7.01.112	Transanal Endoscopic Microsurgery		
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Policy Statement

I. Transanal endoscopic microsurgery may be considered **medically necessary** for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision.

II. Transanal endoscopic microsurgery may be considered **medically necessary** for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision and that meet ***all*** of the following criteria:
   A. Located in the middle or upper part of the rectum,
   B. Well- or moderately differentiated (G1 or G2) by biopsy,
   C. Without lymphadenopathy
   D. Less than one-third the circumference of the rectum.

III. Transanal endoscopic microsurgery is considered **investigational** for the treatment of rectal tumors that do not meet the criteria noted above.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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

Coding
A CPT category III code specific to this procedure is available:

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

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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.

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
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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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

Background

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 (e.g., 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 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 (e.g., 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Rectal Adenoma(s)

Clinical Context and Therapy Purpose

The purpose of transanal endoscopic microsurgery (TEM) in individuals who have rectal adenoma(s) is to provide a treatment option that is an alternative to or an improvement on existing therapies. The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is 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 rectal adenoma(s): 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 have focused on the relative safety of the technique. The evidence presented in this section may include adenomas. However, the focus of this research is on the safety of the procedure.

Systematic Reviews

Barendse et al (2011) reported on a systematic review that compared TEM with endoscopic mucosal resection (EMR) for rectal adenomas larger than 2 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 with EMR directly. Early adenoma recurrence rates, within 3 months of the procedure, were 5.4% (95% confidence interval [CI], 4.0% to 7.3%) with TEM and 11.2% (95% CI, 6.0% to 19.9%) with EMR (p=.04) in pooled estimates. After 3 months, late adenoma recurrence rates in pooled estimates were 3.0% (95% CI, 1.3% to 6.9%) with TEM and 1.5% (95% CI, 0.6% to 3.9%) for EMR (p=.29). Lengths of hospitalization and readmission rates did not differ significantly between procedures. For TEM, the mean hospital length of stay was 4.4 days and 2.2 days for EMR (p=.23). Hospital readmission rates were 4.2% for TEM and 3.5% for EMR (p=.64). Complication rates after TEM, for rectal adenomas only, were 13.0% (95% CI, 9.8% to 17.0%) and 3.8% (95% CI, 2.8% to 5.3%) after EMR, for colorectal adenomas (p<.001). Postoperative complications increased significantly with larger polyp size (p=.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% to 12.7%) than in EMR studies (4.2%; 95% CI, 2.9% to 6.3%; p=.007). These results would suggest that TEM may be associated with lower early cancer recurrence than with EMR but late cancer recurrence (after 3 months) may not differ significantly 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 an RCT, and 55 case series were included. The first area of study was the safety and efficacy in the 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 to 1.29). TEM resulted in lower local recurrence (6% [6/98]) than direct local excision (22% [20/90]) (relative risk, 0.28; 95% CI, 0.12 to 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.[3,4,5,6,7,8,9,10,11,12,13,14,15,16,] Most were retrospective, and a few compared outcomes with other case series of standard excision. These case series offer useful information on the completeness of resection, local recurrence, and complications, but 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.

Long-Term Outcomes

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.[17,] Most patients (n=163 [63%]) had benign disease. Postoperative complications were more frequent in malignant cases (24.0%) than in benign cases (10.8%; p=.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, recurrence rates were 8.3% and 13.5%, respectively.

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.[18,] Consecutive patients (N=297) with pathology-confirmed rectal adenoma treated by TES between May 2007 and September 2016 who had at least 1 year 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 concluded 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 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 had lower disease severity than patients undergoing standard excision. Therefore, it is not possible to form conclusions about the comparative efficacy of TEM and alternative approaches.

Early Rectal Adenocarcinoma

Clinical Context and Therapy Purpose

The purpose of TEM in individuals who have early rectal adenocarcinoma is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with early rectal adenocarcinoma.

Interventions

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

Comparators

The following practices are currently being used to treat early rectal adenocarcinoma: standard TAE and laparoscopic excision.

Outcomes

The general outcomes of interest are OS, functional outcomes, health status, QOL, 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

Systematic Reviews

Systematic reviews/meta-analyses are summarized in Tables 2 to 4.
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 cacner.[19,] Four RCTs were included in the analysis. Disease-free survival was nonsignfiicantly 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 (I^2, 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. A 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 stage T1 and T2 rectal cancer treatment that compared TEM with standard resection and TAE.[22,] Eleven studies were selected for analysis and included 3 randomized controlled, 1 prospective, and 7 retrospective trials (N =1191; 514 TEM, 291 standard resections, 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 to 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 studies was a mean or median of more than 30 months (except for follow-up >20 months in 1 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 to 13.41), as was overall recurrence (OR, 2.03; 95% CI, 1.15 to 3.57). Distant metastasis (OR, 1.05; 95% CI,

0.47 to 2.39) and OS (OR, 1.14; 95% CI, 0.55 to 2.34) did not differ significantly between groups. Results were similar when data were analyzed for 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 rates, and no differences in the long-term OS.

Table 2. Comparison of Trials/Studies Included in SR & M-As for Adenocarcinoma

Study	Motamedi (2023)[19,]	Li (2023)[20,]	Xiong (2021)[21,]	Sgourakis (2011)[Sgourakis G, Lanitis S, Gockel I, et al. Transanal.... ; 77(6): 761-72. PMID 21679648]
Bach (2021)	●	●		
Lai (2019)			●	
Stornes (2016)		●	●	
Elmessiry (2014)			●	
De Graaf (2011)		●		
Christoforidis (2009)				●
Lebedyev (2009)				●
Moore (2008)				●
Ptok (2007)		●	●	
Langer (2003)			●	
Allaix (2012)		●	●	
Chen (2013)	●	●		
Lezoche (2012)	●	●	●	
Palma (2009)		●	●	
				●
Winde (1996)	●	●	●	
				●
Lezoche (2008)		●		
				●
Langer (2003)		●		
				●
Heintz (1998)		●	●	
				●
Lee (2003)		●	●	
				●
De Graaf (2009)			●	
				●
Dixon (2006)				
				●

MA: meta-analysis; SR: systematic reviews.

Table 3. SR & M-A Characteristics for Adenocarcinoma

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Motamedi (2023)[19,]	1997-2020	4	Patients with rectal cancer undergoing local excision or RR	266 (53 to 100)	RCT	17.5 mos to 9.6 yrs
Li (2023)[20,]	NR	13	Patients with rectal cancer undergoing TEM or RR	3583 (50 to 2136)	RCT and cohort	NR
Xiong (2021)[21,]	1996-2019	12	Patients with rectal cancer undergoing TEM or RR	3526	Retrospective and prospective	NR

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Sgourakis (2011)[22,]	1996-2009	11	Patients with stage I rectal cancer	1191 (NR)	RCT	NR

MA: meta-analysis; NR: not reported; RCT: randomized controlled trial; RR: radical resection; SR: systematic reviews; TEM: transanal endoscopic microsurgery.

Table 4. SR & M-A Results for Adenocarcinoma

Study	Post operative Complication Rate	Recurrence Rate
Motamedi (2023)[19,]		
Odds ratio	0.53	NR
95% CI	0.22 to 1.28	
p-value	.16	
Li (2023)[20,]		
Risk ratio	0.35	1.49
95% CI	0.21 to 0.59	0.96 to 2.31
p-value	<.05	NS
Xiong (2021)[21,]		
Risk ratio	0.23	1.60
95% CI	0.11 to 0.45	1.09 to 2.36
p-value	<.0001	.02
Sgourakis (2011)[22,]		
OR	0.16	2.03
95% CI	0.06 to 0.38	1.15 to 3.57

CI: confidence interval; MA: meta-analysis; NR, not reported; NS, not significant; OR: odds ratio; SR: systematic review.

Randomized Controlled Trials

Tables 5 and 6 summarize key RCTs for TEM in rectal cancer.

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.

Lezoche et al (2012) published an 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 also received neoadjuvant chemoradiation before surgery. All patients in the TEM group completed the procedure. With laparoscopic resection, 5 (10%) patients required conversion to open surgery (p=.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=.686) at a median follow-up of 9.6 years (range, 4.7 to 12.3 years for laparoscopic resection; range, 5.5 to 12.4 years for TEM). Local recurrence or metastases occurred in 6 TEM patients and 5 laparoscopic patients.

Lezoche et al (2008) reported on a similar RCT evaluating 70 subjects with stage 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 to 96 months). Two (5.7%) local recurrences were observed after TEM and 1 (2.8%) after laparoscopic resection. Distant metastases occurred in 1 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.

Table 5. Summary of Key RCT Characteristics for Adenocarcinoma

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Bach (2021)[23,]	UK	21	2012-2014	Patients with ≤T2 rectal cancer	TEM + radiotherapy (n=27)	Total resection (n=28)
Lezoche (2012) [24,]	Italy	1	1997-2004	Patients with T2 rectal cancer	TEM (n=50)	Laparoscopic total mesorectal excision (n=50)
Lezoche (2008)[25,]	Italy	1	NR	Patients with T2 rectal cancer	TEM (n=35)	Laparoscopic resection via total mesorectal excision (n=35)

NR: not reported; RCT: randomized controlled trial; TEM: transanal endoscopic microsurgery.

Table 6. Summary of Key RCT Results for Adenocarcinoma

Study	Local Recurrence	Distant Metastases	Probability of Survival	Disease-Free Survival
Bach (2021)[23,]			No significant difference (HR, 1.95; 95% CI, 0.47 to 8.16; p=.35)	No significant difference (HR, 2.32; 95% CI, 0.77 to 6.95; p=.35)
TEM	3 (11%)			
Resection	0			
Lezoche (2012)[24,]				No significant difference between groups (p=.686)
TEM	4 (8%)	2 (4%)		
LR	3 (6%)	2 (4%)		
Lezoche (2008)[25,]				
TEM	2 (5.7%)	1 (2.8%)	94%	
LR	1 (2.8%)	1 (2.8%)	94%	

LR: laparoscopic resection; RCT: randomized controlled trial; TEM: transanal endoscopic microsurgery.

The purpose of the limitations tables (see Tables 7 and 8) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Bach (2021)[23,]		5. Includes specific radiotherapy regimen			
Lezoche (2012)[24,]				2. No CONSORT reporting of harms	
Lezoche (2008)[25,]				2. No CONSORT reporting of harms	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference

not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness [d]	Power[e]	Statistical[f]
Study	**Population[a]**	**Intervention[b]**	**Comparator[c]**	**Outcomes[d]**	**Duration of Follow-Up[e]**	
Bach (2021)[23,]		1,2. Unblinded			3. Not powered for cancer outcome	
Lezoche (2008)[25,]	3. Allocation concealment unclear	1,2,3. Blinding unclear			1. Some power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Case Series

A large number of case series and retrospective nonrandomized comparative reviews have been published.[4,5,6,7,8,9,10,11,12,13,14,] The case series offer useful information on the completeness of resection, local recurrence, and complications, but do not provide definitive evidence on the comparative efficacy of TEM because the comparisons are 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 and its impact on 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-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 years (range, 2.5 to 8.0) with a median patient age of 72 years (range, 49 to 86). Major and minor low anterior resection syndrome 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 low anterior resection syndrome. Patients with major low anterior resection syndrome demonstrated significantly higher symptom burden on nausea and vomiting, pain, insomnia, diarrhea, and other colorectal-specific QOL domains.

Section Summary: Rectal Adenocarcinoma

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 have compared TEM with laparoscopic excision, rather than to standard TAE, and might have included overlapping populations. This evidence generally supports the conclusion that TEM may be associated with lower complication rates than other surgical approaches but that local recurrence rates may be higher with TEM. However, at least 1 RCT has 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 and alternative techniques.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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)."[27,]

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 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 updated guideline recommendations 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 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.[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 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 9.

Table 9. 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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Documentation for Clinical Review

Please provide the following documentation:

- History and physical, and/or consultation reports and progress notes including:
  - Clinical indications/justification of procedure
  - Eastern Cooperative Oncology Group functional status (if applicable)
  - Previous treatment(s), duration, and response(s)
  - Treatment plan
  - Tumor type and description (i.e., resectable or unresectable, primary or metastatic, tumor burden)
- Pertinent radiological imaging results (i.e., CT and/or MRI and/or PET)
- Pathology report including tumor node metastasis (TNM) classification
- Current serum chemistry and tumor marker results

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS), including muscularis propria (i.e., full thickness)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/30/2015	BCBSA Medical Policy adoption
12/01/2016	Policy revision without position change
10/01/2017	Policy revision without position change
01/01/2018	Policy revision without position change
01/01/2019	Policy revision without position change
02/01/2024	Policy reactivated. Previously archived from 04/01/2020 to 01/31/2024.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	I. Transanal endoscopic microsurgery may be considered **medically necessary** for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision. II. Transanal endoscopic microsurgery may be considered **medically necessary** for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision and that meet ***all*** of the following criteria: A. Located in the middle or upper part of the rectum, B. Well- or moderately differentiated (G1 or G2) by biopsy, C. Without lymphadenopathy D. Less than one-third the circumference of the rectum. III. Transanal endoscopic microsurgery is considered **investigational** for the treatment of rectal tumors that do not meet the criteria noted above.