

FEP 7.01.112 Transanal Endoscopic Microsurgery

Effective Date: April 15, 2018

Related Policies: None

Transanal Endoscopic Microsurgery

Description

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.

FDA 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. 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 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.

POLICY STATEMENT

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 one-third the circumference of the rectum.

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

POLICY GUIDELINES

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

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BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

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

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on the treatment of rectal cancer (v.3.2017) 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.³¹ The National Comprehensive Cancer 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 2017 National Cancer Institute (NCI) 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.³² 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

In 2013, the American Society of Colon and Rectal Surgeons updated its 2010 practice parameters for the management of rectal cancer.³³ The 2013 guidelines indicated that curative local excision is an appropriate treatment modality for carefully selected, well to moderately differentiated T1 rectal cancers.

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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) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer in 2015.^{34,35} 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
March 2013	Update Policy	Policy updated with literature search, reference number 4-5 and 17 added, 14-15 updated. Policy statement unchanged.
December 2013	Update Policy	Policy updated with literature review. Reference 18 added. Policy statement unchanged.
December 2014	Update Policy	Policy updated with literature review, reference 5 added. Policy statement unchanged.
March 2016	Update Policy	Policy updated with literature review through August 25, 2015; references 3-13, and 16 added. Policy statements unchanged.
March 2017	Update Policy	Policy updated with literature review, references 16-17 added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through September 26, 2017; no references added. Policy statements unchanged.

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