

Subject: Transanal Endoscopic Microsurgical (TEM) Excision of Rectal Lesions

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Description

This document addresses transanal endoscopic microsurgery (TEM) as a means of excising rectal lesions.

TEM is a minimally invasive surgical procedure that offers the opportunity for local excision of rectal lesions that cannot be directly visualized. As such, it is an alternative to open or laparoscopic surgical excision of rectal lesions.

Clinical Indications

Medically Necessary:

Transanal endoscopic microsurgery (TEM) is considered **medically necessary** for treatment of rectal lesions including rectal tumors and rectal polyps that are appropriate for treatment by local excision but are too proximal to be reached using conventional transanal excision methods.

Not Medically Necessary:

Transanal endoscopic microsurgery (TEM) is considered **not medically necessary** when the criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services may be Medically Necessary when criteria are met:

CPT

0184T Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)

ICD-10 Procedure

0DBP8ZZ Excision of rectum, via natural or artificial opening endoscopic [when specified as TEM]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met.

Discussion/General Information

Surgery is the most common treatment for rectal tumors. The type of surgery chosen will depend upon several factors including, but not necessarily limited to the location of the tumor, how deeply it has penetrated the rectal wall, and whether the tumor has spread to nearby lymph nodes or other parts of the body.

TEM is a minimally invasive surgical procedure that offers the opportunity for local excision of rectal lesions that cannot be directly visualized. As such, it is an alternative to open or laparoscopic surgical excision of rectal lesions. The TEM operating system includes a specialized magnifying resectoscope, ports for carbon dioxide gas insufflation and irrigation and allows the passage of dissecting instruments. The operating system also monitors and regulates intrarectal pressure. Suction is used to remove blood, smoke, and particulate matter from the surgical field. TEM is being investigated as a less invasive surgical option in order to avoid the possible adverse effects (sexual and urinary dysfunction, colostomy) associated with radical surgical techniques.

TEM is an inpatient procedure that can be performed with the individual under general anesthesia or regional anesthesia from a spinal block. In some instances the tumor may be too advanced to be removed by local resection and a more aggressive surgical approach is required.

Surgical excision of rectal lesions involves the balance between adequate excision and surgical morbidity related to sphincter function and quality of life. For an individual with rectal cancer, this balance often involves the choice between local transanal excision versus more extensive open or laparoscopic resection. Local excision has been considered a treatment option for small rectal cancers (less than 4 cm) confined to the submucosa (T1 lesions); even so, it is estimated that 10-15% of individuals will have metastases to the regional lymph nodes, thus increasing the risk of local recurrence. Some individuals are offered local excision based on co-morbidities precluding more extensive surgery, and local excision may also be performed as a palliative procedure.

Local excision has primarily been performed under direct visualization, which is limited to those lesions occurring within 8 cm of the anal verge. TEM attempts to duplicate the surgical techniques of local excision using direct visualization. TEM permits local excision beyond the distal rectum, as far proximally as the rectosigmoid junction (Baxter, 2007). As noted in the rectal cancer guidelines of the National Comprehensive Cancer Network (NCCN, 2023):

Both transanal local excision and TEM involve a full thickness excision performed perpendicularly through the bowel wall into the perirectal fat. Negative (> 3 mm) deep and mucosal margins are required and tumor fragmentation should be avoided. The locally excised specimen should be oriented and pinned before fixation and brought to the pathologist by the surgeon to facilitate an oriented histopathologic evaluation of the specimen. If

pathologic examination reveals adverse features such as positive margins, LVI, poor differential or invasion into the lower third of the submucosa (sm3 level), a more radical resection is recommended.

Key considerations in the evaluation of TEM relate to its ability to duplicate the surgical principles of local excision under direct vision. For example, if TEM results in an incomplete or fragmented resection, then the surgery will likely be followed up with a more radical resection. Thus key outcomes of interest include:

- Rate of conversion to open or other procedures;
- Complete or incomplete resection;
- Need for subsequent radical rectal excision;
- Reoperation rate; and
- Anorectal function.

TEM has been targeted to lesions that are inaccessible by local excision under direct vision. Alternative surgical options for these individuals consist of open or laparoscopic excision. Key outcomes when comparing TEM to alternatives include:

- Operating time;
- Operative complications;
- Length of hospital stay; and
- Readmission rate.

When comparing data regarding the long-term survival and recurrence rates for individuals with rectal cancer, it should be noted that recurrence rates with any type of local excision will likely be higher than more radical excision, and thus survival and recurrence rates should be compared to local excision using direct visualization.

TEM has been extensively used outside of the United States and a large number of case series have been reported, including individuals with both benign and malignant conditions. A systematic review published in 2005 identified 55 case series, 1 randomized study and 2 nonrandomized comparative studies (Middleton, 2005). The majority of the lesions were located between 4 and 22 cm from the anal verge. Although the authors reported that the overall quality of the studies was poor, the review suggested that there were no differences in the recurrence or survival rates or complication between TEM and radical resection for the treatment of carcinomas.

In the single randomized study, individuals with adenomas (n=188) or rectal cancer (n=53) underwent either TEM or open resection. As reviewed by Middleton (2005), the following outcomes were either similar or improved when compared to open resection:

- Overall early complications;
- Late complications (mean follow-up 45 months);
- 5-year local recurrence;
- Operating time;
- Length of hospital stay; and
- Analgesic requirement.

In the entire group of 123 individuals undergoing TEM, there was no report of tumor extending to the resection margin and only one conversion to an open procedure. In a nonrandomized comparison trial, the conversion rate to an open procedure was 2 of 80 TEMs (2.5%).

Lezoche and colleagues published two reports of a randomized trial; these studies likely included overlapping subjects (Lezoche 2005, Lezoche 2008). The 2008 study reported on 5-year follow-up and included more individuals than the initial 2005 report. The 2008 report is summarized as follows: 70 individuals were enrolled with T2 rectal cancer with no imaging evidence of lymph node or distant metastases and individuals were randomized to undergo TEM or laparoscopic resection. All study subjects underwent preoperative neoadjuvant chemoradiotherapy. Local excision, which has generally been limited to individuals with T1 lesions, was also considered in this study for individuals with T2 lesions. This study was not focused on the technical ability of TEM, but rather the role of neoadjuvant chemotherapy to reduce the risk of local recurrence in this higher risk group of individuals. The primary outcome measure was long-term recurrence and survival rates in the two groups of individuals. At the median follow-up period (56 months) in both groups, 1 local failure (5%) occurred after 6 months in the TEM group and 1 (5%) after 48 months in the laparoscopic group. Distant metastases occurred in 1 individual (5%) in the TEM group after 26 months and 1 individual (5%) in the laparoscopic group at 31 months. The probability of survival was 95% for TEM and 83% for laparoscopic resection.

Lezoche and colleagues (2012) reported the results of a prospective randomized trial which compared endoluminal locoregional resection (ELRR) by transanal endoscopic microsurgery versus laparoscopic total mesorectal excision (TME) as a treatment for small non-advanced low rectal cancer. Study participants were randomized to ELRR or TME and all had rectal cancer which was clinically staged as cT2 N0 M0, histological grade G1-2, tumor less than 3 cm in diameter and within 6 cm of the anal verge. Study participants also received neoadjuvant chemoradiation prior to surgery. After chemoradiation, the participants underwent repeat staging to evaluate tumor response and were subsequently randomized to either the ELRR performed by TEM or the laparoscopic TME group. Fifty participants in each group were analyzed. The primary endpoint of the study was the oncological result in terms of local recurrence or distant metastases, with minimum follow-up of 5 years. Secondary endpoints included cancer-related mortality, duration of operation, blood loss, analgesic use, morbidity, hospital stay and 30-day mortality. Overall tumor downstaging and downsizing rates after neoadjuvant chemoradiotherapy were similar in both groups, 51% and 26% respectively. Tumors were downstaged in 26 participants in the ELRR group (14 to pT0, 12 to pT1) and 25 in the TME group (13 to pT0, 12 to pT1). Of the remaining 46 participants, 26 (13 in each group) had a reduction in tumor diameter of more than 50%. In the remaining subjects, a reduction in tumor diameter of less than 50% was observed. All of the participants had R0 resection with tumor-free resection margins. There were no statistically significant differences between the groups in minor or major postoperative complications. None of the participants in the ELRR group experienced a conversion to open surgery or stoma. However, in the TME group, 6 participants (12%) had a change in the operative program during the operation with the procedure being converted to an open procedure in 5 subjects (10%). Twenty-three participants in this group required a stoma, which was temporary in 11 individuals (22%), and definitive in 12 individuals (24%) who underwent abdominoperineal resection. At long-term follow-up, local disease recurrence developed in 4 individuals (8%) who underwent ELRR and 3 individuals (6%) who had undergone TME. Distant metastases occurred in 2 individuals (4%) in each group. There was no statistically significant difference in disease-free survival ($P=0.686$). Overall survival rates at the end of follow-up were 72% (51 to 86) and 80% (62 to 90) respectively ($P=0.0609$). The authors concluded that the probability of developing recurrence or metastases and cancer-related survival was similar in both groups. However, results favored ELRR by TEM in terms of operating time, blood loss and transfusions, need for analgesia and hospital stay.

In 2012, Kumar and colleagues reported on the use of TEM for rectal carcinoids in the United States. Data from subjects who had undergone TEM for rectal carcinoids were prospectively collected and then analyzed. The researchers reviewed participant and tumor characteristics, operative and perioperative details, as well as oncological outcomes. During a 12-year period, 24 subjects underwent

TEM for rectal carcinoids. Of these, 6 (25%) surgical procedures were primary surgical resections and 18 (75%) were performed after incomplete snare excisions during colonoscopy. Histopathological examination revealed 3 (17%) of the participants who underwent full-thickness resection after snare excision had a residual tumor. Negative margins were obtained in all cases and no recurrences were noted. The researchers concluded that TEM is an effective and safe surgical option for rectal carcinoids less than 2 cm in diameter, with typical features and located more than 5 cm from the anal verge. The authors also concluded that TEM can be used for primary resection or for resection after incomplete colonoscopic snare excision.

As a representative example of reported case series, Baatrup and colleagues reported on the outcomes of 143 consecutive individuals undergoing TEM for rectal cancer (Baatrup, 2009). TEM was performed for curative intent in 43% of the subjects, in 52% of individuals considered unfit for more extensive surgery and for palliation in 5% of individuals. A total of 15% of individuals had immediate reoperation. The cancer specific survival for T1 lesions was 94%. Guerrieri and colleagues (2008) reported on a 15-year experience with TEM in 196 individuals with rectal cancer with either T1, T2, or T3 lesions. Individuals with T2 or T3 lesions underwent neoadjuvant therapy. Minor complications were reported in 8.6% of individuals, the local recurrence rate was 4.1%. As a representative example of a comparative study, Moore and colleagues (2008) compared the results in two groups of individuals undergoing either traditional transanal excision (n=89) or TEM (n=82) for rectal cancer. Medical records were reviewed to determine type of surgery, resection margins, specimen fragmentation, complications, recurrence, lesion type stage and size. The two groups were similar in baseline characteristics. There was no difference in complication rates between the two groups, and TEM was more likely to yield clear surgical margins and a nonfragmented specimen. This study suggests that TEM may be preferred over conventional transanal excision in any location. Lee and colleagues retrospectively compared the outcomes in 74 individuals treated with TEM compared to 100 individuals treated with radical surgery and reported 5-year recurrence and survival rates (Lee, 2003). For individuals with T1 rectal cancer, there was no difference in recurrence or survival rates in the two groups. For individuals with T2 cancer, there was a higher incidence of recurrence in the TEM group, but the overall survival was similar in the two groups.

A variety of guidelines and practice parameters have recognized TEM as a treatment option for individuals with rectal cancer.

The American Society of Colon and Rectal Surgeons (ASCRS) practice parameters for the management of rectal cancer indicate that the criteria for local excision "involves full-thickness excision, ideally with a ≥ 10 mm grossly normal circumferential margin with a depth down to perirectal fat providing a minimum of a 2-mm-deep margin" (You, 2020).

The NCCN Clinical Practice Guidelines in Oncology on Rectal Cancer (2023) provide selection criteria for transanal excision, and then note that "TEM can facilitate excision of small tumors through the anus when lesions can be adequately identified in the rectum. TEM may be technically feasible for more proximal lesions."

The National Cancer Institute (NCI) provides general information about the treatment of rectal cancer and notes that the surgical approach to treatment varies according to the location, stage, and presence or absence of high-risk features (for example, positive margins, lymphovascular invasion, perineural invasion and poorly differentiated histology). The guideline does specifically indicate that TEM may be an appropriate treatment option for "select clinically staged T1/T2 N0 rectal cancers" (NCI, 2023).

The European Association for Endoscopic Surgery (EAES) clinical consensus guidelines on early rectal cancer concluded that TEM is an established approach for local excision of selected early rectal cancer (Morino, 2015).

Summary

TEM is designed to duplicate the surgical principles of local excision under direct visualization. As such, it can be considered a surgical tool that enables access to more proximal rectal lesions. While there are minimal controlled trials directly comparing the technical abilities of TEM and conventional local excision, small randomized trials and numerous case series suggest that the two techniques have similar technical performance. In addition, for proximal rectal lesions, the surgical alternative is a more extensive open or laparoscopic resection with associated increased morbidity. Cancer recurrence rates are a concern with any type of local excision, but the recurrence rates are primarily related to the status of the lymph nodes, which are not removed with either TEM or conventional local excision. Lymphovascular invasion and adverse histologies are predictors of local recurrence, but these parameters can only be verified postoperatively in both techniques. Finally, the ASCRS, NCCN and the NCI all recognize TEM as a surgical option in carefully selected individuals.

Definitions

Colostomy: Surgical procedure where a part of the colon (large intestine) is brought through the abdominal wall to pass stool out of the body.

LVI (lymphovascular invasion): The spread of spread of a cancer into the lymphatics and/or blood vessels.

Lymph node: Small, round or bean-shaped small bodies located along the lymphatic vessels that filter foreign particles and bacteria from lymph fluid.

References

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Government Agency, Medical Society, and Other Authoritative Publications:

1. Kahi CJ, Boland CR, Dominitz JA, et al. American Society of Colon and Rectal Surgeons: Colonoscopy Surveillance after Colorectal Cancer Resection: Recommendations of the US Multi-Society Task Force on Colorectal Cancer. *Am J Gastroenterol*. 2016; 111(3):337-346.
2. Morino M, Risio M, Bach S, et al. Early rectal cancer: the European Association for Endoscopic Surgery (EAES) clinical consensus conference. *Surg Endosc*. 2015; 29(4):755-773.
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4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. Rectal Cancer. V4.2023. Revised July 25, 2023. For additional information visit the NCCN website: Available at: <http://www.nccn.org/index.asp>. Accessed on September 12, 2023.
5. Tjandra JJ, Kilkeny JW, Buie WD, et al. Practice parameters for the management of rectal cancer (revised). *Dis Colon Rectum*. 2005; 48(3):411-423.
6. You YN, Hardiman KM, Bafford A, et al; On Behalf of the Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of rectal cancer. *Dis Colon Rectum*. 2020 Sep; 63(9):1191-1222.

Websites for Additional Information

1. American Cancer Society. Colorectal cancer. Treating colorectal cancer. Treatment of rectal cancer, by stage. Last revised June 29, 2020. Available at: <https://www.cancer.org/cancer/types/colon-rectal-cancer/treating/by-stage-rectum.html>. Accessed on September 12, 2023.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References, Websites for Additional Information and History sections.
Reviewed	11/10/2022	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information and History sections.
Reviewed	11/11/2021	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information and History sections.
Reviewed	11/05/2020	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information and History sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information and History sections.
Reviewed	01/24/2019	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information and History sections.
New	03/22/2018	MPTAC review. Initial document development. Moved content of SURG.00110 Transanal Endoscopic Microsurgical (TEM) Excision of Rectal Lesions to new clinical utilization management guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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