Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/12**
(See policy history boxes for previous effective dates)

Title: Transanal Endoscopic Microsurgery (TEMS)

Description / Background

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

Transanal endoscopic microsurgery (TEMS) is a minimally invasive surgical approach to local excision (LE) 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 such as malignant polyps. Use of TEMS for resection of rectal cancers is more controversial. TEMS can avoid morbidity and mortality associated with major rectal surgery, including 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 for over 20 years in Europe but has not been used widely in the United States. Two reasons for this slow diffusion are the steep learning curve for the procedure and the limited indications. For example, most rectal polyps can be removed endoscopically, and many rectal cancers need a wide excision and are thus not amenable to local resection.

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 this decision. Open, wide resections have the highest cure rate but may also have significant adverse effects. Most patients find the potential adverse effects of lifelong colostomy, bowel; bladder; or sexual dysfunction acceptable in the face of a terminal illness. Laparoscopic-assisted surgery, with

lymph node dissection as indicated, is technically difficult in the pelvic region but is being investigated as a less invasive alternative to open resection.

Local excision 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 LE ability to the proximal rectosigmoid junction. Adenomas, small carcinoid tumors, and non-malignant conditions; such as strictures or abscesses; are amenable to LE by either method.

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

Regulatory Status:

In March 2001, “The Transanal Endoscopic Microsurgery (TEMS) Combination System and Instrument Set” (Richard Wolf Medical Instruments Corp, Vernon Hills, IL) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in inflating the rectal cavity, endoscopically visualizing the surgical site, and accommodating up to 3 surgical instruments.

Medical Policy Statement

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

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:
TEMS 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; and
- 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

Literature Review
This policy was originally created in 2007 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period September 2010 through September 2011. The following is a summary of key findings.

Rectal Adenomas and Benign Rectal Conditions
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. Although the evidence presented in this section may include adenocarcinoma, the focus is on safety of the procedure. Middleton et al. authored a systematic review of this procedure in 2005 based on published results through August 2002. (1) Three comparative studies, including one 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 transanal endoscopic microsurgery (TEMS, 10.3% of 98 patients) and direct local excision (LE, 17% of 90 patients) for a relative risk (RR) of 0.61; 95%, confidence interval (CI): 0.29-1.29). Transanal endoscopic microsurgery resulted in less local recurrence (6/98; 6%) than direct LE (20/90; 22%) (RR: 0.28; 95%, CI: 0.12-0.66). The 6% rate of local recurrence for TEMS in this trial is consistent with the rates found in case series of transanal endoscopic microsurgery.

Zacharakis et al. reported results on 76 patients from a single British hospital who were treated with this technique between 1996 and 2005. (2) Forty-eight patients had adenomas, and 28 had adenocarcinoma. Overall morbidity was 18.9%; 14 patients had minor complications and 4 had major complications. During follow-up, benign tumor recurrence was 8% (3 patients), and recurrence rates among patients with T1, T2, and T3 malignancies were 7%, 43%, and 67%, respectively.

Additional details are also needed about complications from this procedure. As noted in an article by Cataldo, complications are rare but can be significant. (3) This article notes that major complication rates around 5% are reported in some series; these complications include

intraperitoneal sepsis, rectovaginal fistulae, and postoperative hemorrhage requiring reoperation. This article also notes that some investigators have found that the anal dilation and insertion of the 40 mm special proctoscope has been associated with a temporary decrease in postoperative continence, while others have not found a change in clinical continence.

Rectal Adenocarcinomas

In 2011, Wu and colleagues published a meta-analysis on TEMS and conventional surgery for T1 rectal cancers. (4) Five studies were included in the analysis including 1 prospective RCT and 4 retrospective, nonrandomized studies for a total of 397 (216 TEMS and 181 conventional rectal surgery) patients. Combined analyses were performed for mortality, postoperative complications, recurrence rate, and 5-year survival. No deaths were reported from either procedure, and TEMS resulted in fewer postoperative complications than conventional surgery (16/196 vs. 77/163). On combined analysis the odds ratio (OR) 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-months' follow-up for the TEMS group versus conventional radical surgery (CRS (12% [26 of 216] vs. 0.5% [1 of 181]). On the combined analysis the odds ratio for recurrence in the CRS group was 8.64 (95% CI: 2.63 to 28.39). The 5-year survival (not specified as disease specific or overall), as reported in 4 studies, was not significantly different between groups at 80.1% (157 of 196) in TEMS patients and 81% (132 of 163) in conventional surgery patients. These results support the conclusion that TEMS is associated with less early complications but a higher rate of recurrence compared to standard resection, with no demonstrable differences in overall survival.

Sgourakis et al., in 2011, conducted a meta-analysis of T1 and T2 rectal cancer treatment with TEMS compared to standard resection and transanal excision (TAE). (5) Eleven studies were included in the analysis and included 3 randomized controlled, one prospective, and 7 retrospective studies for a total of 1,191 (514 TEMS, 291 standard resection, and 386 TAE) patients. Numerous combined analyses were performed for measures of mortality, complications and recurrence rates. For postoperative complication rates, combined analysis showed a significantly lower rate of major complications for TEMS versus standard resection (OR: 0.24, 95% CI: 0.07-0.91). Minor complications were not significantly different between these groups. Overall postoperative complications were not significantly different between TEM versus TAE when T1 andT2 tumor data were pooled. Follow-up for all of the studies was a mean/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 TEMS versus the standard resection group (OR: 4.92, 95% CI: 1.81-13.41), as was overall recurrence (odds ratio: 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) were not significantly different between groups. Results were similar when data were analyzed with T1 and T2 tumors, except that disease-free survival was significantly greater with TEMS versus TAE. There was less evidence available for T2 tumors, and conclusions for that group of patients were less clear. The results of this review also support the conclusions that TEMS is associated with less postoperative complications compared with standard resection, a higher local and distant recurrence rate, and no difference in long-term overall survival.

Doornebosch and colleagues, in a 2009 systematic review, discussed weaknesses in the available evidence and still unanswered questions about the role of TEMS. (6) They pose 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 note that selection bias in studies complicates 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. The authors note that the published case series reporting outcomes after TEMS for T1 rectal carcinomas utilized inclusion criteria that were not always clear and use of salvage procedures may introduce bias. TEMS was demonstrated to be a safe procedure in all series; complications rates vary between 5% and 26%, and complications were generally minor. Local recurrence rates for TEMS varied between 4% and 33% in the studies reviewed. Regarding the third question, the authors wonder if high recurrence rates could be improved by better tumor selection. The authors note that TEMS has been incorporated into surgical practice based largely on retrospective case series. They also note that despite the lack of level I evidence, its use seems justified in well-selected T1 rectal cancers. Some might view TEMS as an alternative for those with T1 lesions who are currently undergoing other methods of LE, such as LE according to the Parks technique, instead of radical surgery, for their T1 lesions.

In 2008, Lezoche and colleagues published an additional RCT. (7) A total of 70 subjects were enrolled with T2 rectal cancer without evidence of lymph node or distant metastasis on imaging; patients were randomly assigned to TEMS or laparoscopic resection via total mesorectal excision. All patients received chemoradiation prior to surgery. As compared to previous studies, this RCT intended to examine the use of TEMS on T2 tumors in combination with chemoradiotherapy. Median follow-up was 84 months (range: 72–96 months). Two local recurrences (5.7%) were observed after TEMS and 1 (2.8%) after laparoscopic resection. Distant metastases occurred in 1 patient in each group. The probability of survival for rectal cancer was 94% for TEMS and 94% for laparoscopic resection.

Additional evidence is based on a large number of case series and retrospective comparative reviews. Much of the evidence focuses on technical aspects of the procedure, as well as on other, non-neoplastic applications. Other literature is investigating use of TEMS with adjuvant therapy or additional techniques. For example, in 2010, Walega and colleagues reported a small study on the addition of endoscopic mesorectum resection to TEMS. (8)

In 2008, Moore and colleagues reported a retrospective review of patients who underwent transanal excision for rectal neoplasms and compared results for traditional transanal resection and TEMS. (9) Of 296 patients identified, 76 were excluded because surgery was for 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 transanal resection were analyzed. For patients who received TEMS, those with T1 lesions without adverse histologic features (poor differentiation or lymphovascular invasion) received LE 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, 7 T2, 8 T3, 0 indeterminate, and 1 carcinoid, and in the transanal resection group: 38 polyps, 4 carcinoma in situ, 20 T1, 19 T2, 6 T3, 1 indeterminate, and 1 carcinoid. All patients treated before December 2001 received transanal resection (7 surgeons), TEMS was performed by one surgeon. Since the introduction of TEMS, 20 transanal resections were performed. 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 versus 71% negative and 15% indeterminate in the transanal resection patients. There were 4 recurrences in the TEMS group and 24 in the transanal resection group. Local recurrence was less frequent after TEMS versus transanal resection (4 vs. 24%, respectively, p=0.004). The difference between groups in distant recurrence was not significant. Three TEMS patients with malignant lesions underwent radical resection and were excluded from recurrence analyses. The recurrence rate among cancer patients was not statistically different between groups. For patients with adenomas, the overall recurrence rate after TEMS was 3% versus 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 articles were identified that begin to raise questions about disease recurrence following TEMS for T1 rectal cancer. (10-12) In one of these studies, Doornebosch et al. reported on treatment of recurrence following TEMS for T1 rectal cancer. (10) In that series of 88 patients, 18 (20.5%) patients had a local recurrence. Of those, 16 patients had salvage surgery. At 3-year follow-up, overall survival was 31% and cancer-related survival was 58%. The authors concluded that further tailoring patient and tumor selection prior to a decision for LE may improve survival.

In an editorial accompanying this study, Friel comments on issues concerning the use of LE in the treatment of T1 rectal lesions. (13) Friel notes that the reported recurrence rate should raise concerns and calls for additional studies of recurrence with LE to verify the Doornebosch et al. study. Friel also notes 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.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov in October 2010 found one Phase III, multi-center, RCT in which 173 patients with T2-T3s N0, M0 rectal cancer will be treated with either preoperative chemoradiotherapy and TEMS or total mesorectal excision to evaluate 2-year local recurrence rates (NCT01308190). This trial is being conducted in Spain and is expected to be completed in 2013. In a Phase IV study, expected to begin in January 2012 in Italy, 120 patients with large rectal adenomas of equal to or greater than 2 cm will be treated with either TEMS or endoscopic submucosal dissection to evaluate 1-year recurrence (NCT01023984). This trial is also expected to be completed in 2013.

Summary

In summary, based on review of the published data and clinical input, there is sufficient evidence to conclude that transanal endoscopic microsurgery (TEMS) is a safe and effective (low recurrence rates) procedure for excision of rectal adenomas that cannot be removed by traditional local approaches such as endoscopic removal.

For stage T1 rectal cancer, the evidence supports the conclusions that TEMS is associated with less postoperative complications but a higher local recurrence rate and possibly a higher rate of metastatic disease. There is no demonstrated difference in long-term overall survival in the available studies. Based on this evidence and clinical input, use of TEMS may be considered medically necessary in selected, low-risk T1 rectal cancers. These clinical-stage

T1 cancers are those that are located in the middle or upper part of the rectum, are well or moderately differentiated (G1 or G2) by biopsy, without lymphadenopathy, and involving less than one-third of the circumference of the rectum. While additional follow-up studies are being completed, it is important that patients with T1 rectal cancer be fully informed of the tradeoffs (risks and benefits) with this procedure.

The data on use of TEMS in other rectal cancers are much more limited. There are still important questions about selection of other cancers for local excision. In comparison to more extensive resection, TEMS may have reduced adverse effects of fecal and bladder incontinence, but the overall effect on health outcomes is uncertain. Thus, use of TEMS for rectal cancers that do not meet the criteria noted above, including T2 lesions, is considered investigational.

Practice Guidelines and Position Statements

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. (14) It further states that TEMS for more proximal lesions (greater than 8 cm from anal verge) may be technically feasible. The guideline is based on level 2A evidence.

The National Cancer Institute states that the surgical approach to treatment varies according to location, stage, and presence or absence of high-risk features (i.e., positive margins, lymphovascular invasion, perineural invasion, and poorly differentiated histology) and may include transanal local excision and transanal endoscopic microsurgery for select clinical staged T1/T2N0 rectal cancers. (15)

The American Society of Colon and Rectal Surgeons has published practice parameters for the management of rectal cancer. (16) They state that curative local excision is an appropriate treatment modality for carefully selected T1 rectal cancer. Transanal endoscopic microsurgery uses similar surgical principles as a transanal local excision but is designed to remove lesions up to approximately 20 cm from the anal verge. Both transanal local excision and transanal endoscopic microsurgery may afford reasonable palliation for patients with metastatic disease who are poor candidates for a more extensive surgical procedure.

The American College of Radiology (ACR) has issued appropriateness criteria on local excision of early-stage rectal cancer. (17) The ACR notes TEMS is an appropriate operative procedure for locally complete excision of distal rectal lesions and has been “evaluated for curative treatment of invasive cancer.” TEMS is noted to have “been shown to be as effective, and possibly better 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.

Government Regulations

National:

There is no national coverage determination.

Local:

There is no local coverage determination.

Michigan Department of Community Health:

MDCH does not have any published information concerning the TEMS procedure.

(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 Colon Cancer with MSI
- KRAS and BRAF Mutation Analysis in Metastatic Colorectal Cancer
- Virtual Colonoscopy

References

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7. Lezoche G, Baldarelli M, Guerrieri M et al. A prospective randomized study with a 5-year minimum follow-up evaluation of transanal endoscopic microsurgery versus laparoscopic total mesorectal excision after neoadjuvant therapy. Surg Endosc 2008; 22(2):352-8.
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14. National Comprehensive Cancer Network (NCCN). Rectal Cancer. Clinical Practice Guidelines in Oncology v1.2012. Available online at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last accessed June 2012
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 1, 2012, 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.

Next Review Date: 3rd Qtr, 2013

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

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Non-covered by Medicare.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Non-covered by Medicaid.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- 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.