Anthem

Medical Policy

Subject: High-volume Colonic Irrigation
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Description/Scope

Colonic irrigation (also known as colonic lavage, hydrotherapy of the colon and colonics) is a procedure to wash out (or lavage) fecal material on walls of the large bowel. High-volume colonic irrigation involves the use of 35 or more liters of water, which is fed by gravity, to cleanse the colon. High-volume colonic irrigation has been proposed as an alternative to the traditional oral bowel preparations that are used to cleanse the colon prior to colonoscopy or other endoscopic procedure and as a treatment for constipation and bloating.

This document addresses the use of high-volume colonic irrigation and does not address other types of colonic irrigation which utilize smaller quantities of water, including, but not necessarily limited to, transanal and intraoperative (antegrade and retrograde) colonic irrigation.

Position Statement

Investigational and Not Medically Necessary:

High-volume colonic irrigation is considered **investigational and not medically necessary** for all indications.

Rationale

During a colonic irrigation procedure, water is instilled into the colon via a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the procedure. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the flow, temperature, and pressure of water through the nozzle to be controlled. Because the method involves an enclosed system, the waste materials are removed without the unpleasant odors or discomfort usually associated with enemas. Sometime ingredients such as herbal extracts, vitamins, probiotics, or enzymes are added to the water. The device may also include a console-type toilet and the fittings needed to connect to the water and sewer pipes. Additionally, the device may utilize electrical power to heat the water. Some devices consist of disposable nozzles and tubing while others employ components that need to be sterilized. The device does not include an enema kit (§ 876.5210) (U.S. FDA, 1996).

Historically, colonic irrigation has been investigated as a treatment for various indications including, but not limited to, detoxifying the body, normalizing bowel function, managing symptoms associated with inflammatory bowel disease (IBD), promoting weight loss, managing menstrual irregularities, preventing colon cancer and fostering general well-being. More recently, high-volume colonic irrigation which uses large volumes (35 liters or more) of water to remove fecal matter from the large bowel, has been promoted as an alternative to traditional bowel preparation prior to colonoscopy and as a treatment for chronic constipation. This document addresses the use of high-volume colonic irrigation and does not provide guidance on the other types of colonic irrigation which use smaller quantities of water, including but not necessarily limited to transanal, intraoperative (antegrade and retrograde) and colonic irrigation performed to promote wellness or detoxify the body.

The United States Food and Drug Administration (FDA) classifies colonic irrigation systems as Class II (performance standards) or Class III (premarket approval) devices. Class II colonic irrigation devices can legally only be marketed for medically indicated colon cleansing (such as before a radiologic endoscopic examination). Class III devices includes colonic irrigation devices intended for other uses, including colon cleansing routinely for general well-being. No system has been approved by the FDA for "routine" colon cleansing to promote the general well-being of a patient (§ 876.5210) (U.S. FDA, 1996).

Currently, at least one high-volume colonic irrigation system, the HyGIeaCare® System (HyGIeaCare, Inc., Austin, TX), is commercially available in the United States. According to information on the manufacturer's website, the HyGIeaCare® System "is an FDA cleared prescription medical device, approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations." At the time of this review, two high-volume colonic irrigation procedures utilizing the HyGIeaCare Prep System were identified: the HygiPrep® and the HygiRelief® (HyGIeaCare System, 2020).

- The HygiPrep is marketed as an alternative to the traditional oral purgatory preparations given to individuals undergoing a colonoscopy. In preparation for the HygiPrep procedure, the high-volume colonic irrigation is scheduled to take place on the same day as but prior to the colonoscopy. On the day prior to the colonoscopy, the patient is asked to consume a clear diet, take a mile over the counter laxative, and get a good night's rest. The patient is asked to arrive at the HyGIeaCare® facility at the scheduled time, typically a few hours prior to the colonoscopy. The high-volume colonic irrigation procedure is generally completed within one hour. Once the HygiPrep is completed, the patient is free to go to their colonoscopy appointment. Proponents of the HygiPrep report the high-volume colonic irrigation lowers barriers to colonoscopy because it is a safe and effective means to obtain adequate visualization of the colon while eliminating the need and time for conventional oral bowel preparation prior to colonoscopy.
- The HygiRelief® is carried out at HyGIeaCare, Inc facilities and is marketed as a natural, medication -free and nonsurgical treatment to provide relief from bloating and constipation (described on the HyGIeaCare site as three or fewer bowel movements per week). Unlike the HygiPrep, bowel preparation is not required prior to the HygiRelief procedure (HyGIeaCare System, 2020).

The diagnostic accuracy and therapeutic safety of colonoscopy depends upon the quality of bowel cleansing which is sometimes perceived as the most unpleasant part of the procedure in individuals undergoing this examination. The ideal colonoscopy bowel prep should reliably and safely empty the colon of all fecal material allowing the optimal visualization of the entire colonic mucosa without causing significant shifts in fluids or electrolytes or great patient discomfort. Currently, there is a lack of evidence in the peer-reviewed scientific literature to permit conclusions about the net health outcomes of high-volume colonic irrigation for any indication. Information on the HyGIeaCare web site states "several studies, including a recently published randomized-control trial, have shown this method

to be a safe alternative with a high percentage of adequate bowel preparation and increased patient satisfaction when compared to traditional oral purgatory preparations". However, an examination of the peer-reviewed, published literature indexed in the PubMed database identified a single study exploring the use of high-volume colonic irrigation as an alternative to standard bowel prep for colonoscopy, other endoscopic procedures or as a treatment for constipation or bloating.

Gajera and colleagues (2022) reported the results of a retrospective clinical trial that evaluated the use of an FDA cleared, defecation-inducing high-volume colon irrigation (> 40 L) to prepare individuals with inflammatory bowel disease (IBD) for colonoscopy. Data were collected at four Hygieacare centers in the United States from September 2016 to March 2021. The study population consisted of 314 participants that underwent 343 bowel preparations (BPs). The BPs were prescribed by a total of 65 physicians and performed by 16 technicians and nurses. Study participants ranged from 20-85 years of age, 76% females and 24% males and 97% of the subjects were adequately prepared for their colonoscopy (n=309). Per post-procedure surveys and open-ended response text analyses, patient satisfaction with the BP was very high. Adverse events that occurred during and immediately after the high-volume gravity-fed colonic lavage with induced defecation BP procedures were documented by the center's staff and included nausea, vomiting, dizziness, and abdominal cramping. No serious adverse events were reported. The authors concluded that the defecation-inducing high-volume colon irrigation BP for colonoscopy is safe, effective, and a favorable strategy for colonoscopy preparation in individuals with IBD.

Although known possible side-effects of colonic irrigation include nausea, diarrhea, abdominal pain, bloating and perianal soreness. electrolyte imbalance (Norlela 2004), bowel perforation (Handley 2004; Tan 1999), water intoxication (Norlela 2004) and infection (Istre 1982), no peer-reviewed scientific literature was found that examined the safety of high-volume colonic irrigation when compared to traditional bowel preparation prior to colonoscopy for any indication. While no guidelines, recommendations or position statements from professional organizations or medical societies were identified that specifically addressed high-volume colonic irrigation, the National Center for Complementary and Integrative Health (NCCIH) issued the following caution with regards to the safety of colonic irrigations in general: "Colon cleansing procedures may have side effects, some of which can be serious. Harmful effects are more likely in people with a history of gastrointestinal disease, colon surgery, severe hemorrhoids, kidney disease, or heart disease" (NCCIH, 2019).

Summary

Currently there is insufficient scientific evidence published in peer-reviewed medical literature that permits reasonable conclusions concerning the safety, efficacy, or improved net health outcomes of high-volume colonic irrigation for any indication. Additionally, the early publications on colonic irrigation raised safety concerns including, but not limited to, rectal perforation, post procedure infection, water intoxication and electrolyte imbalances. Inasmuch as high-volume colonic irrigations are now being performed, it is important and reasonable that well-designed studies be conducted that provide quantitative estimates of the potential for adverse events when high-volume colonic irrigation is performed.

Background/Overview

High-volume colonic irrigation involves the instillation of large volumes of water (at least 35 liters) via the rectum which are not retained and are almost immediately evacuated. High-volume colonic irrigation is being investigated as an alternative to traditional oral bowel preps prior to colonoscopy and as a treatment for constipation and bloating.

Definitions

Colon cleansing: The ingestion of any number or combination of liquid or powdered laxative substances for the purpose of cleansing the colon of waste materials. Colon cleansing is distinct from but may be administered during a colonic irrigation.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Gajera A, South C, Cronley KM, et al. High-volume colonic lavage is a safe and preferred colonoscopy preparation for patients with inflammatory bowel disease. Crohns Colitis 360. 2022; 4(3):otac024.
2. Handley DV, Rieger NA, Rodda DJ. Rectal perforation from colonic irrigation administered by alternative practitioners. Med J Aust. 2004; 181(10):575-576.
3. Istre GR, Kreiss K, Hopkins RSet al. An outbreak of amebiasis spread by colonic irrigation at a chiropractic clinic. N Engl J Med. 1982; 307(6):339-342.
4. Norlela S, Izham C, Khalid BA. Colonic irrigation-induced hyponatremia. Malays J Pathol. 2004; 26(2):117-1118.
5. Tan MP, Cheong DM. Life-threatening perineal gangrene from rectal perforation following colonic hydrotherapy: a case report. Ann Acad Med Singap. 1999; 28(4):583-585.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Disease Control (CDC). Amebiasis associated with colonic irrigation--Colorado. MMWR Morb Mortal Wkly Rep. 1981; 30(9):101-102.

2. HyGIeaCare System (2020). Available at: https://www.hygieacare.com/hygieacare-prep/. Accessed on June 12, 2023.
3. National Institutes of Health. National Center for Complementary and Integrative Health. Detoxes and “Cleanses: What you need to know” (2019). Available at: https://www.nccih.nih.gov/health/detoxes-and-cleanses-what-you-need-to-know. Accessed on June 12, 2023.
4. U.S. FDA Center for Devices and Radiological Health (CDRH). Gastroenterology/Urology Devices - Therapeutic Devices: Colonic Irrigation System (Sec. 876.5220) (1996). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=876.5220. Accessed on June 12, 2023.

Websites for Additional Information

1. American Cancer Society/ Complementary and Integrative Methods. Last updated August 25, 2021. Available at: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/complementary-and-integrative-medicine/complementary-and-alternative-methods-and-cancer.html. Accessed on June 12, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References, and Websites for Additional Information sections.
New	08/11/2022	MPTAC review. Initial document development.
