Clinical Policy: Colonoscopy Preparation Products

Reference Number: CP.PCH.43
Effective Date: 12.01.21
Last Review Date: 11.22
Line of Business: Commercial, 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)

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

MoviPrep®, OsmoPrep®, Plenvu®, and Sutab® 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.

Nulytely® is indicated for bowel cleansing prior to colonoscopy in adults and pediatric patients aged 6 months or greater.

Suprep® is indicated for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age 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, Colyte, GoLYTELY, MoviPrep, Nulytely, OsmoPrep, Plenvu, Prepopik, Suprep, and Sutab 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 or b), unless contraindicated or clinically significant adverse effects are experienced:
   a. For members 18 years and older: generic alternative (e.g., generic MoviPrep (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid));
   b. For members ≥ 6 months but < 18 years: generic Nulytely.

Approval duration: 4 weeks (one colonoscopy preparation)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

Approval duration: 4 weeks (one colonoscopy preparation)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 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 – CP.CPA.09 for commercial, HIM.PA.154 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
PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid (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
PEG-3350, sodium bicarbonate, sodium chloride, potassium chloride (Nulytely)	Adults: drink a total of up to 4 L at a rate of 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. For NGT, rate is 20-30 mL per minute (1.2 – 1.8 liters per hour). Pediatric Patients ≥ 6 Months: 25 mL/kg/hour until the stool is watery, clear, and free of solid matter. If pediatric patients are unable to drink the reconstituted Nulytely solution, the solution may be given by NGT at the rate of 25 mL/kg/hour.	Not applicable
PEG-3350, sodium sulfate (anhydrous), sodium bicarbonate,	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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sodium chloride, potassium chloride (Golytely, Gavilyte-C)		

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	Not applicable
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
Nulytely	Adults: drink a total of up to 4 L at a rate of 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	Not applicable

Drug Name	Dosing Regimen	Maximum Dose
	continuously. For NGT, rate is 20-30 mL per minute (1.2 – 1.8 liters per hour). Pediatric Patients ≥ 6 Months: 25 mL/kg/hour until the stool is watery, clear, and free of solid matter. If pediatric patients are unable to drink the reconstituted Nulytely solution, the solution may be given by NGT at the rate of 25 mL/kg/hour.	
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
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
Suprep	Split-dose regimen (two-day) regimen consists of two doses of Suprep Bowel Prep Kit: first dose during the evening prior to colonoscopy and second dose the next day, during the morning of colonoscopy. Recommended Suprep Bowel Prep Kit dosage is: Adults: Two 6-ounce doses Pediatric Patients 12 Years of Age and Older: Two 4.5-ounce doses	Not applicable

Drug Name	Dosing Regimen	Maximum Dose
Sutab	Split dose (2 day regimen) (preferred method): Day 1 (day prior to colonoscopy): Take 12 tablets PO, then drink 16 oz of water over 15-20 minutes. 1 hour after the last tablet is ingested, drink another 16 oz of water over 30 minutes. 30 minutes after the second container of water is finished, drink another 16 oz of water over 30 minutes. Day 2 (day of colonoscopy): The morning of colonoscopy (5 to 8 hours prior to the colonoscopy and no sooner than 4 hours from starting Dose 1), take 12 tablets PO, then drink 16 oz of water over 15-20 minutes. 1 hour after the last tablet is ingested, drink another 16 oz of water over 30 minutes. Complete all tablets and water at least two hours prior to colonoscopy.	Not applicable

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
Colyte with flavor packs	Powder for oral solution: 4L bottle of PEG 3350 240 grams, sodium chloride 5.84 grams, potassium chloride 2.98 grams, sodium bicarbonate 6.72 grams, sodium sulfate (anhydrous) 22.72 grams
GoLYTELY	Powder packet for oral solution: PEG 3350 236 grams, sodium sulfate (anhydrous) 22.74 grams, sodium bicarbonate 6.74 grams, sodium chloride 5.86 grams, potassium chloride 2.97 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
Nulytely	Powder for oral solution: 4L bottle of PEG 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and flavoring ingredients 2.0 g
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

Drug Name	Availability
Suprep	Adults: Two bottles each containing 6 ounces of an oral solution of 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate Pediatric patients 12 years of age and older: Two bottles each containing 4.5-ounces of an oral solution of 13.13 grams sodium sulfate, 2.35 grams potassium sulfate, and 1.2 grams magnesium sulfate
Sutab	Tablet: 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride

VII. References

1. Colyte with flavor packs Prescribing Information. Somerset, NJ: Meda Pharmaceuticals Inc.; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/018983s051lbl.pdf. Accessed July 11, 2022.
2. GoLYTELY Prescribing Information. Braintree, MA: Braintree Laboratories, Inc.: May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/019011Orig1s031lbl.pdf. Accessed July 11, 2022.
3. Prepopik Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2018. Available at: http://www.prepopik.com. Accessed July 11, 2022.
4. Osmoprep Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; March 2019. Available at: https://shared.salix.com/shared/pi/osmoprep-pi.pdf. Accessed July 11, 2022.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 11, 2022.
6. Clenpiq Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; October 2019. Available at: www.clenpiq.com. Accessed July 11, 2022.
7. Plenvu Prescribing Information. Hengoed, UK: Norgine Limited; May 2021. Available at: https://shared.salix.com/shared/pi/plenvu-pi.pdf. Accessed July 11, 2022.
8. MoviPrep Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; April 2022. Available at: https://moviprep.salix.com. Accessed July 11, 2022.
9. Sutab Prescribing Information. Holbrook, MA: Braintree Laboratories, Inc.; January 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213135s000lbl.pdf. Accessed July 11, 2022.
10. Nulytely Prescribing Information. Braintree, MA: Braintree Laboratories, Inc.; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/019797s029lbl.pdf. Accessed July 11. 2022.
11. Suprep Prescribing Information. Braintree, MA: Braintree Laboratories, Inc.; August 2020. Available at: https://www.suprepkit.com/. Accessed July 11, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created combining Commercial and HIM line of business per July SDC redirecting to generic alternatives; retire CP.CPA.245 and HIM.PA.04.	07.20.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.11.22	11.22

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.

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

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members 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 and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2021 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.