

Direct Current Therapy for Treatment of Hemorrhoids

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr go to "Provedores", and click "Políticas Médicas".]

Medical Policy:	MP-SU-03-10
Original Effective Date:	June 17, 2010
Revised:	September 6, 2023
Next Revision:	September, 2024

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider's contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member's benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Hemorrhoids are vascular cushions within the anal canal, usually found in three main locations: left lateral, right anterior, and right posterior portions. They lie beneath the epithelial lining of the anal canal and consist of direct arteriovenous communications, mainly between the terminal branches of the superior rectal and superior hemorrhoidal arteries, and, to a lesser extent, between branches originating from the inferior and middle hemorrhoidal arteries and the surrounding connective tissue.

Hemorrhoids are classified according to their origin; the dentate line (pectinate line) serves as an anatomic - histologic border. External hemorrhoids originate distal to the dentate line, arising from the inferior hemorrhoidal plexus, and are lined with modified squamous epithelium, which is richly innervated with somatic pain fibers (delta type, unmyelinated). Internal hemorrhoids originate proximal to the dentate line, arising from the superior hemorrhoidal plexus, and are covered with mucosa. Internal hemorrhoids do not have cutaneous innervation and can therefore be destroyed without ulcerated, bleed, or thromboses.

Internal hemorrhoids are further classified into four stages according to the extent of prolapsed, as follows:

- Stage I - Bleed and Prominent hemorrhoidal vessels without prolapsed
- Stage II - Prolapsed with Valsalva with spontaneous reduction, with or without bleeding
- Stage III - Prolapsed with Valsalva requiring manual reduction, with or without bleeding
- Stage IV – Irreducible and Chronically prolapsed, manual reduction is ineffective

The initial conservative treatment for symptomatic hemorrhoids should include dietary management consisting of adequate fluid and fiber intake to relieve constipation and eliminate straining at defecation. At least six weeks may be required for significant improvement. Conservative treatment should continue even if a procedure is required.

Direct current therapy is one of several non-surgical therapies for the treatment of internal hemorrhoids without the need for anesthesia. The direct current probe is said to not be a thermal device, but rather it causes the production of sodium hydroxide at the negative electrode of the device, creating the desired

tissue effects. The medical results for this medical procedure will be the reduction or elimination of swollen tissues. Treating hemorrhoids by using direct current technology is limited by the large amount of time necessary to treat the involved tissue, up to 14 minutes per site, and this depends on the grade of the hemorrhoid and the mill amperage tolerated by the patient (110 V up to 16 mA). This technique has had limited application because of post-procedure pain that occurs in some patients, poor control of prolapse, and the prolonged treatment time.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

INDICATIONS

Medical Card System, Inc. (MCS) considers destruction of hemorrhoid(s) by Direct Current Therapy **medically necessary** for the following indication:

1. For the treatment of symptomatic Stage I and Stage II internal hemorrhoids, without significant prolapse that have not responded to conservative treatment.

CONTRAINDICATIONS

1. Pregnancy.
2. Implants (Pacemakers and/or Defibrillator).
3. Transplants placed in the lower abdominal/lower quadrant.
4. Bleeding disorders.
5. Inflammatory bowel disease (IBD).
6. Active anorectal infection.
7. Anti-coagulation therapy.
8. Purely for external hemorrhoids.

LIMITATIONS

1. Only one unit of service should be submitted per patient per global period (90 days), regardless of the number of sites treated by Direct Current Therapy. Any subsequent or re-treatment during the 90-day global period should NOT be separately billed.

2. Direct current therapy treatments do not exceed 14 minutes.
3. When the services are performed in excess of established parameters, they may be subject to review for medical necessity.

DOCUMENTATION REQUIREMENTS FOR THE PERFORMER PROVIDER

Medical record documentation maintained by the performing provider should include the following, and made available upon request:

1. A problem-specific history and physical examination, which should include:
 - a. Information regarding any prior treatments for hemorrhoids and patient's response.
 - b. The type of conservative treatments utilized and patient's response.
 - c. The length of time allowed for the resolution of symptoms.
2. Results of the physical examination, which should typically include visual inspection of the anus, digital rectal examination and anoscopy.
 - a. Patients with rectal bleeding usually undergo sigmoidoscopy.
 - b. The proximal colon should be evaluated by colonoscopy or air-contrast barium enema to assess bleeding that is not typical of hemorrhoids (e.g., dark blood or blood mixed in the feces), guaiac-positive stools, or anemia. The individual patient's risk factors for colorectal cancer (age, family history, or personal history of polyps) should also be considered when deciding on the extent of colonic evaluation.
3. The classification (stage) of the hemorrhoidal disease:
 - a. Stage I - Bleed without prolapse.
 - b. Stage II - Prolapse with Valsalva with spontaneous reduction, with or without bleeding.
 - c. Stage III - Prolapse with Valsalva requiring manual reduction, with or without bleeding.
 - d. Stage IV - Irreducible prolapsed and manual reduction is ineffective.

RATIONALE

MCS considers the options of non-invasive and non-surgical treatment for underlying medical conditions in which either the best available therapeutics alternatives have failed, or the patient is not a candidate; and may bring benefit of a better quality of life. For patients with Hemorrhoids that are vascular cushions within the anal canal; they respond to Direct current therapy as one of several non-surgical therapies for the treatment of hemorrhoids without the need for anesthesia. Direct Current Therapy for Treatment of Hemorrhoids procedure and the conservative treatment for Hemorrhoids are considered medically necessary when the specific group of criteria mentioned in this policy have been met.

CODING INFORMATION

CPT® Codes (List may not be all inclusive)

CPT® Codes	DESCRIPTION
46930	Destruction of internal hemorrhoid(s) by thermal energy (eg, infrared coagulation, cautery or radiofrequency)

Current Procedural Terminology (CPT®) 2023 American Medical Association: Chicago, IL.

ICD-10 Codes (List may not be all inclusive)

ICD -10 Codes	DESCRIPTION
K64.0	First degree hemorrhoids
K64.1	Second degree hemorrhoids

REFERENCES

1. American Gastroenterological Association (AGA). (2004, May). Technical Review on the Diagnosis and Treatment of Hemorrhoids. *Gastroenterology*, 126 (5), 1463 – 1473. Accessed August 15, 2023. Available at URL address: [https://www.gastrojournal.org/article/S0016-5085\(04\)00355-5/pdf](https://www.gastrojournal.org/article/S0016-5085(04)00355-5/pdf)
2. American Society of Colon and Rectal Surgeons (ASCRS). (2020). Diseases and Conditions – Hemorrhoids: Expanded Version. Dated online: Not Dated. Accessed August 15, 2023. Available at URL Address: <https://fascrs.org/patients/diseases-and-conditions/a-z/hemorrhoids-expanded-version#>
3. Centers of Medicare & Medicaid Services (CMS). First Coast Services Options, Inc. Retired Local Coverage Determination (LCD) for Destruction of Internal Hemorrhoid(s) by Infrared Coagulation (IRC) (L33571). Original Effective Date: 10/01/2015. Retirement Date: 08/22/2018. Accessed August 16, 2023. Available at URL address: https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=33571%3a4
4. Davis, B.R., Lee-Kong, S.A., Migaly, J., Feingold, D.L., & Steele, S.R. (2018). Clinical Practice Guidelines – The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Hemorrhoids. *Dis Colon Rectum*, 61(3), 284–292. DOI: 10.1097/DCR.0000000000001030. Accessed August 16, 2023. Available at URL address: https://fascrs.org/ascrs/media/files/downloads/Clinical%20Practice%20Guidelines/cpg_management_of_hemorrhoids.pdf
5. Ganz, R.A. (2013). The Evaluation and Treatment of Hemorrhoids. A Guide for the Gastroenterologist. *Clin Gastroenterol Hepatol.*, 11(6), 593 - 603. Accessed August 16, 2023. Available at URL Address: [https://www.cghjournal.org/article/S1542-3565\(13\)00017-7/pdf](https://www.cghjournal.org/article/S1542-3565(13)00017-7/pdf)
6. Ultroid Technologies, Inc. (2010). Package Insert: Ultroid® Hemorrhoid Management System - 3053. Revised: 10.5.2010a. Accessed August 16, 2023. Available at URL Address:

https://ziladoc.com/download/ultriod-technologies-inc_pdf or
https://ziladoc.com/queue/ultriod-technologies-inc_pdf?queue_id=-1

7. UpToDate® / Bleday, R. & Breen, E. (2023). Hemorrhoids: Clinical manifestations and diagnosis. Literature review current through: August 2023. This topic last updated: July 11, 2023. Accessed September 6, 2023. Available at URL Address:
https://www.uptodate.com/contents/hemorrhoids-clinical-manifestations-and-diagnosis/print?search=Hemorrhoids&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

8. UpToDate® / Bleday, R. & Elizabeth Breen, E. (2023). Home and office treatment of symptomatic hemorrhoids. Literature review current through: August 2023. This topic last updated: Oct 05, 2021. Accessed September 6, 2023. Available at URL Address:
https://www.uptodate.com/contents/home-and-office-treatment-of-symptomatic-hemorrhoids?search=Hemorrhoids&topicRef=2541&source=see_link

POLICY HISTORY

DATE	ACTION	COMMENT
June 17, 2010	Origination of Policy	
June 21, 2011	Revised	Indication changed from treatment of symptomatic internal and mixed hemorrhoids', Grade I, II, III and some Grade IV hemorrhoids to: New Indication: For the treatment of Stage I and Stage II internal hemorrhoids, without significant prolapsed.
November 2, 2012	Yearly Review	References updated.
November 18, 2013	Yearly Review	1. References updated. 2. Indication for this policy was re-written according to the LCD (L30862): "For the treatment of symptomatic Stage I and Stage II internal hemorrhoids, without significant prolapse that have not responded to conservative treatment."
February 21, 2014	Revised	To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.
Nov 06, 2014	Revised	References updated. <u>To the description section:</u> <ul style="list-style-type: none"> ➤ Last Paragraph was restructured: Conservative treatment should continue even if a procedure is required. Direct current Therapy is one of several non-surgical therapies for the treatment of internal hemorrhoids without the need for anesthesia. The direct current probe is said to not be a thermal device, but rather it causes the production of sodium hydroxide at the negative electrode of the device, creating the desired tissue effects. The medical results for this medical procedure will be the reduction or elimination of swollen tissues. Treating hemorrhoids by using direct current technology is limited by the large amount of time necessary to treat the involved tissue, up to 14 minutes per site, and this depends on the grade of the hemorrhoid and the milliamperage tolerated by the patient (110 V up to 16 mA). This technique has had limited application because of post-procedure pain that occurs in some patients, poor control of prolapse, and the prolonged treatment time. <u>To the Limitation Section:</u> <ul style="list-style-type: none"> ➤ Limitation #2 was reviewed to change the time limit of the treatment to "14" minutes. <u>To the References Section:</u> <ul style="list-style-type: none"> ➤ New References #10, 11, 13, and 14 were added to the Medical Policy.

November 23, 2015	Revised	<p>To the coding section:</p> <ul style="list-style-type: none"> Eliminate ICD-9 codes since they are no longer valid for diagnosis classification. Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015.
October 25, 2016	Revised	<p><u>References were Updated.</u></p> <p>To the Contraindications Section:</p> <ul style="list-style-type: none"> New Phrase “And/or Defibrillator” was added to the Contraindication #2. <p>To the Limitations Section:</p> <ul style="list-style-type: none"> Name of the Therapy was exchanged for “Direct Current Therapy” instead of Infrared Coagulation at the Limitation #1. <p>New “Documentation Requirements for the Performer Provider” Section was added to the Policy from: <u>LCD (L33571)</u></p> <p>To the Coding Section:</p> <ul style="list-style-type: none"> <u>To the ICD-10 Codes Section:</u> the following ICD-codes (K64.2, K64.3 and K64.8) were deleted from this Policy. <p>To the References Section:</p> <ul style="list-style-type: none"> References #4 and #5 were deleted from this Policy.
September 17, 2018		<p>To the description section:</p> <ul style="list-style-type: none"> Stage I - Bleed and Prominent hemorrhoidal vessels without prolapsed Stage IV – Irreducible and Chronically prolapsed, manual reduction is ineffective <p>To the References Section:</p> <ul style="list-style-type: none"> References 3, 5, 6, 7, 9 are eliminated Links of references 1,2,4 and 8 are updated
July 15, 2019	Revised	<p>To the Contraindications Section:</p> <ul style="list-style-type: none"> New Contraindication #8 was added to the Policy. <p>To the References Section:</p> <ul style="list-style-type: none"> The following references were added to the Policy: References #3 and #6.
June 30, 2020	Revised	<p>To the References Section:</p> <ul style="list-style-type: none"> The following references were deleted from this Policy: #4.
June 25, 2021	Revised	References updated.
July 5, 2022	Revised	References updated. No changes were incorporated to this Policy.
September 6, 2023	Revised	References updated. No changes were incorporated to this Policy.
April 11, 2024	UMC Approval	

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