

<b>Subject:</b>	High-volume Colonic Irrigation	<b>Publish Date:</b>	10/05/2022
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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**

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**This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.**

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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).

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- 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 HyGleaCare® 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 HyGleaCare, Inc facilities and is marketed as a natural, medication - free and nonsurgical treatment to provide relief from bloating and constipation (described on the HyGleaCare site as three or fewer bowel movements per week). Unlike the HygiPrep, bowel preparation is not required prior to the HygiRelief procedure (HyGleaCare 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 HyGleaCare 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 databased failed to identify any studies 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. 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 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

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**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**

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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. Handley DV, Rieger NA, Rodda DJ. Rectal perforation from colonic irrigation administered by alternative practitioners. Med J Aust. 2004; 181(10):575-576.
2. 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.
3. Norlela S, Izham C, Khalid BA. Colonic irrigation-induced hyponatremia. Malays J Pathol. 2004; 26(2):117-1118.
4. 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. HyGleaCare System (2020). Available at: <https://www.hygieacare.com/hygieacare-prep/>. Accessed on June 8, 2022.
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 8, 2022.

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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 8, 2022.**

### Websites for Additional Information

1. **American Cancer Society/ Complementary and Integrative Methods. 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 14, 2022.**

### Index

#### Colonic Irrigation

**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

<u>Status</u>	<u>Date</u>	<u>Action</u>
New	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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