

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.



Transanal Endoscopic Microsurgery (TEMS) (for Louisiana Only)

Policy Number: CS369LA.A
Effective Date: TBD

[➔ Instructions for Use](#)

<u>Table of Contents</u>	<u>Page</u>
<u>Application.....</u>	<u>1</u>
<u>Coverage Rationale.....</u>	<u>1</u>
<u>Definitions.....</u>	<u>1</u>
<u>Applicable Codes.....</u>	<u>2</u>
<u>Description of Services.....</u>	<u>2</u>
<u>Clinical Evidence.....</u>	<u>2</u>
<u>U.S. Food and Drug Administration.....</u>	<u>5</u>
<u>References.....</u>	<u>5</u>
<u>Policy History/Revision Information.....</u>	<u>6</u>
<u>Instructions for Use.....</u>	<u>6</u>

Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Transanal Endoscopic Microsurgery (TEMS)

Transanal Endoscopic Microsurgery is proven and medically necessary for the following:

- The excision of small tumors that are verified as localized to the rectum via endorectal ultrasound or MRI, and there is no evidence of systemic disease. These include:
 - T1N0 cancer without high-risk features (deep submucosal invasion, lymphovascular invasion, poorly differentiated adenocarcinoma, signet-ring cell or mucinous carcinoma, tumor budding)
 - Low Risk malignant pedunculated or sessile polyps
 - Adenomas

Transanal Endoscopic Microsurgery is unproven and not medically necessary for all other indications.

Definitions

Adenoma: A tumor that is not cancer. It starts in gland-like cells of the epithelial tissue (NCI).

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.

Low Risk Cancer: Cancer that tends to grow slowly, usually does not spread to other parts of the body and may have a good chance of being cured. Knowing whether a cancer is low risk may help plan treatment. Some low-risk cancers may not need treatment right away (NCI).

Transanal Endoscopic Microsurgery: A minimally invasive technique for the excision of certain anal lesions via the rectum (Kunitake 2021).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<u>CPT Code</u>	<u>Description</u>
<u>*0184T</u>	<u>Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS), including muscularis propria (i.e., full thickness)</u>

CPT® is a registered trademark of the American Medical Association

Codes labeled with an asterisk (*) are not on the Louisiana Medicaid Fee Schedule and therefore may not be covered by the state of Louisiana Medicaid Program.

Description of Services

Transanal endoscopic microsurgery (TEM) is a minimally invasive alternative to radical resection. This surgical approach utilizes a closed endoscopic system that instills carbon dioxide gas creating constant rectal distention to visualize and excise rectal lesions. Control of bleeding and closure of the wound defect are also accomplished. The endoscopic equipment has a long reach and provides stereoscopic magnified imaging (Saclarides 2015).

Clinical Evidence

Ahmad et al. (2021) conducted a meta-analysis of three randomized controlled trials, comprised of 208 participants that compared the oncological and perioperative outcomes of TEMS as compared to total mesorectal excision (TME) in the treatment of early rectal cancers. All 3 included extensive preoperative staging. Local recurrence and postoperative complications were analyzed as the primary end points. Intraoperative blood loss, operation time, and duration of hospital stay were compared as the secondary end points. The results showed that local recurrence was seen in 6.7% of the TEMS group, compared to 2.8% in the TME group. There was a significant difference in the follow up that explains the recurrence in the trial with the longest follow up, and the meta-analysis of local recurrence using the fixed effect model did not show any statistical difference between the two groups. The post operative complication rate was 17.47% for the TEMS group, and 23.8% in the TME group. 11 major intraoperative bleeds occurred in the TME group, and none were observed in the TEMS group. Operating time and hospital stays were much shorter for the TEMS group. The authors concluded that TEMS may be an

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.

option for carefully selected patients in the treatment of radiologically and histologically proven early rectal cancers. TME surgery remains the standard of care in more advanced rectal cancers.

In a 2021 systematic review and meta-analysis, Xiong et al. compared the safety and outcomes of TEMS with radical surgery (RS) in patients with T1 or T2 rectal cancer. Included were 3526 patients compiled from 12 studies. The results showed that compared with RS, TEM had a shorter operative time, less intraoperative blood loss, lower perioperative mortality, and fewer postoperative surgical complications. It was also associated with more patients with a positive margin or a doubtfully complete margin than RS and higher local and overall recurrence. TEM had a negative effect on 5-year overall survival, especially in the T2 without neoadjuvant therapy (NAT) subgroup, but in the subgroups of T1 or T2 with NAT before TEM, TEM did not yield a significantly lower overall survival than RS. The authors concluded that TEM seems appropriate for T1 rectal cancer with favorable histopathology. For patients with T2 rectal cancer, NAT before TEM may contribute to achieving oncological outcomes equivalent to that achieved with RS.

The United States Multi-Society Task Force on Colorectal Cancer (USMSTF) consists of gastroenterologists with expertise in colorectal neoplasia and is represented by The American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. In 2020, the task force reviewed the literature and developed recommendations to guide endoscopists on the assessment of how to assess lesions for endoscopic features associated with cancer, discuss how these factors guide endoscopic management, and to outline the factors that frame whether to advise surgery after a malignant polyp has been endoscopically resected. They recommend the following:

- Optimal management of potentially malignant lesions includes careful endoscopic evaluation and estimation of the degree of invasiveness before resection.
- When there are no endoscopic features of deep submucosal invasion, most colorectal lesions are candidates for endoscopic resection.
 - There are no endoscopic signs with high sensitivity or specificity for superficial (less than 1mm) invasion, however, there are certain endoscopic features associated with a higher risk of superficial submucosal invasion, including large size (2 cm), depressed or sessile morphology in nongranular lateral spreading tumors (LSTNG), and discrete nodules in granular lateral spreading tumors (LST-G). Some lesions with these features should be considered for en bloc resection. (Shaukat et al., 2020)

Naughton et al. (2020) conducted a systematic review and meta-analysis to compare the oncological effectiveness of endoscopic techniques with transanal surgery in the treatment of early rectal neoplasms. Main outcomes measured were R0 (a microscopically margin-negative resection, in which no gross or microscopic tumor remains in the primary tumor bed) and en bloc resection rates, secondary outcomes included complications, reoperation rates, major morbidity, operating time, length of stay, and 30-day mortality and recurrence. Eleven studies comprised of 1044 patients were included. Among the treatments, 530 were treated endoscopically, and 514 underwent transanal surgery. The results showed that transanal surgery had increased R0 resection rates versus endoscopic management. The latter was associated with higher rates of incomplete resection and further intervention. There was no difference in the rates of late recurrence or further major surgery. Endoscopic treatment was associated with a shorter operating time as well as lower rates of urinary retention post-operatively. The authors concluded that endoscopic techniques should be favored for benign early rectal neoplasms given their

decreased morbidity, however, where malignancy is suspected transanal surgery should be the preferred option given the superior R0 resection rate.

In a 2019 retrospective multicenter, observational cohort study Leijtens et al. compared the oncologic outcomes and short-term morbidity following TEM only, and total mesorectal excision (TME) following TEM for T2 and T3 rectal adenocarcinoma. 81 total patients were included with 41 having TEM-only and 40 having TME following TEM. In these patients, initial TEM was performed as treatment when a benign lesion or a T1 rectal cancer was clinically assumed, or as diagnostic procedure when T2-3 rectal cancer was suspected on endorectal ultrasound, but multiple biopsies could not prove malignancy, or the lesion was found to be obviously malignant at colonoscopy. No patient received a TEM with palliative intent. The median follow-up was 29 months for the TEM-only group and 31 months for the TME group. The results showed a local recurrence rate of 35% and 11% for the TEM-only and TME, respectively, with distant metastasis occurring in 16% of the patients in both groups. The 3-year overall survival (OS) was 63% in the TEM-only group and 91 % in the TME group, respectively, with a 3-year disease-specific survival (DSS) of 91% versus 93%, respectively. The authors concluded that although local recurrence after TEM-only for T2-3 rectal cancer was worse compared to the recurrence that occurred after completion surgery, DSS was comparable between both groups. The lower unadjusted OS in the TEM-only group indicated that TEM-only may be a valid alternative in older and frail patients, especially when high morbidity of completion surgery was taken into consideration. Nevertheless, completion surgery should always be advised when curation is intended.

Clinical Practice Guidelines

National Comprehensive Cancer Network (NCCN)

The 2022 NCCN clinical practice guideline on rectal cancer principals of surgery provides the following criteria for transanal local excision of rectal tumors:

- < 30% circumference of the bowel
- < 3 mm in size
- Margin clear (>3 mm)
- Mobile, nonfixed
- Within 8 cm of anal verge
- T1 only
- Endoscopically removed polyp with cancer or indeterminate pathology
- No lymphovascular invasion or PNI
- Well to moderately differentiated
- No evidence of lymphadenopathy on pretreatment imaging
- Full-thickness excision must be feasible
-

A variety of surgical approaches, depending on the location and extent of disease, are used to treat primary rectal cancer lesions. These methods include local procedures, such as polypectomy, transanal local excision, and transanal endoscopic microsurgery (TEM)

- 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).
- 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.

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.

- Data are limited on long-term patient outcomes, including risk of local recurrence, for patients undergoing local excision for high-risk T1 or T2 tumors

The American Society of Colon and Rectal Surgeons (ASCRS)

The 2022 ASCRS clinical practice guideline for the management of colon cancer states that transanal endoscopic microsurgery is appropriate for the following:

- For patients with a "malignant polyp", a T1 cancer arising in an adenomatous polyp, either endoscopic excision or oncological resection may be appropriate and is dependent largely on polyp histopathological features and completeness of excision. This will be curative in >80% of patients. Grade of recommendation: strong recommendation based on moderate quality evidence
- For low-risk malignant pedunculated or sessile polyps
- For carefully selected patients with cT1N0 rectal cancer without high-risk features. Grade of recommendation: Strong recommendation based on moderate-quality evidence, 1B

The European Association for Endoscopic Surgery (EAES)

In a 2015 clinical consensus guideline in collaboration with the European Society of Coloproctology, the EAES concluded that TEM is an established approach for local excision of selected early rectal cancers, and patient selection should always be based on a multidisciplinary approach to increase the rate of organ-preserving procedures without jeopardizing survival. (Morino, 2015).

National Institute of Health and Care Excellence (NICE)

The 2020 NICE guideline on colorectal states that Transanal excision (TAE), including transanal minimally invasive surgery (TAMIS) and transanal endoscopic microsurgery (TEMS) should be offered to people with early rectal cancer (cT1-T2, cN0, M0) after discussing the implications of each treatment and reaching a shared decision with the person about the best option.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

There are multiple devices cleared by the FDA for transanal endoscopic microsurgery. Refer to the following website using product code HIF:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Accessed December 14, 2022.

References

Ahmad NZ, Abbas MH, Abunada MH, et al. A Meta-analysis of Transanal Endoscopic Microsurgery versus Total Mesorectal Excision in the Treatment of Rectal Cancer. Surg J (N Y). 2021 Sep 14;7(3): e241-e250.

American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Colon Cancer. 2022. Available at:
<https://fascrs.org/ascrs/media/files/downloads/2022-Colon-Cancer-CPG.pdf>. Accessed December 13, 2022.

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.

Ichimasa K, Kudo SE, Miyachi H, et al. Risk stratification of T1 colorectal cancer metastasis to lymph nodes: current status and perspective. Gut Liver. 2021 Nov 15;15(6):818-826.

Kunitake H, Abbas MA. Transanal endoscopic microsurgery for rectal tumors: a review. Perm J. 2012 Spring;16(2):45-50.

Leijtens JWA, Koedam TWA, Borstlap WAA, et al. Transanal endoscopic microsurgery with or without completion total mesorectal excision for T2 and T3 rectal carcinoma. Dig Surg. 2019;36(1):76-82. doi: 10.1159/000486555. Epub 2018 May 23. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6390444/>. Accessed December 16, 2022.

Morino M, Risio M, Bach S, et al.; European Association for Endoscopic Surgery; European Society of Coloproctology. Early rectal cancer: the European Association for Endoscopic Surgery (EAES) clinical consensus conference. Surg Endosc. 2015 Apr;29(4):755-73.

National Cancer Institute (NCI). Dictionary of Cancer Terms. 2022.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Rectal Cancer. Version 3.2022. October 27, 2022.

National Institute for Health and Care Excellence (NICE). NICE guideline [NG151]. Colorectal Cancer. January 2020. Updated 2021.

Naughton AP, Ryan ÉJ, Bardon CT, et al. Endoscopic management versus transanal surgery for early primary or early locally recurrent rectal neoplasms-a systematic review and meta-analysis. Int J Colorectal Dis. 2020 Dec;35(12):2347-2359.

Saclarides TJ. Transanal Endoscopic Microsurgery. Clin Colon Rectal Surg. 2015 Sep;28(3):165-75.

Shaukat A, Kaltenbach T, Dominitz JA, et al. Endoscopic Recognition and Management Strategies for Malignant Colorectal Polyps: Recommendations of the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2020 Nov;159(5):1916-1934.

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. 2021 Jun;37:101561. doi: 10.1016/j.suronc.2021.101561. Epub 2021 Apr 2.

Policy History/Revision Information

Date	Summary of Changes
TBD	New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical

UnitedHealthcare, Inc. ("UHC") Proprietary and Confidential Information: The information contained in this document is confidential, proprietary and the sole property of UHC. The recipient of this information agrees not to disclose or use it for any purpose other than to facilitate UHC's compliance with applicable State Medicaid contractual requirements. Any other use or disclosure is strictly prohibited and requires the express written consent of UHC.

Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

DRAFT