chemoradiation prior to surgery. All patients in the TEM group completed the procedure. With laparoscopic resection, 5 patients (10%) required conversion to open surgery ($p=0.028$), and 23 patients required a stoma. Postoperative complications did not differ significantly between groups. Disease-free survival also did not differ significantly between groups ($p=0.686$) at a median follow-up of 9.6 years (range 4.7-12.3 years for the laparoscopic resection; range 5.5-12.4 years for TEM). Local recurrence or metastases occurred in six TEM patients and five laparoscopic patients.

G. Lezoche et al (2008) published an RCT evaluating a total of 70 subjects with T2 rectal cancer without evidence of lymph node or distant metastasis on imaging.(25) Patients were randomized to TEM or laparoscopic resection via total mesorectal excision. All patients received chemoradiation before surgery. Median follow-up was 84 months (range: 72–96 months). Two (5.7%) local recurrences were observed after TEM and 1 (2.8%) after laparoscopic resection. Distant metastases occurred in one patient in each group. The probability of survival from rectal cancer was 94% for both groups. Overlap of patients studied in the 2008 and 2012 trials could not be determined.

Case Series

A large number of case series and retrospective non-randomized comparative reviews have been published.(4-14) The case series offer useful information on completeness of resection, local recurrence, and complications, but do not provide definitive evidence on the comparative efficacy of TEM because the comparisons were limited by potential selection bias leading to differences in patient characteristics. Information on long-term outcomes was provided by a case series published by van Heinsbergen et al (2020).(26)

Long-Term Outcomes

van Heinsbergen et al (2020) conducted a study to assess the development of low anterior resection syndrome (LARS) and its impact on quality of life (QOL) following TEM.(26) Patients with T1 or T2 rectal cancer who underwent TEM in a single-center in the Netherlands between January 2008 and December 2013 were included (N=73). Bowel dysfunction was assessed by the Low Anterior Resection Syndrome (LARS) -Score and QOL was assessed by the European Organization for the Research and Treatment of Cancer QLQ-C30 and -CR-29 questionnaires. Responses from 55 patients (75.3%) were available for analysis. At follow-up, the median interval post-intervention was 4.3 y (range, 2.5 to 8.0) with a median patient age of 72 y (range, 49 to 86). Major and minor LARS were observed in 29% and 26% of patients, respectively. Female gender (OR 4.00; 95% CI, 1.20 to 13.36), neo-adjuvant chemoradiotherapy (OR 3.63; 95% CI, 1.08 to 12.17) and specimen thickness (OR 1.10 for each mm increase in thickness; 95% CI, 1.01 to 1.20) were associated with the development of major LARS. Patients with major LARS demonstrated significantly higher symptom burden on nausea and vomiting, pain, insomnia, diarrhea, and other colorectal specific QOL domains.

Section Summary: Rectal Adenocarcinomas

The evidence on the use of TEM for rectal adenocarcinoma consists of a limited number of RCTs, nonrandomized studies, numerous case series, and systematic reviews of these studies. Two RCTs compared TEM with laparoscopic excision, rather than to standard transanal excision and may have included overlapping populations. This evidence generally supports the conclusion that TEM may be associated with a lower complication rate than other surgical approaches but that the local recurrence rate may be higher with TEM. However, at least one RCT reported that the complication rates with TEM did not differ from those for laparoscopic resection. 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. Overall, this evidence has demonstrated that TEM has efficacy in treating early rectal cancer, but the evidence base is not sufficient to determine the comparative efficacy of TEM compared to alternative techniques.

SUMMARY OF EVIDENCE

For individuals who have rectal adenoma(s) who receive TEM, the evidence includes a few nonrandomized comparative studies, and numerous single-arm case series. The relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports the conclusions that the removal of polyps by transanal endoscopic microsurgery (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 health outcome.

For individuals who have early rectal adenocarcinoma who receive TEM, the evidence includes 2 small randomized controlled trials, a few nonrandomized comparative studies, numerous single-arm case series, and systematic reviews of these studies. Relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports conclusions that TEM is associated with fewer postoperative complications but a higher local recurrence rate and possibly a 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.

Supplemental Information

CLINICAL INPUT RECEIVED THROUGH 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.

In response to requests, Blue Cross Blue Shield Association received input through 2 Academic Medical Centers in 2009. Those providing input supported the policy statements as

adopted in October 2009. One of the reviewers had specific comments that this technique should be limited to selected T1 rectal cancers.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network

The National Comprehensive Cancer Network 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 microscopic surgery (TEM) or transanal minimally invasive surgery (TAMIS).”(27)

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 National Cancer Institute guidelines on treatment of rectal cancer (2021) 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.(28) 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 evidence review 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 an updated guideline recommendation for the management of rectal cancer in 2020.(29) 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 lymphovascular or perineural invasion. The guidelines noted that 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 resection unless the patient is a poor candidate for a more extensive surgical procedure.

American College of Radiology

The American College of Radiology (ACR; 2015) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer.(30,31) 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 are based on expert consensus and analysis of current literature.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
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.

Government Regulations

National:

There is no national coverage determination.

Local:

According to LCD L35490 “Category III Codes”, Effective: 10/1/15; Revised: 3/28/24

Associated Information

The patient's medical record must contain documentation that fully supports the medical necessity for services or procedures described by Category III CPT Codes as they are covered by Medicare. (See section entitled “Coverage Indications, Limitations, and/or Medical Necessity”). This documentation includes, but is not limited to, relevant medical history, physical examination, results of pertinent diagnostic tests or procedures, and any other records that describe or support the evaluation and treatment of the patient.

All claims containing any Category III code referenced in this LCD may be subject to review and denial if documentation is incomplete and does not support reasonable and necessary indications.

0184T - The National Comprehensive Cancer Network (NCCN) guideline on treatment of rectal cancer states that, when criteria for transanal resection are met, **transanal endoscopic microsurgery** can be used when the tumor can be adequately identified in the rectum. It further states that TEM for more proximal lesions (greater than 8 cm from anal verge) may be technically feasible.”

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Genetic Testing for *KRAS*, *NRAS* and *BRAF* Mutation Analysis in Metastatic Colorectal Cancer
 - Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes
 - Virtual Colonoscopy/CT Colonography
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/3/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/08	1/29/08	12/19/07	Joint policy established
3/1/09	12/9/08	2/2/09	Routine maintenance
7/1/11	4/19/11	5/3/11	Policy reworded and reformatted to mirror BCBSA policy. Policy status changed from experimental/ investigational to established. References updated.
11/1/12	8/21/12	8/21/12	Routine maintenance.
5/1/14	2/24/14	3/3/14	Routine maintenance; an LCD is established for coverage of 0184T, effective 7/16/12.
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19	4/16/19	Routine maintenance
9/1/19	6/18/19		Updated CMS and NCCN guidelines
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance (slp) Vendor managed: N/A
9/1/24	6/11/24		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 2nd Qtr, 2024

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSANAL ENDOSCOPIC MICROSURGERY (TEM)**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.