



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/16/19
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MOTTEGRITY™ (prucalopride) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

MOTTEGRITY™ (prucalopride) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Motegrity (prucalopride) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in Gastroenterology or is in consultation with a Gastroenterologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of chronic idiopathic constipation
 4. The constipation satisfies **ALL** of the following Rome III/IV criteria:
 - Less than 3 spontaneous bowel movements per week
 - Bristol Stool Form Scale of 1 or 2 for at least 25% of bowel movements
 - Straining during at least 25% of bowel movements
 - Sensation of incomplete evacuation after bowel movements for at least 25% of bowel movements
 5. The constipation is not due to any secondary cause or suspected to be drug induced
 6. Drugs that are known to cause constipation have been discontinued
 7. Individual has failure, contraindication, or intolerance to at least **ONE** agent from **EACH** of the following classes:
 - Oral senna with a stool softener used on schedule (not on an as needed basis)
 - Oral osmotic agent **OR** saline agent used **EITHER** routinely **OR** on an as needed basis
 - Oral **OR** rectal stimulant used on an as needed basis
 8. Individual has failure, contraindication, or intolerance to **ALL** the following preferred step therapy agents:
 - Amitiza (lubiprostone)
 - Linzess (linaclotide)
 9. Individual does not have end-stage renal disease requiring dialysis
 10. There are **NO** contraindications
 - Contraindications include:
 - Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum
 - Hypersensitivity to Motegrity (prucalopride) or excipients in the product

Initial approval duration: 6 months

MOTTEGRITY™ (prucalopride) oral tablet (cont.)

- **Criteria for continuation of coverage (renewal request):** Motegrity (prucalopride) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in Gastroenterology or is in consultation with a Gastroenterologist
 2. Individual's condition responded while on therapy
 - Response is defined as **BOTH**:
 - Achieved and maintains Type 3 or 4 Bristol Stool Form
 - Achieved and maintains 3 or more spontaneous bowel movements per week without laxative use
 3. Individual has been adherent with the medication
 4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
 - Significant adverse effect such as:
 - Persistent worsening of depression or the emergence of suicidal thoughts and behaviors, or any unusual changes in mood or behavior
 - Severe or persistent diarrhea
 - Severe, persistent, or worsening abdominal pain
 5. The constipation is not due to any secondary cause or suspected to be drug induced
 6. Drugs that are known to cause constipation have been discontinued
 7. Individual does not have end-stage renal disease requiring dialysis
 8. There are no significant interacting drugs

Renewal duration: 12 months

- Motegrity (prucalopride) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:
1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

MOTTEGRITY™ (prucalopride) oral tablet (cont.)

Description:

Motegrity (prucalopride) is a serotonin type-4 (5-HT₄) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults. Prucalopride is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis (high-amplitude propagating contractions [HAPCs]), which increases bowel motility. In animal studies, prucalopride facilitates acetylcholine release to enhance the amplitude of contractions and stimulate peristalsis and stimulates gastrointestinal motility with contractions starting from the proximal colon to the anal sphincter.

Constipation is a syndrome that may be defined by symptoms of difficult or infrequent passage of stool, hardness of stool, or a feeling of incomplete evacuation that may occur either alone or due to another medical disorder. The definition of constipation will differ from individual to individual, culture to culture, and even region to region. Patients may define constipation as straining during defecation or change in stool consistency or frequency.

Functional constipation may be defined by the Rome IV criteria as the presence of at least two of the following: straining during at least 25% of bowel movements; passage of lumpy or hard stools at least 25% of bowel movements; sensation of incomplete evacuation at least 25% of bowel movements; anorectal obstruction or blockage at least 25% of bowel movements; the need to use manual maneuvers to facilitate defecation at least 25% of bowel movements; and passing fewer than three stools per week. The criteria also include that loose stools may only rarely be present without the use of laxatives, and that there are insufficient criteria for a diagnosis of irritable bowel syndrome (IBS).

Chronic constipation can result in hemorrhoid formation, rectal pain and burning, bowel obstruction, bowel rupture, as well as upper gut dysfunctions, including gastroesophageal reflux disease, nausea, and abdominal distention.

Definitions:

The Bristol Stool Form Scale (BSFS) – seven types:

- Type 1: separate hard lumps, like nuts (hard to pass), also known as *goat feces*
- Type 2: sausage-shaped, but lumpy
- Type 3: like a sausage but with cracks on its surface
- Type 4: like a sausage or snake, smooth and soft
- Type 5: soft blobs with clear-cut edges (passed easily)
- Type 6: fluffy pieces with ragged edges, a mushy stool
- Type 7: watery, no solid pieces, entirely liquid

Types 1 and 2 indicate constipation, with types 3 and 4 indicating the ideal stools (especially the latter), as they are easy to defecate while not containing excess liquid, and types 5, 6 and 7 specify diarrheal stools

Rome III/IV Diagnostic criteria for functional gastrointestinal disorders:

Functional Constipation - adult

ALL of the following diagnostic criteria - Criteria must be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis:

- Must include **two or more** of the following:
 - Straining during at least 25% of bowel movements

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/16/19
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MOTTEGRITY™ (prucalopride) oral tablet (cont.)

- Lumpy or hard stools in at least 25% of bowel movements
- Sensation of incomplete evacuation for at least 25% of bowel movements
- Sensation of anorectal obstruction/blockage for at least 25% of bowel movements
- Manual maneuvers to facilitate at least 25% of bowel movements (e.g., digital evacuation, support of the pelvic floor)
- Fewer than three bowel movements per week
- Loose stools are rarely present without the use of laxatives
- Insufficient criteria for irritable bowel syndrome

Laxatives:

Bulk forming – calcium polycarbophil, methylcellulose, psyllium
Osmotic – glycerin, lactulose, polyethylene glycol, sorbitol
Lubricating – mineral oil
Saline – magnesium citrate, magnesium hydroxide, magnesium sulfate
Softener – dioctyl calcium sulfosuccinate, dioctyl sodium sulfosuccinate
Stimulant – bisacodyl, cascara, senna

Prokinetic agent:

Metoclopramide
Prucalopride

Resources:

Motegrity (prucalopride) product information accessed 04-23-19 at DailyMed:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bca1e4c6-4b2b-4876-8ab3-654629c4ff1b>

Drossman DA.: Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features, and Rome IV. *Gastroenterology* 2016;150: 1262–1279

Lacy BE, Mearin F, Chang L, et al.: Bowel disorders. *Gastroenterology* 2016; 150:1393–1407

Simren M, Palsson OS, Whitehead WE.: Update on Rome IV Criteria for Colorectal Disorders: Implications for Clinical Practice. *Curr Gastroenterol Rep* (2017) 19: 15. DOI 10.1007/s11894-017-0554-0

Ford AC, Moayyedi P, Lacy BE, et al.: American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014; 109:S2 – S26; doi: 10.1038/ajg.2014.187



An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
 Call 866-325-1794 to check the status of a request.
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
 Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:
Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	
Dispensing Pharmacy Information			
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:	
Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:
<input type="checkbox"/> Check if requesting brand only <input type="checkbox"/> Check if requesting generic			
<input type="checkbox"/> Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)			
Turn-Around Time For Review			
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____ <input type="checkbox"/> Exigent (requires prescriber to include a written statement)			
Clinical Information			
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____			
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?			
3. <input type="checkbox"/> Yes <input type="checkbox"/> No There is absence of ALL contraindications.			
4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below. Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.			
Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy	
5. Are there any supporting labs or test results? Please specify below.			
Date	Test	Value	

Pharmacy Prior Authorization Request Form

- 6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:

Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.