

Clinical Policy: Colonoscopy Preparation Products

Reference Number: ERX.XXXX.##

Effective Date: 02.01.17

Last Review Date:

Line of Business: Commercial - NATL

[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

GoLYTELY and Colyte are indicated:

- For cleansing of the colon in preparation for colonoscopy and barium enema X-ray examination in adults

OsmoPrep, Prepopik and Suclear are indicated:

- For cleansing of the colon as a preparation for colonoscopy in adults

### Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions<sup>®</sup> that Colyte, GoLYTELY, OsmoPrep, Prepopik, and Suclear are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Colonoscopy preparation (must meet all):

1. Failure of Suprep or Moviprep unless contraindicated or clinically significant adverse effects are experienced.

##### Approval duration: Length of Benefit

##### B. Other diagnoses/indications

1. Refer to ERX.XXXX.## if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

#### II. Continued Therapy

##### A. Colonoscopy preparation (must meet all):

1. Currently receiving medication via health plan 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 health plan benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to ERX.XXXX.## if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**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 – ERX.XXXX.## or evidence of coverage documents

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

N/A

*Appendix B: General Information*

N/A

*Appendix C: Therapeutic Alternatives*

Drug	Dosing Regimen	Dose Limit/Maximum Dose
Moviprep	<p>Administer 2 L total with an additional 1 L of clear fluid prior to colonoscopy as follows:</p> <p><u>Split dose (2 day regimen) (preferred method):</u></p> <p>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.</p> <p>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.</p>	N/A
Suprep	<p><u>Split-dose regimen:</u></p> <p>Total volume of liquid consumed over the course of treatment: 2880 mL (96</p>	N/A

Drug	Dosing Regimen	Dose Limit/Maximum Dose
	<p>oz)</p> <p>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).</p> <p>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.</p>	

\*Requires prior authorization

## V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
<b>Colyte with flavor packs, GoLYTELY</b>	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	N/A
<b>OsmoPrep</b>	<p>Evening before colonoscopy: Four tablets with 8 ounces of clear liquids every 15 minutes for a total of 20 tablets</p> <p>Next morning: Four tablets with 8 ounces of clear liquids every 15 minutes for a total of 12 tablets</p>	N/A
<b>Prepopik</b>	<p><u>Split-dose regimen (preferred)</u>: 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.</p> <p><u>Day-before regimen (alternative)</u>: 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.</p>	N/A

<p><b>Suclear</b></p>	<p><u>“Split-Dose” method (preferred)</u>          Dose 1 - Evening before the colonoscopy (10 to 12 hours prior to Dose 2)</p> <ul style="list-style-type: none"> <li>- Dilute 6-oz oral solution by pouring the entire contents into the 16-oz mixing container and then filling the container with cool water to the fill line and mix</li> <li>- Drink the entire solution in the container within 20 minutes.</li> <li>- Refill with 16 oz of water to the fill line and drink over the next 2 hours.</li> <li>- Refill with 16 oz of water to the fill line and finish drinking before going to bed.</li> </ul> <p>Dose 2 - Next morning on the day of the colonoscopy (start at least 3 ½ hours prior to colonoscopy)</p> <ul style="list-style-type: none"> <li>- Dissolve powder of Dose 2 by adding water to the fill line on the jug. Shake until all the powder is dissolved. The solution can be used with or without the addition of a flavor pack. The solution should be used within 48 hours of reconstitution.</li> <li>- Drink all the solution in the jug at a rate of one 16-oz container every 20 minutes (four 16-oz containers over a period of 1.5 hours).</li> <li>- Complete drinking the solution at least 2 hours before the colonoscopy. Consume only clear liquids until 2 hours prior to colonoscopy.</li> </ul> <p><u>“Day-Before” method</u>          On the evening before the colonoscopy:          Dose 1 (Begin at least 3 ½ hours prior to bedtime)</p> <ul style="list-style-type: none"> <li>- Dilute the 6-oz oral solution by pouring entire contents into the 16-oz mixing container, fill the container with cool water to the fill line and mix.</li> <li>- Drinking the solution within 20 minutes.</li> <li>- Refill the container with 16 oz of water, drink over the next 2 hours.</li> </ul> <p>Dose 2 (Approximately 2 hours after starting Dose 1)</p> <ul style="list-style-type: none"> <li>- Dissolve powder of Dose 2 by adding water to the fill line on the jug. Shake until all powder is dissolved. Used with or without the addition of a flavor pack. Solution may be refrigerated after adding water. Use within 48 hours of reconstitution.</li> <li>- Drink all the solution in the jug at a rate of</li> </ul>	<p>N/A</p>
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	one 16-oz container every 20 minutes (four 16-oz containers over a period of one and a half hours). - Refill with 16 oz of water to the fill line and finish drinking before going to bed. - Consume only clear liquids until 2 hours prior to colonoscopy.	
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**VI. Product Availability**

<b>Drug</b>	<b>Availability</b>
Colyte with flavor packs	Powder for oral solution: one gallon bottle of PEG 3350 227.10 g, sodium chloride 5.53 g, potassium chloride 2.82 g, sodium bicarbonate 6.36 g, sodium sulfate (anhydrous) 21.50 g
GoLYTELY	Oral solution: one gallon packet of 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
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
Suclear	Oral solution: 6 oz bottle (17.5 g sodium sulfate, 3.13 g potassium sulfate, and 1.6 g magnesium sulfate); 2L jug (210 g PEG-3350, 5.6 g sodium chloride, 2.86 sodium bicarbonate, and 0.74 g potassium chloride)

**VII. References**

1. Colyte with flavor packs [Prescribing Information] Somerset, NJ; Meda Pharmaceuticals Inc.; August 2013.
2. GoLYTELY [Prescribing Information] Braintree, MA; Braintree Laboratories, Inc.: September 2013.
3. Prepopik [Prescribing Information] Parsippany, NJ; Ferring Pharmaceuticals Inc.; April 2015.
4. Osmoprep [Prescribing Information] Raleigh, NC: Salix Pharmaceuticals, Inc.; October 2012.
5. Suclear [Prescribing Information] Braintree, MA: Braintree Laboratories Inc.; January 2013.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 2017.
7. Lexicomp Online [Internet database]. Wolters Kluwer Clinical Drug Information, Inc. Updated periodically. Accessed January 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria created	01.23.17	

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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