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.

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:

- Less than one-third the circumference of the rectum
- Located in the middle or upper part of the rectum
- Well- or moderately differentiated (G1 or G2) by biopsy
- Without lymphadenopathy

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

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

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)

Transanal endoscopic microsurgery (TEMS) 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.

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 Transanal Endoscopic Microsurgery (TEMS) 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 TEMS. 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.

Rationale

Background
Transanal Endoscopic Microsurgery

Transanal endoscopic microsurgery (TEMS) 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 TEMS for resection of rectal cancers is more controversial. TEMS 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 TEMS system has a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. This procedure has been available in Europe but has not been widely used in the United States. 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 patient characteristics and goals are all attributes that will affect treatment approach. Open, wide resections have the highest cure rate but may also have significant adverse events. Most patients 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. TEMS 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. TEMS permits local excision beyond the reach of direct visualization equipment.

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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.

**Transanal Endoscopic Microsurgery**

**Clinical Context and Therapy Purpose**

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

The question addressed in this evidence review is: Does TEMS improve the net health outcome in patients with rectal adenoma(s) or with early rectal adenocarcinoma?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant populations of interest are patients with rectal adenoma(s) or with early rectal adenocarcinoma.

**Interventions**

The therapy being considered is TEMS.

**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).

**Timing**

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

**Setting**

TEMS is performed in an inpatient surgical center, conducted under anesthesia with the specialized equipment needed and surgeons sufficiently experienced with the technology.
Rectal Adenoma(s)

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 compared TEMS with endoscopic mucosal resection (EMR) for rectal adenomas larger than 2 cm.1 Included in the review were 48 TEMS and 20 EMR studies; all were treated as single-arm studies. No controlled trials were identified that compared TEMS 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 TEMS and 11.2% (95% CI, 6.0% to 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% to 6.9%) with TEMS and 1.5% (95% CI, 0.6% to 3.9%) for EMR (p=0.29). Lengths of hospitalization and readmission rates did not differ significantly between procedures. For TEMS, mean hospital length of stay was 4.4 days and 2.2 days for EMR (p=0.23). Hospital readmission rates were 4.2% for TEMS and 3.5% for EMR (p=0.64). Complication rates after TEMS, 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<0.001).

Postoperative complications increased significantly with larger polyp size (p=0.04). However, postoperative complication rates remained higher for TEMS after adjusting for a larger mean polyp size in the TEMS studies (8.7% 95% CI, 5.8% to 12.7%) than in EMR studies (4.2% 95% CI, 2.9% to 6.3% p=0.007). These results would suggest that TEMS 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 TEMS 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 TEMS 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 TEMS (10.3% of 98 patients) and direct local excision (17% of 90 patients) (relative risk, 0.61; 95% CI, 0.29 to 1.29). TEMS 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 TEMS in this trial is consistent with rates found in TEMS case series.

Case Series

Numerous case series of TEMS 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 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.

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 TEMS.16 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=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, recurrence rates were 8.3% and 13.5%, respectively.
Section Summary: Rectal Adenoma(s)
There is a lack of high-quality trials comparing TEMS with standard surgical approaches for removal of rectal adenomas. The available evidence is primarily from single-arm studies and has reported that TEMS can be performed with relatively low complication rates and low recurrence rates. It is not possible to determine the comparative efficacy of TEMS 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 TEMS may be lower than for other procedures, but that short-term complication rates may be higher. These conclusions are limited by potential selection bias, leading to differences in the patient populations. In particular, it is possible that patients undergoing TEMS had lower disease severity than patients undergoing standard excision. Therefore, it is not possible to form conclusions about the comparative efficacy of TEMS and alternative approaches.

Rectal Adenocarcinoma

Systematic Reviews
A meta-analysis by Lu et al (2015) compared TEMS with total mesorectal excision for T1 rectal cancer. Studies selected included 1 RCT and 6 non-RCTs (303 treated with TEMS; 557 treated with total mesorectal excision). For the outcome of postoperative recurrence, the rate of local recurrence was higher after TEMS (odds ratio [OR], 4.63; 95% CI, 2.03 to 10.53; p < 0.001, I² = 0%). For the 6 studies reporting on OS, there were no significant differences between the TEMS and total mesorectal excision groups (OR=0.87; 95% CI, 0.55 to 1.38; p=0.55, I² = 0%).

Clancy et al (2015) published a systematic review of the comparative efficacy of TEMS and standard TAE for early rectal cancer. Six studies including outcomes for 927 excisions were selected, all of which were nonrandomized. On combined analysis, TEMS had a higher rate of negative surgical margins (OR=5.3; 95% CI 3.2 to 8.7) and a lower rate of recurrence (OR=0.25; 95% CI, 0.15 to 0.40) compared with standard excision. Complication rates did not differ significantly between techniques (OR=1.018; 95% CI, 0.658 to 1.575).

Sajid et al (2014) reported on a systematic review and meta-analysis of TEMS and radical resection for stage T1 and T2 rectal cancers. Included in the review were 5 RCTs and 5 cohort studies (445 TEMS patients, 438 radical resection patients). In random-effects models, there was a greater risk of local recurrence with TEMS than with radical resection (OR=2.78; 95% CI, 1.42 to 5.44; p < 0.003) and a greater risk of overall recurrence (OR=2.01; 95% CI, 1.18 to 3.42; p < 0.01). The risk of distant recurrence did not differ significantly between procedures (OR=0.87; 95% CI, 0.41 to 1.83; p=0.71) nor did OS rates (OR=0.90; 95% CI, 0.49 to 1.66; p=0.74). In a subgroup analysis of the 5 RCTs, the risk of overall recurrence remained higher with TEMS (OR=2.21; 95% CI, 1.10 to 4.41; p < 0.03). OS rates, however, did not differ significantly between TEMS and radical resection (OR=0.80; 95% CI 0.43 to 1.47; p=0.47), and postoperative complications were significantly lower with TEMS (OR=0.19; 95% CI, 0.08 to 0.44; p < 0.001).

Wu et al (2011) published a meta-analysis on TEMS and conventional surgery for stage T1 rectal cancers. Five studies were selected, including a prospective RCT and 4 retrospective, nonrandomized studies for a total of 397 (216 TEMS, 181 conventional rectal surgery) patients. Combined analyses were performed for mortality, postoperative complications, recurrence rates, and 5-year survival. No deaths were reported from either procedure, and TEMS had fewer postoperative complications (16/196) than conventional surgery (77/163). On combined analysis, the odds for complications was 0.10 (95% CI, 0.05 to 0.18). There was a higher rate of local recurrence or distant metastasis at 40-month follow-up for TEMS (12% [26/216]) than for conventional radical surgery (0.5% [1/181]). On combined analysis, the odds for recurrence in the conventional surgery group was 6.64 (95% CI, 2.63 to 28.39). The 5-year survival (not specified as disease-specific or overall), as reported in 4 studies, did not differ significantly between groups (80.1% [157/196] for TEMS vs 81% [132/163] for conventional surgery). These results supported the conclusion that TEMS is associated with fewer early complications but higher rates of recurrence than standard resection, with no demonstrable differences in OS.
Sgourakis et al (2011) conducted a meta-analysis of stage T1 and T2 rectal cancer treatment that compared TEMS with standard resection and TAE.21 Eleven studies were selected for analysis and included 3 randomized controlled, 1 prospective, and 7 retrospective trials (total N=1191 patients; 514 TEMS, 291 standard resections, 386 TAE). Numerous combined analyses were performed to measure mortality, complications, and recurrence rates. For postoperative complication rates, combined analysis showed a significantly lower rate of major complications for TEMS 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 TEMS 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 TEMS 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 TEMS 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 TEMS is associated with fewer postoperative complications than standard resection, higher local and distant recurrence rates, and no differences in the long-term OS.

Doornebosch et al (2009) discussed weaknesses in the evidence and unresolved issues about the role of TEMS.22 Reviewers posed 3 questions: “First, is there enough evidence to propagate LE [local excision] as a curative option in selected (T1) rectal carcinomas? Second, if LE is justified, which technique should be the method of choice? Third, can we adequately identify, pre- and postoperatively, tumors suitable for LE?” They noted that selection bias in studies complicated answering the first question; and a significant portion of tumors recurred in all studies using various techniques for LE (including TEMS), although it seemed not to influence survival rates. Reviewers noted that the published case series reporting outcomes after TEMS for T1 rectal carcinomas used inclusion criteria that were not always clear and used salvage procedures that could introduce bias. TEMS was demonstrated to be a safe procedure in all series; complication rates varied between 5% and 26%, and complications were generally minor. Local recurrence rates for TEMS varied between 4% and 33% in the studies reviewed. On the third question, reviewers assessed whether high recurrence rates could be improved by better tumor selection. They noted that TEMS had been incorporated into surgical practice based largely on retrospective case series, and noted that, despite the lack of level I evidence, its use seemed justified in well-selected T1 rectal cancers. They also indicated that some view TEMS as an alternative for patients with T1 lesions who are currently undergoing other methods of LE (e.g., using the Parks technique instead of radical surgery).

**Randomized Controlled Trials**

E. Lezoche et al (2012) published an RCT of 100 patients with T2 rectal cancers without evidence of lymph node or distant metastasis randomized to TEMS or laparoscopic total mesorectal excision.23 All patients also received neoadjuvant chemoradiation before surgery. All patients in the TEMS group completed the procedure. With laparoscopic resection, 5 (10%) patients 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 laparoscopic resection; range, 5.5-12.4 years for TEMS). Local recurrence or metastases occurred in 6 TEMS patients and 5 laparoscopic patients.

G. Lezoche et al (2008) reported on a similar RCT evaluating of 70 subjects with stage T2 rectal cancer without evidence of lymph node or distant metastasis on imaging.24 Patients were randomized to TEMS 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 TEMS 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.

**Case Series**

A large number of case series and retrospective nonrandomized comparative reviews have been published. 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 TEMS because the comparisons were limited by potential selection bias leading to differences in patient characteristics.

Much of the research has focused on the technical aspects of TEMS and on other, non-neoplastic applications. Other studies have investigated the use of TEMS with adjuvant therapy or additional techniques. For example, Walega et al (2010) reported on a small study that added endoscopic mesorectum resection to TEMS.

Moore et al (2008) retrospectively reviewed patients who underwent TAE for rectal neoplasms and compared results for traditional transanal resection with TEMS. Of 296 patients identified, 76 were excluded because of surgery due to abscesses, fistulas, inflammatory bowel disease, or multiple lesions. Forty-nine patients were excluded because of incomplete or missing charts. Records of 171 patients were analyzed; 82 patients who underwent TEMS and 89 who had a transanal resection. For patients who received TEMS, those with stage T1 lesions without adverse histologic features (poor differentiation, lymphovascular invasion) received local excision alone. Patients with T1 lesions with adverse features or T2 lesions received postoperative chemoradiation. Local excision was performed for T3 lesions only in high-risk patients or those who refused radical resection. In the TEMS group, there were 40 polyps, 5 carcinoma in situ, 21 T1 lesions, 7 T2 lesions, 8 T3 lesions, no indeterminate lesions, and 1 carcinoid lesion; in the transanal resection group, there were: 38 polyps, 4 carcinoma in situ, 20 T1 lesions, 19 T2 lesions, 6 T3 lesions, 1 indeterminate lesion, and 1 carcinoid lesion. There were 12 (15%) postoperative complications (4 major) in the TEMS group and 15 (17%) complications in the transanal resection group (6 major). In the TEMS group, 90% had negative tumor margins, and none had indeterminate margins vs 71% negative and 15% indeterminate margins in the transanal resection patients.

Local recurrence was less frequent after TEMS (4%) than after transanal resection (24%; p=0.004). The difference between groups in distant recurrence was not statistically significant. Three TEMS patients with malignant lesions underwent radical resection and were excluded from recurrence analyses. The recurrence rate among cancer patients did not differ statistically between groups. For patients with adenomas, the overall recurrence rate after TEMS was 3% and 32% for transanal resection. In patients with polyps, clear margins were achieved more frequently after TEMS (83%) than after transanal resection (61%).

A number of studies identified have raised questions about disease recurrence after TEMS for stage T1 rectal cancer. For example, Doornebosch et al (2010) reported on TEMS for 88 patients, 18 (20.5%) of whom had a local recurrence. Of them, 16 patients had salvage surgery. At the 3-year follow-up, the OS rate was 31% and the cancer-related survival rate was 58%. Authors concluded that further tailoring patient and tumor selection before a decision for LE might improve survival.

In an editorial accompanying this study, Friel (2010) commented on the use of LE in the treatment of T1 rectal lesions. He noted that the reported recurrence rate should raise concerns and calls for additional studies of recurrence with LE to verify the Doornebosch findings. Friel also noted that LE must still be considered as an oncologic compromise between lower surgical morbidity but higher disease recurrence and that, once fully informed, patients may find this compromise acceptable.

**Section Summary: Rectal Adenocarcinoma**

The evidence on the use of TEMS for rectal adenocarcinoma consists of a limited number of RCTs, nonrandomized studies, and numerous case series. Two RCTs have compared TEMS with
laparoscopic excision, rather than to standard TAE, and might have included overlapping populations. This evidence generally supports the conclusion that TEMS may be associated with lower complication rates than other surgical approaches but that local recurrence rates may be higher with TEMS. However, at least one RCT has reported that the complication rates with TEMS did not differ from those for laparoscopic resection. No differences in OS rates have been reported for TEMS vs other approaches. Overall, this evidence has demonstrated that TEMS has efficacy in treating early rectal cancer, but the evidence base is not sufficient to determine the comparative efficacy of TEMS and alternative techniques.

Summary of Evidence
For individuals who have rectal adenoma(s) who receive TEMS, the evidence includes a few nonrandomized comparative studies and numerous single-arm case series. Relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports conclusions that removal of polyps by TEMS 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 TEMS and standard procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have early rectal adenocarcinoma who receive TEMS, the evidence includes 2 small randomized controlled trials, a few nonrandomized comparative studies, and numerous single-arm case series. Relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports conclusions that TEMS is associated with fewer postoperative complications but higher local recurrence rates and possibly higher rates of metastatic disease. There is no demonstrated difference in long-term overall survival with TEMS in available studies. However, due to the low quality of the evidence base, these conclusions lack certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

In response to requests Blue Cross Blue Shield Association, input was received from 2 academic medical centers 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
National Comprehensive Cancer Network
The National Comprehensive Cancer Network guidelines on the treatment of rectal cancer (v.3.2018) state that, when criteria for transanal resection are met, transanal endoscopic microsurgery (TEMS) can be used when the tumor can be adequately identified in the rectum. The Network further states that TEMS for more proximal lesions (>8 cm from anal verge) may be technically feasible. The guidelines are based on level 2A evidence.

National Cancer Institute
The 2018 National Cancer Institute (NCI; 2018) guidelines on treatment of rectal cancer indicate the management of rectal cancer is multimodal and involves a multidisciplinary team of cancer specialists with expertise in gastroenterology, medical oncology, surgical oncology, radiation oncology, and radiology. Based on the increased risk of local recurrence and poor overall prognosis, management of rectal cancer diverges from colon cancer. The differences include surgical technique, use of radiotherapy, and method of chemotherapy administration.
Additional issues are maintenance or restoration of the normal anal sphincter and genitourinary function. NCI recommends as a primary treatment for patients with rectal cancer surgical resection of the primary tumor. 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 (2013) updated its 2010 practice parameters for the management of rectal cancer. The 2013 guidelines indicated 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 one-third of the bowel lumen circumference. Additionally, patients must not have lymphovascular or perineural invasion. The guidelines noted that visualization with TEMS appears to be superior to the transanal approach, but randomized controlled trials are lacking. T2 lesions should be treated with radical mesenteric excision unless the patient is a poor candidate for a more extensive surgical procedure.

American College of Radiology
The American College of Radiology (ACR; 2015) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer. ACR noted that TEMS 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 TEMS 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 unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<td>NCT01308190a</td>
<td>Prospective Randomized Clinical Trial for no Inferiority With Preoperative Chemoradiotherapy and Transanal Endoscopic Microsurgery (TEM) Versus Total Mesorectal Excision in T2-T3s N0, M0 Rectal Cancer</td>
<td>173</td>
<td>Dec 2018</td>
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<tr>
<td>NCT01023984</td>
<td>Transanal Endoscopic Microsurgery Versus Endoscopic Submucosal Dissection For Large Rectal Adenomas (TEMENDO)</td>
<td>120</td>
<td>Dec 2019 (suspended)</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

References


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):

- 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

Reproduction without authorization from Blue Shield of California is prohibited
Current serum chemistry and tumor marker results

Post service
• 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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<td>0184T</td>
<td>Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS), including muscularis propria (i.e., full thickness)</td>
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<tr>
<td>HCPCS</td>
<td>None</td>
<td></td>
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<tr>
<td>ICD-10 Procedure</td>
<td>0DBP8ZZ</td>
<td>Excision of Rectum, Via Natural or Artificial Opening Endoscopic</td>
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Policy History

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

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<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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<tr>
<td>12/01/2016</td>
<td>Policy revision without position change</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.