Clinical Policy: Colonoscopy Preparation Products

Reference Number: HIM.PA.04
Effective Date: 01.01.20
Last Review Date: 11.20
Line of Business: HIM

Revision Log

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

Description

Colonoscopy preparation products contain a combination of osmotic laxatives, stimulant laxatives, and electrolytes used for cleansing of the colon to allow for imaging during a colonoscopy.

FDA Approved Indication(s)

MoviPrep® and OsmoPrep® are indicated for cleansing of the colon as a preparation for colonoscopy in adults

Clenpiq® and Prepopik® are indicated for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ages 9 years and older

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Clenpiq, MoviPrep, OsmoPrep, and Prepopik are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Colonoscopy Preparation (must meet all)**:**

1. For patients 12 years and older, failure of Suprep® unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 4 weeks (one colonoscopy preparation)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Colonoscopy Preparation (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria.

Approval duration: 4 weeks (one colonoscopy preparation)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Suprep® (magnesium sulfate, potassium sulfate, sodium sulfate)	Split-dose regimen: Total volume of liquid consumed over the course of treatment: 2880 mL (96 oz) Evening before colonoscopy: Drink the entire contents of 1 bottle, diluted to a final volume of 480 mL (16 oz). Then drink 2 additional containers of water each (filled to the 16-ounce line) over the next hour, for an additional volume of 960 mL (32 oz). Morning of the colonoscopy (10-12 hours after the evening dose): Repeat entire process with the second bottle: Drink entire contents of second bottle diluted to a final volume of 480 mL (16 oz); then drink 2 additional containers of water (each filled to the 16-ounce line) over the next hour, for an additional volume of 960 mL (32 oz). Complete at least 2 hours before the procedure.	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):

- All colonoscopy prep products: gastrointestinal obstruction, ileus (except OsmoPrep), or gastric retention (except OsmoPrep); bowel perforation; toxic colitis or toxic megacolon; hypersensitivity
- Prepopik: severely reduced renal function (creatinine clearance less than 30 mL/min)
- OsmoPrep: biopsy-proven acute phosphate nephropathy, gastric bypass or stapling surgery

- Boxed warning(s): OsmoPrep – acute phosphate nephropathy

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Clenpiq	Split-dose regimen: 160 mL evening before colonoscopy. Second 160 mL the morning of the colonoscopy Day-before regimen: 160 mL during afternoon or early evening before colonoscopy. Second 160 mL 6 hours later during evening before colonoscopy	Not applicable
MoviPrep	Split dose (2 day regimen) (preferred method): Dose 1: Evening before colonoscopy (10-12 hours before dose 2): 240 mL (8 oz) every 15 minutes until 1 L (entire contents of container) is consumed. Then fill container with 480 mL (16 oz) of clear liquid and consume prior to going to bed. Dose 2: On the morning of the colonoscopy (beginning at least 3.5 hours prior to procedure): 240 mL (8 oz) every 15 minutes until 1 L (entire contents of container) is consumed. Then fill container with 480 mL (16 oz) of clear liquid and consume at least 2 hours before the procedure.	Not applicable
OsmoPrep	Evening before colonoscopy: Four tablets with 8 ounces of clear liquids every 15 minutes for a total of 20 tablets Next morning: Four tablets with 8 ounces of clear liquids every 15 minutes for a total of 12 tablets	Not applicable
Prepopik	Adults and pediatrics: *Split-dose regimen (preferred):* 150 mL (5 oz) the evening before the colonoscopy (5 PM-9 PM), followed by a second 150 mL (5 oz) dose ~5 hours before the colonoscopy *Day-before regimen (alternative):* 150 mL (5 oz) in the early evening before the colonoscopy (4 PM-6 PM), followed by a second 150 mL (5 oz) dose 6	Not applicable

Drug Name	Dosing Regimen	Maximum Dose
	hours later (10 PM-12 AM) the night before the colonoscopy	

VI. Product Availability

Drug Name	Availability
Clenpiq	Oral solution: Each bottle contains 10 mg of sodium picosulfate, 3.5 g of magnesium oxide, and 12 g of anhydrous citric acid in 160 mL of solution
MoviPrep	Oral solution: Pouch A – 100 grams PEG 3350, 7.5 grams sodium sulfate, 2.691 grams sodium chloride, 1.015 grams potassium chloride; Pouch B – 4.7 grams ascorbic acid, 5.9 grams sodium ascorbate
OsmoPrep	Tablet: 1.5 g of sodium phosphate
Prepopik	Powder for oral solution: 2 packets each containing 10 mg sodium picosulfate, 3.5 g magnesium oxide, and 12 g anhydrous citric acid

VII. References

1. Prepopik Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2018. Available at: http://www.prepopik.com. Accessed July 7, 2020.
2. Osmoprep Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; March 2019. Available at: https://shared.salix.com/shared/pi/osmoprep-pi.pdf. Accessed July 7, 2020.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 7, 2020.
4. Clenpiq Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; October 2019. Available at: www.clenpiq.com. Accessed July 7, 2020.
5. MoviPrep Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; December 2018. Available at: https://moviprep.salix.com. Accessed July 7, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per SDC and prior clinical guidance; adapted from CP.CPA.245 for HIM line of business requiring redirection to Suprep for members 18 or older.	12.04.19	02.20
4Q 2020 annual review: modified Suprep redirection to require down to age 12 per RT4 to address updated prescribing information for pediatric extension; modified approval duration to 4 weeks (one colonoscopy preparation); references reviewed and updated.	07.07.20	11.20

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 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 are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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