



## FEP Medical Policy Manual

### FEP 7.01.112 Transanal Endoscopic Microsurgery

**Annual Effective Policy Date: April 1, 2026**

**Original Policy Date: June 2012**

**Related Policies:**

None

## Transanal Endoscopic Microsurgery

### Description

#### Description

Transanal endoscopic microsurgery (TEM) 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.

#### OBJECTIVE

The objective of this evidence review is to determine whether the use of transanal endoscopic microsurgery, as an alternative to open or laparoscopic excision, improves the net health outcome for individuals with rectal adenomas or early rectal cancer.

## 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.

## BENEFIT APPLICATION

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

Screening (other than the preventive services listed in the brochure) is not covered. Please see Section 6 General exclusions.

Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's existing medical condition. Benefits are not provided for genetic panels when some or all of the tests included in the panel are not covered, are experimental or investigational, or are not medically necessary.

## FDA REGULATORY STATUS

In 2001, the TEM 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. 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. In 2011, the SILS™ Port (Covidien) was cleared for marketing by the FDA through the 510(k) process. The SILS Port is a similar instrument that can be used for rectal procedures including TEM. 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. Table 1 lists some of the TEM devices cleared by the FDA.

### Table 1. Transanal Endoscopic Microsurgery Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Applied Medical Anoscope	Applied Medical Resources	01/06/2021	K200021	For use in transanal endoscopic microsurgery
AP50/30 Insufflator with Insufflow Port	Lexion Medical LLC	8/28/2019	K191780	For use in transanal endoscopic microsurgery
AirSeal	ConMed Corporation	3/28/2019	K190303	For use in transanal endoscopic microsurgery
GRI-Alleset Veress Needle	GRI Medical and Electronic Technology Co. Ltd.	6/11/2018	K172835	For use in transanal endoscopic microsurgery
SurgiQuest AIRSEAL iFS System	ConMed Corporation	3/16/2018	K172516	For use in transanal endoscopic microsurgery
TEMED Gas Diffuser	TEMED	2/14/2018	K173545	For use in transanal endoscopic microsurgery
Veress Needle	WickiMed (Huizhou) Medical Equipment Manufacturing Co.Ltd.	9/14/2017	K172120	For use in transanal endoscopic microsurgery
GelPOINT Path Transanal Access Platform	Applied Medical Resources Corp.	7/20/2017	K171701	For use in transanal endoscopic microsurgery
HumiGard Surgical Humidification System HumiGard Humidified Insufflation Kit	FISHER & PAYKEL HEALTHCARE	6/23/2017	K162582	For use in transanal endoscopic microsurgery
LaparoLight Veress Needle	Buffalo Filter LLC	5/18/2017	K171139	For use in transanal endoscopic microsurgery
PNEUMOCLEAR	W.O.M World Of Medicine GmbH	5/15/2017	K170784	For use in transanal endoscopic microsurgery
ENDOFLATOR 40 ENDOFLATOR 50	KARL STORZ ENDOSCOPY-AMERICA INC.	3/2/2017	K161554	For use in transanal endoscopic microsurgery
U-Blade Veress Needle	TIANJIN UWELL MEDICAL DEVICE MANUFACTURING CO.LTD.	12/12/2016	K162648	For use in transanal endoscopic microsurgery
S698 Symbioz flow	SOPRO - ACTEON GROUP	6/17/2016	K153367	For use in transanal endoscopic microsurgery
Insufflator 50L FM134	W.O.M WORLD OF MEDICINE GMBH	3/4/2016	K153513	For use in transanal endoscopic microsurgery
Unimicro Veress Needle	Unimicro Medical Systems (ShenZhen) Co.Ltd.	7/31/2015	K150068	For use in transanal endoscopic microsurgery
SurgiQuest AirSeal iFS System	SURGIQUEST INC.	3/20/2015	K143404	For use in transanal endoscopic microsurgery

## RATIONALE

### Summary of Evidence

For individuals who have rectal adenoma(s) who receive transanal endoscopic microsurgery (TEM), the evidence includes a few nonrandomized comparative studies and numerous single-arm case series. Relevant outcomes are overall survival (OS), functional outcomes, health status measures, quality of life (QOL), and treatment-related morbidity. The evidence supports conclusions that the removal of polyps by TEM 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 TEM and standard procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have early rectal adenocarcinoma who receive TEM, the evidence includes small randomized controlled trials (RCTs), a few nonrandomized comparative studies, numerous single-arm case series, and systematic reviews of these studies. Relevant outcomes are OS, functional outcomes, health status measures, QOL, and treatment-related morbidity. The evidence supports conclusions that TEM is associated with fewer postoperative complications but may have higher local recurrence rates and possibly higher rates of metastatic disease. One systematic review indicates improved OS with radical surgery compared with TEM; however, the majority of systematic reviews did not demonstrate significant differences in OS. However, due to the low quality of the evidence base, these conclusions lack certainty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### American College of Radiology

In 2015, the American College of Radiology (ACR) updated its 2010 appropriateness criteria on local excision of early-stage rectal cancer.<sup>30,31</sup> The ACR noted that transanal endoscopic microsurgery (TEM) 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 TEM 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.

#### American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons published updated guideline recommendations for the management of rectal cancer in 2020.<sup>32</sup> The guidelines indicate that curative local excision is an appropriate treatment modality for carefully selected, well to moderately differentiated T1 rectal cancers. Tumor size must be less than 3 cm in diameter and less than 30% of the bowel lumen circumference. Additionally, patients must not have a lymphovascular or perineural invasion. The guidelines noted that visualization with TEM appears to be superior to the transanal approach, but randomized controlled trials are lacking. T2 lesions should be treated with radical resection unless the patient is a poor candidate for a more extensive surgical procedure. A supplement was subsequently published in 2023, with no additional recommendations offered on TEM.<sup>33</sup>

#### National Comprehensive Cancer Network

The National Comprehensive Cancer Network (v.3.2025 ) in its updated guidelines on the treatment of rectal cancer states, "When the lesion can be adequately localized to the rectum, local excision of more proximal lesions may be technically feasible using advanced techniques, such as transanal endoscopic microsurgery (TEM) or transanal minimally invasive surgery (TAMIS)."<sup>34</sup>

However, under discussion is the statement, "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."

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## REFERENCES

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New Policy	
March 2013	Replace policy	Policy updated with literature search, reference number 4-5 and 17 added, 14-15 updated. Policy statement unchanged.
December 2013	Replace policy	Policy updated with literature review. Reference 18 added. Policy statement unchanged.
December 2014	Replace policy	Policy updated with literature review, reference 5 added. Policy statement unchanged.
March 2016	Replace policy	Policy updated with literature review through August 25, 2015; references 3-13, and 16 added. Policy statements unchanged.
March 2017	Replace policy	Policy updated with literature review, references 16-17 added. Policy statement unchanged.
March 2018	Replace policy	Policy updated with literature review through September 26, 2017; no references added. Policy statements unchanged.
March 2019	Replace policy	Policy updated with literature review through September 4, 2018; no references were added. Policy statements unchanged.
March 2020	Replace policy	Policy updated with literature review through September 9, 2019; no references added; references on NCCN updated. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Date	Action	Description
March 2021	Replace policy	Policy updated with literature review through August 20, 2020; references added. Policy statements unchanged.
March 2022	Replace policy	Policy updated with literature review through October 5, 2021; references added. Policy statements unchanged.
March 2023	Replacy policy	Policy updated with literature review through September 9, 2022; no references added. Policy statements unchanged.
March 2024	Replace policy	Policy updated with literature review through September 13, 2023; references added. Policy statements unchanged.
March 2025	Replace policy	Policy updated with literature review through October 9, 2024; reference added. Policy statements unchanged.
March 2026	Replace policy	Policy updated with literature review through September 29, 2025; references added. Policy statements unchanged.

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