



## Transanal Endoscopic Microsurgery

Policy # 00821

Original Effective Date: 02/13/2023

Current Effective Date: 02/13/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transanal endoscopic microsurgery for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision to be **eligible for coverage.\*\***

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transanal endoscopic microsurgery for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision to be **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility for transanal endoscopic microsurgery for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision may be considered when **ALL** of the following criteria are met:

- Located in the middle or upper part of the rectum; **AND**
- Well- or moderately differentiated (G1 or G2) by biopsy; **AND**
- Without lymphadenopathy; **AND**

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- Less than one-third of the circumference of the rectum.

## **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

The use of transanal endoscopic microsurgery for treatment rectal tumors when patient selection criteria are not met is considered to be **investigational**.\*

## **Policy Guidelines**

The clinical staging of rectal cancers is determined from the physical examination, imaging, and biopsy results. T1 tumor invades the submucosa but not into the muscularis propria.

## **Background/Overview**

### **Transanal Endoscopic Microsurgery**

Transanal endoscopic microsurgery (TEM) is a minimally invasive approach to 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 (eg, malignant polyps). Use of TEM for resection of rectal cancers is more controversial. TEM can avoid the morbidity and mortality associated with major rectal surgery, including the fecal incontinence related to stretching of the anal sphincter, and can be performed under general or regional anesthesia.

The TEM system has a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. This procedure has been available in Europe but has not been widely used in the U.S. Two reasons for this slow adoption 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.

### **Other Treatment Options**

The most common treatment for rectal cancer is surgery; the technique chosen will depend on several factors. The size and location of the tumor, evidence of local or distal spread, and an individual's

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characteristics and goals are all attributes that will affect the treatment approach. Open, wide resections have the highest cure rate but may also have significant adverse events. Most Individuals find the potential adverse events of lifelong colostomy and/or bowel, bladder, or sexual dysfunction acceptable in the face of a terminal illness. Laparoscopic-assisted surgery, with lymph node dissection as indicated, is technically difficult in the pelvic region but is being investigated as a less invasive alternative to open resection.

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. TEM extends local excision ability to the proximal rectosigmoid junction. Adenomas, small carcinoid tumors, and nonmalignant conditions (eg, strictures, 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 local excision, 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. TEM permits local excision beyond the reach of direct visualization equipment.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

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<sup>TM†</sup> 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<sup>®‡</sup> Path (Applied Medical Resources). FDA product codes: HIF, GCJ, FER. Table 1 lists some of the TEM devices cleared by the FDA.

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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 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
AP 50/30 Insufflator with Insuflow Port	LEXION Medical LLC	11/14/2017	K170799	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

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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
GELPOINT PATH TRANSANAL ACCESS PLATFORM	APPLIED MEDICAL RESOURCES CORP.	1/2/2014	K133393	For use in transanal endoscopic microsurgery

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical

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practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

### **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.

### **Summary of Evidence**

For individuals who have rectal adenoma(s) who receive 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, a few nonrandomized comparative studies, and numerous single-arm case series. 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. There is no demonstrated difference in long-term OS with TEM in available studies. 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.

### **Additional Information**

Based on clinical input obtained in 2009, supplemented by the outcomes of single-arm series that have shown low complication rates and low recurrence rates of lesions supporting use of TEM when lesions are not amenable to standard excision, TEM 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 are clinical stage T1 cancers that are located in the

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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.

## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### **2009 Input**

In response to requests, input was received from 2 academic medical centers while this policy was under review in 2009. Input supported the policy statements adopted in 2009. One reviewer commented specifically that this technique should be limited to select T1 rectal cancers.

### **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.1.2022) 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)."

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."

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### **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. 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. 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. 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.

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### 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.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03718351	Randomized Controlled Trial of Endoscopic Submucosal Dissection Versus Transanal Endoscopic Microsurgery For Early Rectal Neoplasms And Large Rectal Adenomas: Comparison of Treatment Efficacy And Safety	236	Sep 2021 (unknown)
NCT02945566	Can the Rectum be Saved by Watchful Waiting or TransAnal Surgery Following (Chemo)Radiotherapy Versus Total Mesorectal Excision for Early REctal Cancer? (STAR-TREC)	120	Oct 2021 (unknown)
<i>Unpublished</i>			

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## 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

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3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. Mora Lopez 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
11. 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
12. 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
13. 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
14. 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

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15. Cataldo PA. Transanal endoscopic microsurgery. *Surg Clin North Am.* Aug 2006; 86(4): 915-25. PMID 16905416
16. 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
17. 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
18. 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
19. Lu JY, Lin GL, Qiu HZ, et al. Comparison of Transanal Endoscopic Microsurgery and Total Mesorectal Excision in the Treatment of T1 Rectal Cancer: A Meta-Analysis. *PLoS One.* 2015; 10(10): e0141427. PMID 26505895
20. Clancy C, Burke JP, Albert MR, et al. Transanal endoscopic microsurgery versus standard transanal excision for the removal of rectal neoplasms: a systematic review and meta-analysis. *Dis Colon Rectum.* Feb 2015; 58(2): 254-61. PMID 25585086
21. Sajid MS, Farag S, Leung P, et al. Systematic review and meta-analysis of published trials comparing the effectiveness of transanal endoscopic microsurgery and radical resection in the management of early rectal cancer. *Colorectal Dis.* Jan 2014; 16(1): 2-14. PMID 24330432
22. Wu Y, Wu YY, Li S, et al. TEM and conventional rectal surgery for T1 rectal cancer: a meta-analysis. *Hepatogastroenterology.* Mar-Apr 2011; 58(106): 364-8. PMID 21661397
23. 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
24. Doornebosch PG, Tollenaar RA, De Graaf EJ. Is the increasing role of Transanal Endoscopic Microsurgery in curation for T1 rectal cancer justified? A systematic review. *Acta Oncol.* 2009; 48(3): 343-53. PMID 18855161
25. 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
26. 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

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- mesorectal excision after neoadjuvant therapy. *Surg Endosc.* Feb 2008; 22(2): 352-8. PMID 17943364
27. Walega P, Kenig J, Richter P, et al. Functional and clinical results of transanal endoscopic microsurgery combined with endoscopic posterior mesorectum resection for the treatment of patients with t1 rectal cancer. *World J Surg.* Jul 2010; 34(7): 1604-8. PMID 20174804
  28. Moore JS, Cataldo PA, Osler T, et al. Transanal endoscopic microsurgery is more effective than traditional transanal excision for resection of rectal masses. *Dis Colon Rectum.* Jul 2008; 51(7): 1026-30; discussion 1030-1. PMID 18481147
  29. Doornebosch PG, Ferenschild FT, de Wilt JH, et al. Treatment of recurrence after transanal endoscopic microsurgery (TEM) for T1 rectal cancer. *Dis Colon Rectum.* Sep 2010; 53(9): 1234-9. PMID 20706065
  30. Tsai BM, Finne CO, Nordenstam JF, et al. Transanal endoscopic microsurgery resection of rectal tumors: outcomes and recommendations. *Dis Colon Rectum.* Jan 2010; 53(1): 16-23. PMID 20010345
  31. Allaix ME, Arezzo A, Caldart M, et al. Transanal endoscopic microsurgery for rectal neoplasms: experience of 300 consecutive cases. *Dis Colon Rectum.* Nov 2009; 52(11): 1831-6. PMID 19966628
  32. Friel CM. Local excision of T1 rectal cancer: where are we now?. *Dis Colon Rectum.* Sep 2010; 53(9): 1231-3. PMID 20706064
  33. 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
  34. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 1.2022. [https://www.nccn.org/professionals/physician\\_gls/pdf/rectal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf).
  35. National Cancer Institute (NCI). Rectal Cancer Treatment (PDQ). Healthcare Provider Version. [https://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq#\\_43](https://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq#_43). Updated August 26, 2022.
  36. 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
  37. Blackstock W, Russo SM, Suh WW, et al. ACR Appropriateness Criteria: local excision in early-stage rectal cancer. *Curr Probl Cancer.* May-Jun 2010; 34(3): 193-200. PMID 20541057

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38. Russo S, Blackstock AW, Herman JM, et al. ACR Appropriateness Criteria(R) Local Excision in Early Stage Rectal Cancer. Am J Clin Oncol. Oct 2015; 38(5): 520-5. PMID 26371522

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01/05/2023 Medical Policy Committee review

01/11/2023 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 01/2024

## **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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# Louisiana

## Transanal Endoscopic Microsurgery

Policy # 00821

Original Effective Date: 02/13/2023

Current Effective Date: 02/13/2023

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0184T
HCPCS	No Codes
ICD-10 Diagnosis	C20, D12.8

**\*Investigational –** A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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