Clinical Policy: Colonoscopy Preparation Products

Reference Number: CP.CPA.245
Effective Date: 02.01.17
Last Review Date: 11.19
Line of Business: Commercial

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)

GoLYTELY® and Colyte® are indicated for cleansing of the colon in preparation for colonoscopy and barium enema X-ray examination in adults

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

Prepopik® is 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 Colyte, GoLYTELY, MoviPrep, OsmoPrep, Plenvu, and Prepopik are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Failure of one of the following:
   a. Adults: Suprep® or Clenpiq® unless contraindicated or clinically significant adverse effects are experienced;
   b. Pediatric patients 9 years and older: Clenpiq® unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: Length of Benefit

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): CP.CPA.09 for commercial.

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: Length of Benefit

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): CP.CPA.09 for commercial.

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 – CP.CPA.09 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
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
Suprep	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).	Not applicable

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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.	

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
Colyte with flavor packs, GoLYTELY	240 mL (8 oz) every 10 minutes until 4 L are consumed or the rectal effluent is clear; rapid drinking of each portion is preferred to drinking small amounts continuously	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	Not applicable

Drug Name	Dosing Regimen	Maximum Dose
	Next morning: Four tablets with 8 ounces of clear liquids every 15 minutes for a total of 12 tablets	
Plenvu	Two-day regimen: Dose 1 (16 ounces) over 30 minutes in the evening before colonoscopy (4 PM-8 PM), Dose 2 (16 ounces) over 30 minutes the next morning (approximately 12 hours after the start of Dose 1) One-day regimen: Dose 1 (16 ounces) over 30 minutes on morning of colonoscopy (3 AM-7AM), Dose 2 (16 ounces) over 30 minutes a minimum of 2 hours after the start of Dose 1	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 hours later (10 PM-12 AM) the night before the colonoscopy	Not applicable

VI. Product Availability

Drug Name	Availability
Colyte with flavor packs	Powder for oral solution: 4L bottle of PEG 3350 240 g, sodium chloride 5.84 g, potassium chloride 2.98 g, sodium bicarbonate 6.72 g, sodium sulfate (anhydrous) 22.72 g
GoLYTELY	Powder packet for oral solution: PEG 3350 227.1 grams, sodium sulfate (anhydrous) 21.5 grams, sodium bicarbonate 6.36 grams, sodium chloride 5.53 grams, potassium chloride 2.82 grams
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
Plenvu	Oral solution: Dose pouch 1 – 100 grams PEG 3350, 9 grams sodium sulfate, 2 grams sodium chloride, 1 gram of potassium chloride; Dose pouch 2A – 40 grams PEG 3350, 3.2 grams sodium chloride, 1.2 grams potassium chloride; Dose pouch 2B – 48.11 grams sodium ascorbate, 7.54 grams ascorbic acid.
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. Colyte with flavor packs Prescribing Information. Somerset, NJ: Meda Pharmaceuticals Inc.; February 2019. Available at: http://pendopharm-gi.com/colyte/. Accessed August 26, 2019.
2. GoLYTELY Prescribing Information. Braintree, MA: Braintree Laboratories, Inc.: September 2013. Available at: http://www.nulytely.com/. Accessed August 26, 2019.
3. Prepopik Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2018. Available at: http://www.prepopik.com. Accessed August 26, 2019.
4. Osmoprep Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; March 2019. Accessed August 26, 2019.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 26, 2019.
6. Clenpiq Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2019. Available at: www.clenpiq.com. Accessed August 26, 2019.
7. Plenvu Prescribing Information. Hengoed, UK: Norgine Limited; May 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209381s000lbl.pdf. Accessed August 26, 2019.
8. MoviPrep Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; December 2018. Available at: https://moviprep.salix.com. Accessed August 26, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria created	01.23.17	
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.23.17	11.17
4Q 2018 annual review: no significant changes; added Clenpiq to policy per SDC; removed Suclear (product discontinued); references reviewed and updated.	07.03.18	11.18
No clinically significant changes; added Plenvu to policy per SDC.	02.01.19	
No clinically significant changes; added Moviprep to policy and modified redirection from Suprep or MoviPrep to Suprep or Clenpiq per SDC in line with prior approved clinical guidance.	04.01.19	
4Q 2019 annual review: no significant changes; made distinction in preferencing requirements for pediatrics vs. adults since Clenpiq is the only preferred agent that is FDA-approved for pediatric patients; references reviewed and updated.	08.26.19	11.19

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.

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