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Medical Policy Manual

Topic: Transanal Endoscopic Microsurgery (TEMS)

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Transanal endoscopic microsurgery (TEMS) is a minimally invasive surgical approach which uses a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. TEMS has been proposed for use in local excision of rectal lesions that cannot be directly visualized, and as an alternative to open or laparoscopic excision.

Local excision (LE) 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. LE can occur under direct visualization for rectal tumors within 10 cm of the anal verge and may be most appropriate for small tumors (less than 4cm) confined to the submucosa (T1, as defined by the TNM staging system). TEMS extends local excision ability to the proximal rectosigmoid junction. Adenomas, large rectal polyps (which cannot be removed through a colonoscope), retrorectal masses, small carcinoid tumors, and non-malignant conditions such as strictures or abscesses are amenable to local excision by either method. 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. Use of TEMS for resection of rectal cancers is more controversial.

The most common treatment for rectal cancer is surgery, either open resection or local excision. The technique chosen depends on the size and location of the tumor, evidence of local or distal spread, and

patient characteristics and goals. Open, wide resections have the highest cure rate, but may also have significant adverse effects, such as lifelong colostomy, bowel, bladder, or sexual dysfunction. The use of LE in rectal adenocarcinoma is an area of much interest; however, because LE alone does not offer the opportunity for lymph node biopsy it has been reserved for patients in whom the likelihood of cancerous extension is small. 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.

Regulatory Status

In March 2001, "The Transanal Endoscopic Microsurgery (TEMS) Combination System and Instrument Set" (Richard Wolf Medical Instruments Corp.) 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. The Covidien SILS Port subsequently received 510(k) approval in 2011. The SILS port is a similar instrument that can be used for rectal procedures including TEMS.

MEDICAL POLICY CRITERIA

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, and

   D. Less than 1/3 the circumference of the rectum

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

SCIENTIFIC EVIDENCE

The principal outcomes associated with removal of rectal tumors are effectiveness (whether a complete resection is achieved), pain, and procedural safety (such as post-operative complication rate). Patient quality of life may be another primary outcome, particularly among patients living with malignant disease. In order to understand the impact of transanal endoscopic microsurgery (TEMS) for treatment of benign or malignant tumors on these outcomes, well-designed randomized controlled trials (RCTs) that compare this therapy to standard medical treatment, such as local excision or anterior resection, respectively, are needed. Further, for treatment of malignant cancers, particularly those with a poor

prognosis, an understanding of any adverse treatment effects must be carefully weighed against any benefits associated with treatment to understand the net treatment effect.

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. Available evidence consists of 2 systematic reviews, a randomized trial (included in the 2005 systematic review) and a nonrandomized study.

Technology Assessments/Systematic Reviews

- Middleton authored a systematic review of this procedure in 2005 based on published results through August 2002.[1] Three comparative studies, including 1 randomized controlled trial, and 55 case series were included. The first area of study was the safety and efficacy in removal of adenomas. In the randomized, controlled trial, 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) for a relative risk of 0.61; 95% confidence interval, 0.29-1.29). TEMS resulted in less local recurrence (6/98; 6%) than direct local excision (20/90; 22%) (relative risk, 0.28; 95 percent confidence interval, 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 TEMS.

- In 2011, Barendse and colleagues reported on a systematic review to compare transanal endoscopic microsurgery (TEMS) to endoscopic mucosal resection (EMR) for rectal adenomas larger than 2 cm.[2] 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 to EMR directly. Early adenoma recurrence rates, within 3 months of the procedure, were 5.4% (95% confidence interval [CI]: 4.0-7.3) with TEMS versus 11.2% (95% CI: 6.0–19.9) with EMR (p=0.04) in pooled estimates. After 3 months, late adenoma recurrence rates in pooled estimates were 3.0% (95% CI: 1.3-6.9) with TEMS versus 1.5% (95% CI: 0.6-3.9) for EMR (p=0.29). Lengths of hospitalization and readmission rates were not significantly different between procedures. For TEMS, there was a mean hospitalization of 4.4 days versus 2.2 days for EMR (p=0.23). Hospital readmission rates were 4.2% for TEMS versus 3.5% for EMR (p=0.64). Complication rates after TEMS, for rectal adenomas only, were 13.0% (95% CI: 9.8-17.0) versus 3.8% (95% CI: 2.8-5.3) after EMR, for colorectal adenomas (p<0.001). Postoperative complications were found to increase significantly in studies with larger polyp size (p=0.04). However, postoperative complication rates remained higher in TEMS after adjusting for a larger mean polyp size in the TEMS studies (8.7% [95 %CI: 5.8–12.7]) than in EMR (4.2% [95 % CI: 2.9–6.3; p=0.007]). These results suggest that TEMS may be associated with less early recurrence compared to EMR but late recurrence (after 3 months) may not be significantly different between procedures. Complications in these studies were significantly higher with TEMS for rectal adenomas larger than 2 cm. This systematic review is limited by the low quality of the available studies, in particular the reliance on single-arm studies to compare the two techniques.

Nonrandomized Studies

Zacharakis reported results on 76 patients from a single hospital who were treated with this technique between 1996 and 2005.[3] 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 needed regarding complications from this procedure. As noted in an article by Cataldo, complications are rare but can be significant.[4] 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

The available evidence on TEMS for rectal adenocarcinomas consists of 3 systematic reviews, 2 RCTs, and several non-randomized studies not included in the systematic review.

Systematic Reviews and Meta-Analysis

- In 2011, Wu and colleagues published a meta-analysis on TEMS and conventional surgery for T1 rectal cancers.[5] 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-month 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.

- Also in 2011, Sgourakis et al. conducted a meta-analysis of T1 and T2 rectal cancer treatment with TEMS compared to standard resection and transanal excision (TAE).[6] 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 and T2 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 (OR: 2.03, 95% CI: 1.15-3.57). Distant metastasis (OR: 1.05, 95% CI: 0.47-2.39) and overall survival (OR:

1.14, 95% CI: 0.55-2.34) 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, conducted a systematic review of both observational and randomized studies, and reviewed weaknesses in the available evidence and unanswered questions regarding the role of TEMS.[7] They posed 3 questions: "First, is there enough evidence to propagate [local excision] (LE) 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 observed that selection bias in current studies complicates answers for the first question. A significant portion of tumors recurred in all studies using various techniques for local excision (including TEMS), although it seemed not to influence survival rates. The authors noted 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 varied 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 wondered if high recurrence rates could be improved by better tumor selection. The authors noted that TEMS has been incorporated into surgical practice based largely on retrospective case series. They also noted that despite the lack of level I evidence, its use seems justified in well-selected T1 rectal cancers. TEMS may be considered as an alternative for those with T1 lesions who are currently undergoing other methods of local excision, such as local excision according to the Parks technique, instead of radical surgery, for their T1 lesions.

Randomized Controlled Trials (RCTs)

- In 2008, G. Lezoche and colleagues published an additional RCT.[8] A total of 70 subjects were enrolled with T2 rectal cancer without evidence of lymph node or distant metastasis on imaging; patients were randomized 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 one (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.

- In 2012, E. Lezoche et al. published an additional report of a similar RCT of 100 patients with T2 rectal cancers without evidence of lymph node or distant metastasis randomized to receive either TEMS or laparoscopic total mesorectal excision.[9] All patients received neoadjuvant chemoradiation prior to surgery. All patients in the TEMS group were able to complete the procedure. However, with laparoscopic resection, 5 patients (10%) required conversion to open surgery (p=0.028), and 23 patients required a stoma. Postoperative complications were not significantly different between groups. Disease-free survival was also not significantly different

between groups (p=0.686) after a median follow-up of 9.6 years (range 4.7-12.3 years for the laparoscopic resection group and 5.5-12.4 for the TEMS group). Local recurrence or metastases occurred in 6 TEMS patients and 5 laparoscopic patients. Overlap of patients from the 2008 and 2012 studies cannot be determined.

Nonrandomized Studies

Additional evidence is based on a large number of case series and retrospective comparative reviews[10]. Much of the evidence focuses on technical aspects of the procedure, as well as other, non-neoplastic applications. Other literature is investigating use of TEMS with adjuvant therapy or additional techniques.[11]

Recently, a number of articles were identified that began to raise questions about disease recurrence following TEMS for T1 rectal cancer.[10,11] In one of these studies, Doornebosch reported on treatment of recurrence following TEMS for T1 rectal cancer.[11] 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 local excision may improve survival.

In an editorial accompanying this study, Friel commented on issues concerning the use of local excision in the treatment of T1 rectal lesions.[12] Friel noted that the reported recurrence rate should raise concerns and calls for additional studies of recurrence with local excision to verify the Doornebosch study. Friel also noted that local excision 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.

Clinical Practice Guidelines and Position Statements

Several clinical practice guidelines have been published on the use of TEMS for treatment of rectal cancer:

National Comprehensive Cancer Network (NCCN)[13]

The NCCN guideline on treatment of rectal cancer states that, when criteria for transanal resection are met, TEMS can be used when the tumor can be adequately identified in the rectum. 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, indicating this recommendation is based upon lower-level evidence which has uniform NCCN consensus that the intervention is appropriate.

National Cancer Institute (NCI)[14]

The NCI states that the surgical approach to treatment varies according to location, stage, and presence or absence of high risk features (ie, positive margins, lymphovascular invasion, perineural invasion and poorly differentiated histology), and may include transanal local excision and TEMS for select clinical staged T1/T2 N0 rectal cancers.

American Society of Colon and Rectal Surgeons (ASCRS)[15]

The ASCRS published practice parameters for the management of rectal cancer. They state that curative local excision is an appropriate treatment modality for carefully selected well- to moderately-differentiated T1 rectal cancer. 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 note visualization with transanal endoscopic microsurgery appears to be superior to the transanal approach but randomized controlled trials on the issue are lacking. TEMS 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 TEMS may afford reasonable palliation for patients with metastatic disease who are poor candidates for a more extensive surgical procedure.

American College of Radiology (ACR)[16]

The ACR issued appropriateness criteria on local excision of early-stage rectal cancer. 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 analysis of current literature and expert consensus, for issues where there is lack of published literature.

Summary

Based on review of the published data, there is sufficient evidence to conclude that transanal endoscopic microsurgery (TEMS) is a safe and effective procedure for excision of primary or recurrent rectal adenomas that cannot be removed by traditional local approaches such as endoscopic removal. Therefore, TEMS is considered medically necessary for these tumors.

For stage T1 rectal cancer, the evidence supports the conclusions that transanal endoscopic microsurgery (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 TEMS versus other surgical techniques. Based on this evidence, use of TEMS may be considered medically necessary in T1 rectal cancers that meet the policy criteria. While additional follow-up studies are being completed, it is important that patients with T1 rectal cancer be fully informed of the risks and benefits associated with this procedure.

The current evidence is insufficient to permit conclusions regarding the safety and effectiveness of TEMS transanal endoscopic microsurgery (TEMS) for the treatment of rectal cancers staged T2 or higher. . 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. Therefore, the use of TEMS for rectal cancers that do not meet the policy, including stage T2 or higher rectal tumors, is considered investigational.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
NOTE: Codes 45171, Excision of rectal tumor, transanal approach; not including muscularis propria (ie, partial thickness) and 45172, Excision of rectal tumor, transanal approach; including muscularis propria (ie, full thickness) do not apply to the TEMS procedure.		
CPT	0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS), including muscularis propria (i.e., full thickness)
HCPCS	None	