Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/23**
(See policy history boxes for previous effective dates)

Title: Transanal Hemorrhoidal Dearterialization

Description/Background

Transanal hemorrhoidal dearterialization (THD), also called Doppler-guided hemorrhoidal artery ligation, is a surgical technique to treat symptomatic hemorrhoids by placing sutures to occlude hemorrhoidal arterial flow. A doppler transducer is attached to a specially designed proctoscope. The hemorrhoidal arteries originating from the superior rectal artery are identified and selectively ligated with absorbable sutures. The interruption in blood flow to the hemorrhoids allows shrinkage of the tissue without surgical excision. Redundant rectal mucosa is lifted *in situ* with a continuous suture to “lift” the prolapsing tissue back to its anatomical position. Since the hemorrhoidal tissue is not excised, it is believed that patients experience less postoperative pain and shorter recovery time. THD may be performed in an office setting with local anesthesia.

Regulatory Status

The THD Evolution Doppler device and the THD Slide Kit (THD Spa, North Reading, MA) were approved by the FDA, in January 2009, through the premarket 510(k) process. The FDA-approved label reads as follows: “The THD Slide Doppler guided proctoscope is a system for the surgical treatment of the hemorrhoids of second and third degree. It is based on Transanal Hemorrhoidal Dearterialization technique guided by a Doppler probe. The Doppler system, placed inside the THD Evolution Doppler device, is used to detect the terminal branch of the superior hemorrhoid artery, in order to perform ligation with a THD Slide proctoscope, sutures and a needle holder included in the THD Slide Kit.” FDA product code: JAF.

The THD Slide is to be used by physicians in hospitals, clinics and physician offices by prescription or doctor’s order.

In February of 2015, the FDA approved the THD Revolution which “represents an evolution of the original Doppler called THD Evolution” which was cleared together with its specific kit previously. New features on this upgraded device include a double thermoplastic shell containing an 8 MHz continuous wave (CW) Doppler detector with a digital signal processor that improved sound, and an LED light source which improved the quality of lighting from the previous version.

Medical Policy Statement

Transanal hemorrhoidal dearterialization is experimental/investigational. This procedure has not been shown to improve long term clinical outcomes better than conventional surgical treatment for hemorrhoids.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

46948

Rationale

Abdedaim et al (2007) reported on a pilot study demonstrating the initial experience with hemorrhoidal arterial ligation (HAL) in patients with internal hemorrhoidal disease. A prospective study was performed in 35 patients treated by HAL. After a mean of 18 (range 12-24) months, patients were administered a standardized questionnaire by telephone. The treatment's success was observed in 91.5% of patients (11 of 12) in regard to pain, 85% (28 of 33) in regard to bleeding, 93% (14 of 15) in regard to pruritus, 92% (12 of 13) in regard to wound discharge, and 81% (17 of 21) in regard to prolapse. Open hemorrhoidectomy was needed in 8.5% (3 patients) due to bleeding and prolapse. HAL appeared to be a simple, painless, safe and effective method for hemorrhoid ligation based on subjective experiences. However, additional objective long-term studies need to be completed.

Dal Monte et al (2007) retrospectively reviewed the results of THD performed in 330 patients between January 2000 and May 2006. There were 138 patients with second-degree, 162 with third-degree, and 30 with fourth-degree hemorrhoids. There were 23 postoperative complications (7 cases of bleeding, 5 thrombosed piles, 4 rectal hematomas, 2 anal fissures, 2

cases of dysuria, 1 of hematuria, and 2 needle ruptures). The mean postoperative pain score was 1.32 on a visual analog scale. A total of 219 patients were followed for a mean of 46 months. THD completely resolved the symptoms in 132 patients (92.5%) with preoperative bleeding and in 110 patients (92.5%) with preoperative prolapse. The efficacy and relapse rate of this procedure appears to be similar to that of traditional surgery and stapled hemorrhoidopexy. The authors concluded that THD was effective and safe for all degrees of hemorrhoids because of the excellent results, low complication rate and minor postoperative pain.

According to a systematic review by Giordano et al (2009), "Transanal hemorrhoidal dearterialization appears to be a potential treatment option for second-degree and third-degree hemorrhoids. Clinical trials and longer follow-up, comparing it with other procedures which are used to treat hemorrhoids, are needed to establish a possible role for this technique."

Festen et al (2009) published a randomized trial comparing THD to stapled hemorrhoidectomy (SH), the procedure for prolapse and hemorrhoids (PPH). Patients with grade III or IV hemorrhoids were randomized between THD and PPH. Patients were evaluated 1 week, 3 weeks, and 6 weeks postoperatively. The primary endpoint was resolved symptoms 6 weeks postoperatively. Secondary endpoints were pain, measured with a visual analogue scale (VAS) after 1 day, 1 week, and 3 weeks, and complications. Eighteen patients were assigned to PPH versus 23 to THD. Success rates after 6 weeks were 83% in the PPH group versus 78% in the THD group. VAS scores were significantly lower after 1 day and 1 week in the THD group but equaled out after 3 weeks. Twelve percent of the patients after PPH and 4% after THD needed an urgent readmission to treat acute bleeding. Overall complication rates did not differ significantly. The authors concluded that both PPH and THD are safe treatments for grade III and IV hemorrhoids with acceptable complication rates and good short-term results. THD might be the preferred treatment because it carries similar complication rates and short-term results, but results in less postoperative pain when compared with PPH. The authors noted that "further randomized studies with larger number of patients and longer follow-up are needed to confirm these preliminary data."

Infantino et al (2009) prospectively evaluated Doppler-assisted ligation of the terminal hemorrhoidal arteries for II- and III-degree hemorrhoids. A total of 112 patients were treated by Doppler-assisted THD. The mean operative time was 33.9 ± 8.8 minutes, and the mean number of ligatures applied was 7.2 ± 1.5. Postoperatively, 72% of patients did not need analgesics and the other 28% used nonsteroidal anti-inflammatory drugs. All the patients were operated on as a day case. Early postoperative complications included hemorrhoidal thrombosis, bleeding, treated by hemostatic suture, dysuria, and acute urinary retention. After a mean follow-up of 15.6 ± 6.5 months 2/105 (20.9%) patients complained of minor bleeding, while mild pain was still present in 7.8% (4/51) of patients. There were no statistically significant differences in the sample population regarding the gender or stage of the disease. Tenesmus was cured in 15/17 patients, dyschaezia in 20/22 patients and mucous soiling in 10/10 patients. No new cases of altered defecation or fecal incontinence were recorded. Overall, 85.7% of patients were cured and 7.1% improved. Residual hemorrhoids were treated by elastic band ligation in 8% of patients (nine) and by surgical excision in 4.5% of patients (five). The authors concluded that Doppler-assisted ligation of the terminal branches of the hemorrhoidal arteries, for II- and III-degree hemorrhoids, is highly effective and painless. Complications are few and the technique can be performed as a day case. The authors noted that although early results are reassuring, information on long-term outcomes is not yet

available and that “more randomized controlled trials are needed to compare it with stapled haemorrhoidopexy, currently considered the least invasive and painful operation for stage III haemorrhoids.”

Giordano et al (2011) compared THD versus SH for the treatment of second- and third-degree hemorrhoids. Patients (n= 52) who failed conservative treatment were randomly assigned to a THD or a SH group. Twenty-eight patients underwent THD and 24 underwent SH. Preoperative and postoperative symptoms, postoperative pain, time until return to normal activities, complications, patient satisfaction, and recurrence rates were all assessed prospectively. Patients were reassessed at 2 months, 8 months, and when the study was completed. There were no significant differences in terms of postoperative pain, expected pain, and analgesia requirements, but more THD patients returned to work within 4 days *(P* < 0.05). One THD patient developed a sub-mucosal hematoma after surgery, one SH patient occlusion of the rectal lumen, and two rectal bleeding. At 8-month follow-up, two SH patients complained of fecal urgency. At 38-month follow-up, all short-term complications had resolved. Patient satisfaction and recurrence rates were similar in the two groups. The researchers concluded that short-term results, although similar, seem to suggest SH may result in increased morbidity while return to work is quicker after THD. Medium-term results demonstrate that THD and SH have similar effectiveness. The authors noted “While there is now considerable literature on SH, the data regarding THD is still limited and mostly taken from case series, not comparative studies” and “larger randomized studies are needed to better establish the definitive role of this technique.”

Ratto (2011) et al reported on the results of a study involving 35 patients prospectively enrolled with fourth-degree hemorrhoidal disease who underwent THD. There were no intraoperative complications. Postoperative complications included 3 hemorrhoidal thromboses (1 requiring surgery) and 2 episodes of bleeding (1 requiring surgical hemostasis). Five patients experienced urinary retention which required catheterization. At 10 months follow-up, symptoms had resolved or significantly improved in 22 patients. Nine patients had irregular bleeding, 3 had mild anal pain, 4 had transient anal burning, and 4 experienced tenesmus. Ten patients had some degree of residual prolapse; however, it was significant in only 2 cases, and required further surgery. There were no cases of anorectal stenosis and no reports of fecal incontinence. While the study demonstrates success with the THD procedure, the authors acknowledge that further studies with longer follow-up are indicated.

Infantino et al (2012) compare the effectiveness of THD vs. SH in the treatment of third-degree hemorrhoids. One hundred and sixty-nine patients with third-degree hemorrhoids were randomized to receive THD (n = 85) or SH (n = 84). The mean follow-up period was 17 months. Early minor postoperative complications occurred in 30.6% of patients in the THD group and in 32.1% of patients in the SH group. Milder spontaneous pain and pain on defecation were reported in the THD group in the first postoperative week, but this was not statistically significant. Late complications were significantly higher (P = 0.028) in the SH group. Residual hemorrhoids persisted in 12 patients in the THD group and in six patients in the SH group (P = 0.14). Six patients in the SH group and 10 in the THD group underwent further treatment of hemorrhoids (P = 0.34). No differences were found in postoperative incontinence. The obstructed defecation score (ODS) was significantly higher in the SH group (P < 0.02). Improvement in quality of life was similar in both groups. Postoperative in-hospital stay was 1.14 days in the THD group and 1.31 days in the SH group (P = 0.03). Both THD and SH techniques are effective for the treatment of third-degree hemorrhoids in the medium term.

THD has a better cost-effective ratio and lower (not significant) pain compared with SH. Postoperative pain and recurrence did not differ significantly between the two groups.

Lucarelli et al (2013) compared the long-term results of THD with mucopexy and stapler hemorrhoidopexy (SH) in treatment of grade III and IV hemorrhoids. A total of 124 patients with grade III and IV hemorrhoids, were randomized to receive THD with mucopexy (*n*=63) or SH (*n*=61). A telephone interview with a structured questionnaire was performed at a median follow-up of 42 months. The primary outcome was the occurrence of recurrent prolapse. Patients, investigators, and those assessing the outcomes were blinded to group assignment. Recurrence was present in 9% of patients (16 of 21), occurring in 25.4% (16) in the THD group and 8.2% (5) in the SH group (*p*=0.021). A second surgical procedure was performed in eight patients (6.4%). Reoperation was open hemorrhoidectomy in seven cases and SH in one case. Five out of six patients in the THD group and both patients in the SH group, requiring repeat surgery, presented with grade IV hemorrhoids. No significant difference was found between the two groups with respect to symptom control. Patient satisfaction for the procedure was 73.0% after THD and 85.2% after SH (*p*=0.705). Postoperative pain, return to normal activities, and complications were similar. The authors concluded that the recurrence rate after THD with mucopexy is significantly higher than after SH at long-term follow-up, although results are similar with respect to symptom control and patient satisfaction. A definite risk of repeat surgery is present when both procedures are performed, especially for grade IV hemorrhoids.

Elmér et al (2013) compared early and midterm results of THD with anopexy to open hemorrhoidectomy. Forty patients with grade II to III hemorrhoids were randomly assigned to THD with anopexy (group A, n = 20) or open hemorrhoidectomy (group B, n = 20). A diary was used during the first 2 postoperative weeks. A self-reported symptom questionnaire was answered, and a clinical examination was performed preoperatively, after 2 to 4 months, and after 1 year. The main outcome measure was postoperative pain. Postoperative peak pain was lower in group A during the first week than in group B ($p < 0.05$), whereas no difference in overall pain was noted. More patients expressed normal well-being in group A ($p = 0.045$). Pain, bleeding, and the need for manual reduction of the hemorrhoids were all improved in both groups after 1 year ($p < 0.05$). Soiling had decreased after both methods at early follow-up. After 1 year, soiling was significantly decreased only after open hemorrhoidectomy. The grade of hemorrhoids was significantly reduced after 1 year for both methods, but there was a trend to more patients with remaining grade 2 hemorrhoids in group A ($p = 0.06$). Study limitations included no blinding, the sample size was small, only 40/167 pts met inclusion criteria, follow-up was for only 1 year, and the questionnaire was not validated. It was concluded that the difference in postoperative pain between THD with anopexy and open hemorrhoidectomy may be less than expected based on previous literature.

Denoya et al (2014) conducted a follow up study to a randomized controlled trial which showed patients with grade Ill or IV internal hemorrhoids had similar symptomatic relief of symptoms up to 3 months following dearterialization with mucopexy or hemorrhoidectomy albeit with less postoperative pain after the former. The follow up study aimed to compare hemorrhoidal recurrence and chronic complications at 3-year follow-up. This study was carried out on 40 patients with grade III or IV internal hemorrhoids previously enrolled to a randomized trial comparing dearterialization to hemorrhoidectomy. Recurrence was defined as internal hemorrhoids diagnosed on proctoscopy. Chronic complications were non-resolving adverse events related to surgery. Outcome measures included patient-reported outcomes and quality

of life measured by brief pain inventory (BPI), SF-12, and fecal incontinence surveys. At median follow-up of 36 (27-43) months, 32.5% of patients (13) were lost to follow-up. Patient-reported outcomes suggested no difference between dearterialization and hemorrhoidectomy in persistent symptoms, occurring in 1 (8.3%) vs. 2 (13.3%) patients (p = 0.681) and in symptom recurrence, occurring in 6 (50%) vs. 4 (26.7%) patients (p = 0.212). On proctoscopy, recurrence was seen in 13.3% (2) vs. 6.7% (1) patients (p = 0.411), all with index grade IV disease. One patient in each arm required reoperation (p = 0.869). Chronic complications were not seen in the dearterialization arm while they occurred in 2 (13.3%) hemorrhoidectomy patients (p = 0.189) and included unhealed wound (n = 1), anal fissure (n = 1) and fecal incontinence (n = 1). There was a trend toward more patient reported than actual recurrence on proctoscopy (10 vs. 3, p = 0.259). There was no difference in BPI, SF-12, and fecal incontinence quality of life scores. The authors concluded that recurrence rates did not differ significantly at 3-year follow-up and occurred in patients with index grade IV hemorrhoids. Chronic complications occurred only after hemorrhoidectomy. The study was limited by a small study population and nearly one third of the subjects were lost to follow up.

DeNardi et al (2014) published a prospective randomized study evaluating the results of Doppler-guided transanal hemorrhoid dearterialization with mucopexy compared with excisional open hemorrhoidectomy in patients with grade III hemorrhoids. Fifty patients were randomly assigned to undergo either hemorrhoidectomy or Doppler-guided hemorrhoid dearterialization plus mucopexy. The primary outcome was postoperative pain. The secondary outcomes included postoperative morbidity, the resumption of social and/or working activity, patient satisfaction, and the relapse of symptoms at 1 and 24 months. No major complications occurred in either group. The median visual analog scale scores for pain in the hemorrhoidectomy and Doppler-guided dearterialization plus mucopexy groups on days 1, 7, 14, and 30 were 7 vs 5.5, 3 vs 2.5, 1 vs 0, and 0 vs 0 (p> 0.05). The median work resumption day was the 22nd in the hemorrhoidectomy group and the 10th in the Doppler-guided dearterialization plus mucopexy group (p = 0.09). Patient satisfaction at 1 and 24 postoperative months, with the use of a 4-point scale, was 3 vs 4 and 4 vs 4 (p > 0.05). During the follow-up, 2 patients in the dearterialization group required ambulatory treatment, and 1 patient in each group required further surgery for symptom relapse. The authors concluded that compared with hemorrhoidectomy, dearterialization with mucopexy resulted in similar postoperative pain and morbidity, and a similar long-term cure rate. Limitations of this study include a small sample size, non-validated questionnaires were used in the follow-up, and a cost analysis was not performed.

Ratto et al (2015) published results from a multicenter study that evaluated the efficacy of Doppler-guided transanal hemorrhoidal dearterialization (THD Doppler) in the treatment of symptomatic hemorrhoids. The study also identified the factors predicting failure for an effective mid-term outcome. Eight hundred and three patients affected by Grade II (17.1%, 137), III (68.2%, 548) and IV (14.7%, 118) symptomatic hemorrhoidal disease underwent THD doppler, with a rectal mucopexy in patients with hemorrhoidal prolapse. The disease was assessed through a specifically designed symptom questionnaire and scoring system. A uni- and multivariate analyses of the potential predictive factors for failure were performed. The morbidity rate was 18.0%, represented mainly by pain or tenesmus (13.0%, 106 patients). Acute bleeding requiring surgical hemostasis occurred in 0.9% (7 patients). No serious or life-threatening complications occurred. After a mean follow-up period of 11.1 ± 9.2 months, the overall success rate was 90.7% (728 patients), with a recurrence of hemorrhoidal prolapse, bleeding, and both symptoms in 6.3% (51), 2.4% (19) and 0.6% (5) patients, respectively.

Sixteen out of 47 patients undergoing re-operation had a conventional hemorrhoidectomy. All the symptoms were significantly improved in each domain of the score ($P < 0.0001$). At multivariate analysis the absence of morbidity and performance of a distal Doppler-guided dearterialization were associated with a better outcome. The authors concluded that THD Doppler is a safe and effective therapy for hemorrhoidal disease. If this technique is to be employed, an accurate distal Doppler-guided dearterialization and a tailored mucopexy are mandatory to contain and reduce the symptoms.

LaBella et al (2015) assessed postoperative outcomes from a single surgeon experience with the THD device. From January 2009 to December 2011, 108 THD procedures were performed. With Doppler guidance, the THD device makes possible precise ligation of the branches of the superior hemorrhoidal artery. Patients were seen postoperatively at 3 weeks and 6 months. They underwent physical examination to determine whether there was recurrence of hemorrhoidal prolapse. They were asked to describe any bleeding, to rate pain using the visual analog scale, and to rate their level of satisfaction on a scale of 1–5 (with 5 = highly satisfied). A phone interview was used for follow-up at 1 year to determine the rate of recurrent prolapse. Of the 108 patients who underwent THD, two were lost to follow-up and excluded. All of the remaining 106 patients completed follow-up at 3 weeks and 6 months. At 3 weeks, 92% of patients had no pain and 88% were highly satisfied with the procedure at 3 weeks. This increased to 92% satisfaction at 1 year. Prolapse recurrence was 7.5% at 6 months and 10.3% at 1 year. Bleeding was the most common complication but did not require re-intervention or transfusion. The authors concluded that THD for the treatment of hemorrhoidal disease that is safe and effective and offers the potential for immediate return to normal activity. The authors reported limitations of this study include the following: results may not be reproducible, a small sample size, lack of recording of pain medication, and lack of a protocol to assess specific symptoms other than prolapse and patient satisfaction.

Du et al (2019) conducted a meta-analysis to investigate the complications and recurrence rates of the different surgical procedures implemented in recent years for the treatment of grade III and IV hemorrhoids. A systematic literature search was conducted for randomized clinical trials (RCTs) published from January 2013 to August 2018, via PubMed, Embase, the Cochrane Library, and Web of Science. Data related to anal stenosis, fecal incontinence, hemorrhoids thrombosis, and recurrence rates were extracted from the included studies, which were selected based on associations with surgical procedures for grade III and IV hemorrhoids. A network meta-analysis was conducted by using the automated software Aggregate Data Drug Information System (ADDIS) 1.16.8 to evaluate and rank the safety and efficacy of the different surgical methods. Twenty-one studies with 2799 participants involving nine surgical procedures for grade III and IV hemorrhoids were ultimately analyzed. Transanal hemorrhoidal dearterialization (THD) and stapled hemorrhoidectomy (SH) exhibited fewer anal stenosis than open hemorrhoidectomy and Harmonic scalpel (Harmonic). SH presented the highest fecal incontinence rates. Open hemorrhoidectomy and Harmonic presented lower hemorrhoids thrombosis than SH and THD. Importantly, SH and THD exhibited the highest recurrence rates, when compared with the other hemorrhoidectomy surgical procedures.

Xu et al (2019) reported on a meta-analysis comparing the clinical outcomes of stapled hemorrhoidectomy and transanal hemorrhoidal dearterialization for treating hemorrhoidal disease. Nine RCTs (n=1077) were included. The bleeding rate in the SH patient group was higher than that in the THD group. No significant difference was detected between SH and THD in terms of operating time, postoperative pain, hospital time, and return-to-work time. The

total recurrence rate was higher in the THD group than in the SH group. The authors concluded that SH produces better outcomes in terms of a relatively lower recurrence rate. Futures studies with long follow-up periods are needed to confirm these results.

Popov et al (2019) conducted prospective research via a nonrandomized study to compare doppler guided THD for treatment of hemorrhoids with conventional hemorrhoidectomy. Two hundred eighty-seven individuals with Grades II, III and IV hemorrhoids were evaluated. Duration with a minimal follow-up of 18 months indicated that (1) there was lower early (<30 days) post-operative pain in the THD group, (2) a trend toward the THD treated group with remaining grade II hemorrhoids, (3) similar patient satisfaction, HD recurrence and re-operation. Discussion included controversies regarding THD. Theoretically the same results could be achieved by ligating all 6 arteries (at 1, 3 5, 7, 9, and 11 o'clock in the lithotomy position) without expensive doppler instruments. However, 1/3 of the population has at least 1 artery in an even numbered clock position which would be missed and could cause need for re-operation. Authors concluded that future large, high quality, multicenter trials with long-term outcomes are needed to determine whether doppler guidance in THD is truly necessary or not and that THD seems to be efficient and safe option for the treatment of HD.

Rørvik et al (2020) evaluated the effect of minimally open hemorrhoidectomy versus transanal hemorrhoidal dearterialization on patient-reported symptoms in a single center study. Patients with symptomatic hemorrhoids grade II to IV were included. Forty-eight patients received minimal open hemorrhoidectomy, and 50 patients received transanal hemorrhoidal dearterialization. No difference in symptom score at 1-year follow-up was found. Median (range) symptom score was 3 (0-17) after minimal open hemorrhoidectomy and 5 (0-17) after transanal hemorrhoidal dearterialization (median difference = -1.0 (95% CI, -3.0 to 0.0); p = 0.15). Residual hemorrhoidal prolapse was reported more frequently (p = 0.008), and more patients had treatment for recurrence after transanal hemorrhoidal dearterialization (7 vs 0 patients; p = 0.013). Patient satisfaction was higher after minimal open hemorrhoidectomy (p = 0.049). No differences were found in the impact on health-related quality of life, average and peak postoperative pain, recovery, or adverse events (p > 0.05). Transanal hemorrhoidal dearterialization was more expensive (median difference = &OV0556;555 (95% CI, &OV0556;472-&OV0556;693); p < 0.001). Authors concluded that minimal open hemorrhoidectomy had a better effect on the hemorrhoidal prolapse and higher patient satisfaction.

Aibuedefe et al (2021) conducted a meta-analysis to compare surgical treatments for grade III/IV hemorrhoids. A total of 26 studies with 3137 participants and 14 surgical treatments were included. Pain was less in patients with techniques such as laser (OR 0.34, CI 0.01-6.51), infrared photocoagulation (OR 0.38, CI 0.02-5.61), and stapling (OR 0.48, CI 0.19-1.25), compared to open and closed hemorrhoidectomies. There was less recurrence with Starion (OR 0.01, CI 0.00-0.46) and harmonic scalpel (OR 0.00, CI 0.00-0.49), compared to infrared photocoagulation and transanal hemorrhoidal dearterialization. Fewer postoperative clinical complications were seen with infrared photocoagulation (OR 0.04, CI 0.00-2.54) and LigaSure (OR 0.16, CI 0.03-0.79), compared to suture ligation and open hemorrhoidectomy. With Doppler-guided (OR 0.26, CI 0.05-1.51) and stapled (OR 0.36, CI 0.15-0.84) techniques, patients return to work earlier when compared to open hemorrhoidectomy and laser. Multiple favorable techniques were identified and authors recommended communication between the provider and the patient to guide individualized care. The literature did not identify a clear "gold standard".

Rivadeneira et al (UpToDate; 2023) discussed transanal hemorrhoidal dearterialization (THD) in their meta-analysis which compared the multiple surgical treatments for hemorrhoidal disease. Authors concluded that external hemorrhoids generally do not require surgical management, but when indicated, external thrombosed hemorrhoids are best treated with hemorrhoid excision. No discussion of THD was mentioned. Discussion of the treatment for internal hemorrhoids (grade II and II) indicated that conventional hemorrhoidectomies have the highest rate of postoperative complications but the lowest rate of recurrence. In contrast, hemorrhoidal artery ligation has the lowest rate of post-operative complications but the highest rate of recurrence. It was recognized that the providing surgeon may not have either the expertise or equipment to perform all of the available techniques (e.g., stapled hemorrhoidectomy, conventional hemorrhoidectomies with ligasure/harmonic scalpel, monopolar electrocautery). A multicenter RCT of 393 patients with grade II or III internal hemorrhoids compared stapled versus hemorrhoidal artery ligation (HAL). HAL resulted in less postoperative pain and shorter sick leave, but was more expensive, took longer to perform, left more residual grade III disease, and required more repeat procedures. Complication rates and patient satisfaction was comparable. A meta-analysis (28 observational studies involving 2,904 individuals) determined that those treated with doppler-guided hemorrhoidectomy had significantly increased fecal soiling after one year when compared to open hemorrhoidectomy. Authors concluded that additional trials with longer-term observation are needed to determine the utility of the THD approach. For patients with symptomatic grade II or III internal hemorrhoids, a course of rubber band ligation was reported as the first-line procedure of choice due to its low morbidity and cost.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

The American Society of Colon and Rectal Surgeons (2018) revised its clinical practice guideline on the diagnosis and treatment of hemorrhoids. The guideline recommends hemorrhoidectomy typically be offered to patients whose symptoms result from external hemorrhoids or combined internal and external hemorrhoids with prolapse (grades III-IV). Open and closed types of hemorrhoidectomies were listed as surgical excision, hemorrhoidopexy, and doppler guided hemorrhoidectomy by hemorrhoid artery ligation. One technique was not recommended over another. Mention was made of recurrence rates, symptom scores, complications, 5-level EQ-5D version (i.e., a widely used quality-of-life assessment instrument), and continence scores being similar, although patients had more pain in the early postoperative period after doppler-guided/assisted hemorrhoid artery ligation (HAL). HAL was also more expensive and was not found to be cost-effective compared with rubber band ligation in terms of incremental cost per quality- adjusted life-year.

The National Institute for Health and Clinical Excellence (NICE) published its 2010 interventional guidance titled “Haemorrhoidal Artery Ligation.” NICE states that “Current evidence on haemorrhoidal artery ligation shows that this procedure is an efficacious alternative to conventional haemorrhoidectomy or stapled haemorrhoidopexy in the short and medium term, and that there are no major safety concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.” There has been minor maintenance to this article as of January 4, 2012 with no change to the above statement.

The American Gastroenterological Associations (AGA) most recent position statement (2004) titled “American Gastroenterological Association Medical Position Statement: Diagnosis and Treatment of Hemorrhoids” recommends medical therapy for first-degree hemorrhoids. The AGA deems a hemorrhoidectomy the most effective treatment for symptomatic third degree, fourth degree or mixed internal and external hemorrhoids that have failed medical and non-operative therapy. Multiple techniques are mentioned, but THD is not addressed.

The American College of Physicians – Gastroenterology (2018) issued guidance on the treatment of hemorrhoids. For most patients with grade I- and II- internal hemorrhoidal disease and select patients with grade III internal hemorrhoidal disease in whom medical therapy is not effective, office-based procedures such as banding, sclerotherapy, and infrared coagulation are recommended, with hemorrhoid banding typically the most effective.

The American College of Gastroenterology (2021) issued the following recommendations for:

- Grade II internal symptomatic hemorrhoids that fail medical therapy - office-based procedures such as a rubber band ligation and alternative procedures which include infrared coagulation, sclerotherapy, and bipolar coagulation (strong recommendation; quality of evidence: moderate)
- Acutely thrombosed external hemorrhoids may benefit from either surgical excision or incision and evacuation of the thrombus when seen within the first 4d (strong recommendation; quality of evidence: low)
- Grade III hemorrhoids - Doppler-guided procedures such as hemorrhoidal artery ligations have similar outcomes to hemorrhoidectomy (conditional recommendation; quality of evidence: very low).
    - Discussion indicated this procedure is followed by a hemorrhoidopexy or rectoanal repair.

Government Regulations

National:

There is no National Coverage Determination.

Local:

There is no Local Coverage Determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 6/23/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/11	4/19/11	5/3/11	Joint policy established
11/1/12	8/21/12	8/21/12	Routine maintenance; references and rationale updated; no change to policy position.
3/1/2013	12/11/12	12/31/12	Routine maintenance; revised description section and medical policy statement; updated references and rationale sections. Policy position is unchanged.
9/1/14	6/17/14	6/23/14	Routine maintenance; references updated; no change in policy position.
11/1/15	8/18/15	9/14/15	Routine maintenance; references updated; no change in policy position.
11/1/16	8/16/16	8/16/16	• Routine maintenance • Updated to reflect FDA indications • Local determination added
11/1/17	8/15/17	8/15/17	Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance
11/1/19	8/20/19		Routine maintenance
11/1/20	8/18/20		Routine maintenance 0249T replaced with 46948
11/1/21	8/17/21		Routine maintenance
11/1/22	8/16/22		Routine maintenance
11/1/23	8/15/23		Routine maintenance (slp) Vendor Managed: N/A

Next Review Date: 3rd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSANAL HEMORRHOIDAL DEARTERIALIZATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.