

Corporate Medical Policy

Transanal Endoscopic Microsurgery (TEMS)

File Name:	transanal_endoscopic_microsurgery_(tems)
Origination:	6/2008
Last CAP Review:	11/2020
Next CAP Review:	11/2021
Last Review:	11/2020

Description of Procedure or Service

Transanal endoscopic microsurgery (TEMS) is a minimally invasive surgical approach for 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 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 fecal incontinence related to stretching of the anal sphincter, and can be performed under general or regional anesthesia.

This procedure has been available 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 technique requires specialized equipment including a magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. 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, such as strictures or 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 an 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, local excision may be an informed alternative for patients. TEMS permits local excision beyond the reach of direct visualization equipment.

Regulatory Status

As noted, this procedure requires use of specialized equipment. The Transanal Endoscopic Microsurgery (TEMS) Combination System and Instrument Set (Richard Wolf Medical Instruments) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2001. 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 SILS™ Port (Covidien) subsequently received 510(k) approval in 2011. The SILS™ Port is a similar instrument that can be used for rectal procedures including TEMS. Another device determined by FDA to be substantially equivalent to these devices is the GelPOINT® Path (Applied Medical Resources).

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******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Transanal Endoscopic Microsurgery when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Transanal Endoscopic Microsurgery is covered

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:

- Located in the middle or upper part of the rectum,
- Well or moderately differentiated (G1 or G2) by biopsy,
- Without lymphadenopathy, and
- Less than 1/3 the circumference of the rectum

When Transanal Endoscopic Microsurgery is not covered

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

Policy Guidelines

Transanal endoscopic microsurgery (TEMS) is a minimally invasive surgical 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.

For patients with early rectal cancer adenocarcinoma who receive TEMS, the evidence includes 2 small randomized controlled trials, a few nonrandomized comparative studies, and many single-arm case series. Relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports the conclusions that transanal endoscopic microsurgery (TEMS) is associated with fewer postoperative complications but higher local recurrence rates and possibly a higher rate of metastatic disease. There is no demonstrated difference in long-term overall survival in the available studies. However, due to the low quality of the evidence base, these conclusions cannot be made with certainty. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

For patients with rectal adenomas who receive TEMS, the evidence includes a few nonrandomized comparative studies, and many single-arm case series. Relevant outcomes are overall survival, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The evidence supports the 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 alternative

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procedures. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

Based on clinical input obtained by the outcomes of single-arm series that have shown low complication rates and low recurrence rates of lesions supporting use of TEMS when lesions are not amenable to standard excision. TEMs may be considered medically necessary for excision of rectal adenomas and early carcinomas that cannot be removed by standard approaches when specific criteria are met. These criteria include, clinical stage T1 cancers that are located in the middle or upper part of the rectum, are well or moderately differentiated (G1 or G2) by biopsy, are without lymphadenopathy, and involve less than one-third of the circumference of the rectum.

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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0184T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 12/3/2007

Specialty Matched Consultant Advisory Panel - 4/2008

National Comprehensive Cancer Network. Practice Guidelines in Oncology: Rectal Cancer (V.3.2009). Available online at http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 10/06/09

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 11/10/11

Specialty Matched Consultant Advisory Panel – 10/2012

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 11/8/12

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 9/12/13

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 9/11/14

Specialty Matched Consultant Advisory Panel – 11/2014

Senior Medical Director review—12/2014

BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 9/10/2015

Specialty Matched Consultant Advisory Panel 11/2015

Transanal Endoscopic Microsurgery (TEMS)

Senior Medical Director review 11/2015
Specialty Matched Consultant Advisory Panel 11/2016
Medical Director review 11/2016
BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 11/2016
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Medical Director review 11/2019
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Medical Director review 11/2020
BCBSA Medical Policy Manual [Electronic Version] - 7.01.112, 11/2020

Policy Implementation/Update Information

6/16/08 New policy adopted from BCBSA. Specialty Matched Consultant Advisory Panel review 4/30/ 2008. Transanal endoscopic microsurgery is considered investigational for the treatment of rectal conditions including rectal cancers and rectal polyps. (btw)

6/22/10 Policy Number(s) removed (amw)

11/23/10 Description section revised. Policy statement changed from Investigational to Medically Necessary when criteria are met. 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 than cannot be removed using other means of local excision and that meet all of the following criteria: Located in the middle or upper part of the rectum, Well or moderately differentiated (G1 or G2) by biopsy, Without lymphadenopathy, and Less than 1/3 the circumference of the rectum. Transanal endoscopic microsurgery is considered **investigational** for treatment of rectal tumors that do not meet the criteria noted above. Policy Guidelines revised. References updated. Specialty Matched Consultant Advisory Panel review meeting 10/28/10. Policy accepted as written. (adn)

10/30/12 Specialty Matched Consultant Advisory Panel review 10/17/12. Policy Guidelines updated. No change to policy intent. (sk)

1/15/13 Reference added. No change to policy statement. (sk)

11/12/13 Reference added. Specialty Matched Consultant Advisory Panel review 10/16/13. No change to policy intent. (sk)

1/13/15 References updated. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review 12/2014. No change to policy intent. (td)

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- 12/30/15 Policy Guidelines section updated. References updated. Specialty Matched Consultant Advisory Panel review 11/18/2015. Senior Medical Director review 11/2015. (td)
- 12/30/16 Description section and references updated. Specialty Matched Consultant Advisory Panel 11/2016. Medical Director review 11/2016. (jd)
- 12/15/17 References updated. Specialty Matched Consultant Advisory Panel 11/2017. Medical Director review 11/2017. (jd)
- 12/14/18 Minor update to regulatory status. Revision to policy guidelines for consistency. References updated. Specialty Matched Consultant Advisory Panel 11/2018. Medical Director review 11/2018. (jd)
- 12/31/19 References updated. Specialty Matched Consultant Advisory Panel 11/2019. Medical Director review 11/2019. (jd)
- 12/8/20 References updated. Specialty Matched Consultant Advisory Panel 11/2020. Medical Director review 11/2020. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.