Clinical Policy: Fecal Incontinence Treatments

Reference Number: LA.CP.MP.137
Date of Last Revision: ~~9/2022~~08/23

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fecal incontinence is defined as the uncontrolled passage of feces ~~or gas~~ over at least ~~1~~three month's duration~~,~~ in an individual ~~of at least four years of age,~~ who had previously achieved control.~~[1]~~ It has ~~a negative~~substantial social and economic impact ~~on self-esteem~~ and significantly impairs quality of life.~~[1]~~[2] The choice of therapy depends upon the etiology of incontinence, the anatomy of the sphincters, and ~~also on~~ the effect ~~of~~ incontinence has on the quality of life.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that procedures to treat fecal incontinence are **medically necessary** when meeting both of the following:

A. Severe, chronic fecal incontinence (defined as greater than two incontinent episodes on average per week and duration of incontinence greater than six months ~~**or** for more than twelve months after vaginal childbirth~~), that has not responded adequately to conservative treatments (e.g. pharmacotherapy, dietary management, strengthening exercises~~);~~) in a member/enrollee that has previously achieved bowel control;

~~B. Age ≥ 4 years and the member/enrollee has previously achieved bowel control;~~

~~C.~~B. Requested procedure meets one of the following:

1. Sacral nerve stimulation (sacral neuromodulation) for a weak but structurally intact anal sphincter when all of the following criteria are met;
   a. A test of percutaneous stimulation was effective, defined as at least 50% sustained (more than one week) improvement in symptoms;
   b. Condition is not related to anorectal malformation (e.g., congenital anorectal malformation, defects of the external anal sphincter over 60 degrees, visible sequelae of pelvic radiation, active anal abscesses and fistulae) and/or chronic inflammatory bowel disease;
   c. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.
   d. Has none of the following contraindications:
      i. Mechanical outlet obstruction;
      ii. Diathermy use (shortwave, microwave, ultrasound);
      iii. Inadequate response to test stimulation or inability to operate the device;
2. Sphincter repair (sphincteroplasty) when there is a defined defect of the external anal sphincter;
3. Artificial bowel sphincter (Acticon Neosphincter) when all of the following criteria are met:
   a. Age ≥ 18 years;
   b. Failure of, or not a candidate for, medical interventions or surgical sphincter repair;
   c. Incontinence is not complicated by an irreversibly obstructed proximal segment of bowel;
   d. Absence of any physical or mental illness that would increase surgical risk;

4. Colostomy, as last resort, when all other treatments have failed or are contraindicated.

II. It is the policy of Louisiana Healthcare Connections that all the following procedures have not been proven effective for the treatment of fecal incontinence, although they continue to be evaluated in clinical studies:
   A. Transanal radiofrequency therapy (Secca procedure);
   B. Injectable bulking agents [e.g., dextranomer/hyaluronic acid (Solesta)];
   C. Anal electrical stimulation;
   D. Posterior tibial nerve stimulation;
   E. Vaginal bowel control (e.g~~,~~., Eclipse system);
   F. Sacral nerve stimulation for the treatment of chronic constipation or chronic pelvic pain.

Background

Treatment of fecal incontinence is challenging. The goal of treatment is to restore continence and to improve the quality of life. Dietary and medical management are initially recommended for patients with fecal incontinence. If fecal incontinence is a result of or in conjunction with anatomic defects (e.g., rectovaginal fistula, rectal or hemorrhoidal prolapse etc.), the defects should be corrected first as this often improves or eliminates the incontinence.[1] Although most current interventions show modest improvements, there is limited evidence to support any treatments for fecal incontinence past ~~3~~three to ~~6~~six months.[~~23,26~~20,22]

Sacral neuromodulation is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing brain activity relevant to the continence. Sacral neuromodulation has consistently resulted in a reduction in frequency of fecal incontinence episodes and may be considered for incontinent patients with and without sphincter defects. Sphincter repair (sphincteroplasty) can be a treatment option for symptomatic patients with a defined defect of the external anal sphincter. Implantation of an artificial bowel sphincter remains an effective tool for select patients with severe fecal incontinence; however, its use is limited by complications including explanation in up to one-third of patients.[1,2]

Injectable bulking agents [e.g., dextranomer/hyaluronic acid (Solesta)] have been investigated for the treatment of fecal incontinence. However, evidence in the peer review literature evaluating this treatment is limited. There is a paucity of randomized, controlled trials and studies are limited by their small study sizes.[2] A prospective multicenter trial of 136 patients with fecal incontinence who received non-animal stabilized hyaluronic acid/dextranomer (NASHA Dx) bulking agent reported it provided a significant improvement of fecal incontinence symptoms in a majority of patients and this effect was stable during the course of the follow-up and maintained for ~~3~~three years.[3,~~23~~20] Long-term data is lacking, however, regarding the durability of this treatment.[5]

Transanal radiofrequency therapy (e.g., Secca procedure) is another procedure proposed for the treatment of fecal incontinence). This procedure uses thermo-controlled delivery of radiofrequency energy to the anal canal. The reported evidence is relatively sparse and has relevant limitations. Most studies have been small single-center series with short to mid-term follow-up.[4,~~7,10~~9]

The Eclipse System (Pelvalon Inc) is a nonsurgical vaginal bowel-control system for the treatment of fecal incontinence in women 18 to 75 years old who have had four or more FI (fecal incontinence) episodes in a two-week period. The device includes an inflatable balloon, which is placed in the vagina. Upon inflation, the balloon exerts pressure through the vaginal wall onto the rectal area, thereby reducing the number of FI episodes. The device is initially fitted and inflated by a clinician (with the use of a pump) and after proper fitting, the patient can inflate and deflate the device at home as needed. The device was granted FDA approval through the de novo classification process based on non-clinical testing as well as a clinical trial of 61 women with FI treated with the device. The trial showed that after one month almost 80 percent of women in the study experienced a 50 percent decrease in the number of FI episodes while using the device, as compared to baseline. Studies to date are limited by size and lack of long term evidence.~~[21,22]~~[18,19]

American Society of Colon and Rectal Surgeons (ASCRS)
In their most recent guidelines on the treatment of fecal incontinence, the ASCRS assigns ~~strong~~conditional recommendations ~~in favor of~~for sacral neuromodulation~~,~~ and sphincteroplasty based upon ~~moderate~~low quality of evidence. The ASCRS reports that injection of biocompatible bulking agents into the anal canal may help to decrease episodes of passive fecal incontinence. However, ~~based upon moderate-quality evidence, this is a weak recommendation. The~~the ASCRS notes that ~~although modest improvements have been reported in short-term outcomes,~~"given the limited improvement over placebo, diminishing long-term ~~follow-up with regard to safety~~results, and ~~efficacy awaits further experience.~~ cost, injectable bulking agents are not considered first-line treatment for fecal incontinence".[1]

The ASCRS guideline states the application of temperature-controlled radiofrequency energy to the sphincter complex ~~may be used to treat fecal incontinence. However, this is also a weak recommendation based on moderate quality of evidence. The ASCRS reports that most studies have been small single-center series with short-term follow-up. Per the ASCRS, "Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery."~~is not recommended for the treatment of fecal incontinence. Per the ASCRS, "the evidence supporting this approach is relatively sparse and has relevant limitations, additionally, no new studies evaluating this modality have been published since 2014."[1]

American College of Gastroenterology (ACG)
Regarding minimally invasive procedures for the treatment of fecal incontinence, the ACG concluded that minimally invasive procedures such as injectable anal bulking agents may have a role in patients with fecal incontinence who do not respond to conservative therapy. However, they note this is a weak recommendation based on moderate quality of evidence. The ACG reported that there is insufficient evidence to recommend radiofrequency ablation treatment to the anal sphincter (SECCA) at this time.[4]

National Institute for Health and Clinical Excellence
An interventional procedure guidance on injectable bulking agents for fecal incontinence concluded the current evidence on the safety and efficacy of injectable bulking agents for fecal incontinence does not appear adequate for this procedure to be used without special arrangements

for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups.[5]

American College of Obstetricians and Gynecologists (ACOG)
A practice bulletin on fecal incontinence concluded that anal sphincter bulking agents may be effective in decreasing fecal incontinence episodes up to ~~6~~six months and can be considered as a short-term treatment option for fecal incontinence in women who have failed more conservative treatments. However, this was based on limited or inconsistent scientific evidence (Level B).[~~23~~20]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted ~~2019~~2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. ~~–~~Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

CPT codes that support medical necessity

CPT® Codes	Description
46750	Sphincteroplasty, anal, for incontinence or prolapse; adult
46751	Sphincteroplasty, anal, for incontinence or prolapse; child
46760	Sphincteroplasty, anal, for incontinence, adult; muscle transplant
46761	Sphincteroplasty, anal, for incontinence, adult; levator muscle imbrication (Park posterior anal repair)
46999	Unlisted procedure, anus
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585*	Revision or removal of peripheral neurostimulator electrodes
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595*	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (~~e~~e.g. contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters,

CPT® Codes	Description
	responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator /transmitter system [e.g. contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters] by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (~~eg,~~e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator /transmitter [~~eg,~~e.g., contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters] by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (~~eg,~~e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS codes that support medical necessity

HCPCS Codes	Description
A4290*	Sacral nerve stimulation test lead, each
A4335	Incontinence supply; miscellaneous
E0745*	Neuromuscular stimulator, electronic shock unit
L8680*	Implantable neurostimulator electrode, each
L8681*	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682*	Implantable neurostimulator radiofrequency receiver
L8683*	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684*	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685*	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686*	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687*	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688*	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

HCPCS Codes	Description
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only.

~~**ICD-10-CM codes that support medical necessity**~~

~~ICD-10-CM Code~~	~~Description~~
~~R15.0 through R15.9~~	~~Fecal incontinence~~

CPT codes that do not support medical necessity

CPT® Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

HCPCS codes that do not support medical necessity

HCPCS Codes	Description
L8605*	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
Annual review completed. References reviewed, updated, and reformatted. "Experimental/investigational" verbiage replaced in policy statement with "have not been proven effective for the treatment of fecal incontinence, although they continue to be evaluated in clinical studies". Replaced all instances of "member" with "member/enrollee". "Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Minor verbiage changes to background with no clinical significance.	1/22	1/22
Annual review completed. In Section I.B. changed "member" to "member/enrollee". Added "sacral neuromodulation" to Section I.C. Background updated with minor verbiage changes with no clinical significance. Updated description for CPT codes 46760, 46761, 64581, 64590 and HCPCS Code L8683. References reviewed and updated. Specialist reviewed.	9/22	11/28/22
Annual review. Removed "≥ 4 years age" criteria and added "in a member/enrollee that has previously achieved bowel control" to	07/23	07/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
I.A. Also removed "more than twelve months after vaginal childbirth" from definition of severe, chronic fecal incontinence in I.A. Description and background section updated with no clinical significance. References reviewed and updated. External specialist reviewed.		

References

~~1.~~ Bordeianou LG, Thorsen AJ, Keller DS, et al. The American Society of Colon and Rectal ~~Surgeons'~~Surgeons Clinical Practice ~~Guideline~~Guidelines for the ~~Treatment~~Management of Fecal Incontinence. *Dis Colon Rectum*. ~~2015;58(7):623-636.~~

1. 2023;66(5):647 to 661. doi:10.1097/DCR.~~0000000000000397~~0000000000002776
2. Robson K.M, Lembo A.J. Fecal incontinence in adults: management. UpToDate. www.updtodate.com. ~~Updated~~Published November 2, 2021. Accessed June ~~1, 2022~~21, 2023.
3. Mellgren A, Matzel KE, Pollack J, et al. Long-term efficacy of NASHA Dx injection therapy for treatment of fecal incontinence. *Neurogastroenterol Motil*. 2014;26(8):1087- to 1094. doi:10.1111/nmo.12360
4. Wald A, Bharucha, AE, ~~Cosman BC, Whitehead WE.~~Limketkai B, et al. ACG ~~clinical guideline: management~~Clinical Guidelines: Management of ~~benign anorectal disorders.~~Benign Anorectal Disorders. *Am J Gastroenterol*. ~~2014;109(8):1141-1058.~~2021;116(10):1987-2008. doi:10.~~1038~~14309/ajg.~~2014.190~~0000000000001507
5. National Institute for Health and Clinical Excellence. Injectable bulking agents for fecal incontinence. https://www.nice.org.uk/guidance/ipg210/resources/injectable-bulking-agents-for-faecal-incontinence-pdf-1899865208328901 Published February 28, 2007~~. Updated~~ (updated January 16, 2012~~.~~). Accessed June ~~1, 2022~~21, 2023.
6. Sanchez JE, Brenner DM, Franklin H, Yu J, Barrett AC, Paterson C. Validity of the ≥50% Response Threshold in Treatment With NASHA/Dx Injection Therapy for Fecal Incontinence. *Clin Transl Gastroenterol*. 2015;6(1):e70. Published 2015 Jan 15. doi:10.1038/ctg.2014.20

~~7. Lefebure B, Tuech JJ, Bridoux V, et al. Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. *Int J Colorectal Dis*. 2008;23(10):993-997. doi:10.1007/s00384-008-0514-0~~

~~8.~~ Ruiz D, Pinto RA, Hull TL, Efron JE, Wexner SD. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? *Dis Colon Rectum*. 2010 Jul;53(7):1041- to 6.

7. doi: 10.1007/DCR.0b013e3181defff8

~~9.~~ Felt-Bersma RJ. Temperature-controlled radiofrequency energy in patients with anal incontinence: an interim analysis of worldwide data. *Gastroenterol Rep* (Oxf). 2014 May;2(2):121- to 5.

8. doi: 10.1093/gastro/gou016

~~10.~~ Lam TJ, Visscher AP, Meurs-Szojda MM, Felt-Bersma RJ. Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy (Secca) in patients with faecal incontinence: 3 years follow-up. *Int J Colorectal Dis.* 2014 Jun;29(6):755- to 61.

9. doi: 10.1007/s00384-014-1882-2

~~11.~~10. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Zarate X, Bada O, Velasco L. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. *Dis Colon Rectum*. 2008 Mar;51(3):355~~-9.~~ to 9. doi: 10.1007/s10350-007-9169-0
~~doi: 10.1007/s10350-007-9169-0~~

~~12. Efron JE, Corman ML, Fleshman J, Barnett J, Nagle D, Birnbaum E, Weiss EG, Nogueras JJ, Sligh S, Rabine J, Wexner SD. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum*. 2003 Dec;46(12):1606-16; discussion 1616-8. doi: 10.1007/BF02660763~~

~~13. Sanchez JE, Brenner DM, Franklin H, Yu J, Barrett AC, Paterson C. Validity of the ≥50% Response Threshold in Treatment With NASHA/Dx Injection Therapy for Fecal Incontinence. *Clin Transl Gastroenterol*. 2015;6(1):e70. Published 2015 Jan 15. doi:10.1038/ctg.2014.20~~

~~14.~~11. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. *Colorectal Dis*. 2013 May;15(5):569-to 74. doi: 10.1111/codi.12155

~~15.~~12. Franklin H, Barrett AC, Wolf R. Identifying factors associated with clinical success in patients treated with NASHA(®)/Dx injection for fecal incontinence. *Clin Exp Gastroenterol*. 2016 Mar 2;9:41- to 7. doi: 10.2147/CEG.S95238

~~16.~~13. Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *Lancet*. 2011;377(9770):997- to 1003. doi:10.1016/S0140-6736(10)62297-0

~~17.~~14. Frascio M, Stabilini C, Casaccia M, et al. Radiofrequency Procedure (SECCA®) for Fecal Incontinence: One-Year Experience. *Surg Technol Int*. 2017;30:97- to 101.

~~18.~~ Visscher AP, Lam TJ, Meurs-Szojda MM, Felt-Bersma RJF. Temperature-Controlled Delivery of Radiofrequency Energy in Fecal Incontinence: A Randomized Sham-Controlled Clinical Trial. *Dis Colon Rectum*. 2017 Aug;60(8):860- to 865.
15. doi:-10.1097/DCR.0000000000000861

~~19.~~16. Al-Bayati I, Saadi M, Elhanafi S, McCallum RW. Effectiveness of Bulking Agent (Solesta) Therapy in Fecal Incontinence in Patients Refractory to Conventional Therapies. *Am J Med Sci*. 2017 Nov;354(5):476- to 479. doi:-10.1016/j.amjms.2017.09.001

~~20.~~17. van der Wilt AA, Giuliani G, Kubis C, et al. Randomized clinical trial of percutaneous tibial nerve stimulation versus sham electrical stimulation in patients with faecal incontinence. *Br J Surg*. 2017;104(9):1167- to 1176. doi:10.1002/bjs.10590

18. van der Wilt AA, Giuliani G, Kubis C, et al. Randomized clinical trial of percutaneous tibial nerve stimulation versus sham electrical stimulation in patients with faecal incontinence. *Br J Surg*. 2017;104(9):1167 to 1176. doi:10.1002/bjs.10590
~~doi:10.1002/bjs.10590~~

~~21. Richter HE, Matthews CA, Muir T, et al. A vaginal bowel-control system for the treatment of fecal incontinence. *Obstet Gynecol*. 2015;125(3):540-547. doi:10.1097/AOG.0000000000000639.~~

~~22.~~19. Varma MG, Matthews CA, Muir T, et al. Impact of a novel vaginal bowel control system on bowel function. *Dis Colon Rectum*. 2016;59(2):127-131. doi:10.1097/DCR.0000000000000517

~~23.~~20. ACOG Practice Bulletin No. 210: Fecal Incontinence [published correction appears in Obstet Gynecol. 2019 Nov;134(5):1121]. *Obstet Gynecol*. 2019;133(4):e260-e273. doi:10.1097/AOG.0000000000003187

~~24.~~21. Local coverage article: billing and coding: sacral nerve stimulation for urinary and fecal incontinence (A53017). Centers for Medicare and Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed June ~~1, 2022~~21, 2023.

~~25. Ellsworth, P.I. Sacral nerve stimulation. Medscape website. https://emedicine.medscape.com/article/2036909-overview#a1. Published December 9, 2015 (updated June 7, 2018). Accessed June 1, 2022.~~

~~26.~~22. Forte ML, Andrade KE, Butler M, et al. *Treatments for Fecal Incontinence*. Rockville (MD): Agency for Healthcare Research and Quality (US); March 2016.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable ~~LHCC administrative~~LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical ~~treatment~~treatment, or medical care. ~~-~~It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate ~~care, and~~care and are solely responsible for the medical advice and treatment of members/enrollees. ~~-~~This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.