BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.112 Transanal Endoscopic Microsurgery

Annual Effective Policy Date: April 1, 2024

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).

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 Insuflow 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	ConMed Corporation	3/16/2018	K172516	For use in transanal endoscopic

System				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 2 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 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.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (v.4.2023) 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)."[27,]

However, under discussion is the statement, "TEM [transanal endoscopic microsurgery] 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."

National Cancer Institute

In 2021, the National Cancer Institute (NCI) guidelines on treatment of rectal cancer indicated 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.[28,] 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. The NCI recommends surgical resection of the primary tumor as a primary treatment for patients with rectal cancer. The 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

The American Society of Colon and Rectal Surgeons published updated guideline recommendations for the management of rectal cancer in 2020.[29,] 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.

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.[30,31,] The ACR noted that 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.

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

1. Barendse RM, van den Broek FJ, Dekker E, et al. Systematic review of endoscopic mucosal resection versus transanal endoscopic microsurgery for large rectal adenomas. Endoscopy. Nov 2011; 43(11): 941-9. PMID 21971923
2. Middleton PF, Sutherland LM, Maddern GJ. Transanal endoscopic microsurgery: a systematic review. Dis Colon Rectum. Feb 2005; 48(2): 270-84. PMID 15711865
3. Zhang Y, Yu P, Wang P, et al. Analysis of the therapeutic effect of transanal endoscopic microsurgery on large rectal adenoma. J Minim Access Surg. 2022; 18(4): 571-577. PMID 36204937
4. Restivo A, Zorcolo L, D'Alia G, et al. Risk of complications and long-term functional alterations after local excision of rectal tumors with transanal endoscopic microsurgery (TEM). Int J Colorectal Dis. Feb 2016; 31(2): 257-66. PMID 26298182
5. Issa N, Murninkas A, Schmilovitz-Weiss H, et al. Transanal Endoscopic Microsurgery After Neoadjuvant Chemoradiotherapy for Rectal Cancer. J Laparoendosc Adv Surg Tech A. Aug 2015; 25(8): 617-24. PMID 26258267
6. Verseveld M, Barendse RM, Gosselink MP, et al. Transanal minimally invasive surgery: impact on quality of life and functional outcome. Surg Endosc. Mar 2016; 30(3): 1184-7. PMID 26139488
7. D'Ambrosio G, Paganini AM, Balla A, et al. Quality of life in non-early rectal cancer treated by neoadjuvant radio-chemotherapy and endoluminal loco-regional resection (ELRR) by transanal endoscopic microsurgery (TEM) versus laparoscopic total mesorectal excision. Surg Endosc. Feb 2016; 30(2): 504-511. PMID 26045097
8. Verseveld M, de Graaf EJ, Verhoef C, et al. Chemoradiation therapy for rectal cancer in the distal rectum followed by organ-sparing transanal endoscopic microsurgery (CARTS study). Br J Surg. Jun 2015; 102(7): 853-60. PMID 25847025
9. Laliberte AS, Lebrun A, Drolet S, et al. Transanal endoscopic microsurgery as an outpatient procedure is feasible and safe. Surg Endosc. Dec 2015; 29(12): 3454-9. PMID 25801107
10. Samalavicius N, Ambrazevicius M, Kilius A, et al. Transanal endoscopic microsurgery for early rectal cancer: single center experience. Wideochir Inne Tech Maloinwazyjne. Dec 2014; 9(4): 603-7. PMID 25561999
11. Mora Lpez L, Serra Aracil X, Hermoso Bosch J, et al. Study of anorectal function after transanal endoscopic surgery. Int J Surg. Jan 2015; 13: 142-147. PMID 25486265
12. Hompes R, Ashraf SQ, Gosselink MP, et al. Evaluation of quality of life and function at 1 year after transanal endoscopic microsurgery. Colorectal Dis. Feb 2015; 17(2): O54-61. PMID 25476189
13. Stipa F, Picchio M, Burza A, et al. Long-term outcome of local excision after preoperative chemoradiation for ypT0 rectal cancer. Dis Colon Rectum. Nov 2014; 57(11): 1245-52. PMID 25285690
14. Verseveld M, Barendse RM, Dawson I, et al. Intramucosal carcinoma of the rectum can be safely treated with transanal endoscopic microsurgery; clinical support of the revised Vienna classification. Surg Endosc. Nov 2014; 28(11): 3210-5. PMID 24939156
15. Zacharakis E, Freilich S, Rekhraj S, et al. Transanal endoscopic microsurgery for rectal tumors: the St. Mary's experience. Am J Surg. Nov 2007; 194(5): 694-8. PMID 17936438
16. Cataldo PA. Transanal endoscopic microsurgery. Surg Clin North Am. Aug 2006; 86(4): 915-25. PMID 16905416
17. Al-Najami I, Rancinger CP, Larsen MK, et al. Transanal endoscopic microsurgery for advanced polyps and early cancers in the rectum-Long-term outcome: A STROBE compliant observational study. Medicine (Baltimore). Sep 2016; 95(36): e4732. PMID 27603369
18. Chan T, Karimuddin AA, Raval MJ, et al. Predictors of rectal adenoma recurrence following transanal endoscopic surgery: a retrospective cohort study. Surg Endosc. Aug 2020; 34(8): 3398-3407. PMID 31512037
19. Motamedi MAK, Mak NT, Brown CJ, et al. Local versus radical surgery for early rectal cancer with or without neoadjuvant or adjuvant therapy. Cochrane Database Syst Rev. Jun 13 2023; 6(6): CD002198. PMID 37310167
20. Li W, Xiang XX, Da Wang H, et al. Transanal endoscopic microsurgery versus radical resection for early-stage rectal cancer: a systematic review and meta- analysis. Int J Colorectal Dis. Feb 17 2023; 38(1): 49. PMID 36800079
21. Xiong X, Wang C, Wang B, et al. Can transanal endoscopic microsurgery effectively treat T1 or T2 rectal cancer?A systematic review and meta-analysis. Surg Oncol. Jun 2021; 37: 101561. PMID 33848762
22. Sgourakis G, Lanitis S, Gockel I, et al. Transanal endoscopic microsurgery for T1 and T2 rectal cancers: a meta-analysis and meta-regression analysis of outcomes. Am Surg. Jun 2011; 77(6): 761-72. PMID 21679648
23. Bach SP, Gilbert A, Brock K, et al. Radical surgery versus organ preservation via short-course radiotherapy followed by transanal endoscopic microsurgery for early-stage rectal cancer (TREC): a randomised, open-label feasibility study. Lancet Gastroenterol Hepatol. Feb 2021; 6(2): 92-105. PMID 33308452

24. Lezoche E, Baldarelli M, Lezoche G, et al. Randomized clinical trial of endoluminal locoregional resection versus laparoscopic total mesorectal excision for T2 rectal cancer after neoadjuvant therapy. Br J Surg. Sep 2012; 99(9): 1211-8. PMID 22864880
25. Lezoche G, Baldarelli M, Guerrieri M, et al. A prospective randomized study with a 5-year minimum follow-up evaluation of transanal endoscopic microsurgery versus laparoscopic total mesorectal excision after neoadjuvant therapy. Surg Endosc. Feb 2008; 22(2): 352-8. PMID 17943364
26. van Heinsbergen M, Leijtens JW, Slooter GD, et al. Quality of Life and Bowel Dysfunction after Transanal Endoscopic Microsurgery for Rectal Cancer: One Third of Patients Experience Major Low Anterior Resection Syndrome. Dig Surg. 2020; 37(1): 39-46. PMID 31185474
27. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 4.2023. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed September 13, 2023.
28. National Cancer Institute (NCI). Rectal Cancer Treatment (PDQ). Healthcare Provider Version. https://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq#_43. Updated June 30, 2023. Accessed September 13, 2023.
29. You YN, Hardiman KM, Bafford A, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Rectal Cancer. Dis Colon Rectum. Sep 2020; 63(9): 1191-1222. PMID 33216491
30. Blackstock W, Russo SM, Suh WW, et al. ACR Appropriateness Criteria: local excision in early-stage rectal cancer. Curr Probl Cancer. 2010; 34(3): 193-200. PMID 20541057
31. Russo S, Blackstock AW, Herman JM, et al. ACR Appropriateness Criteria Local Excision in Early Stage Rectal Cancer. Am J Clin Oncol. Oct 2015; 38(5): 520-5. PMID 26371522

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.
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.