Effective Date: 07/2019
Last P&T Approval/Version: 04/28/2022
Next Review Due By: 04/2023
Policy Number: C16791-A

Motegrity (prucalopride)

PRODUCTS AFFECTED

Motegrity (prucalopride)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Chronic idiopathic constipation

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. CHRONIC IDIOPATHIC CONSTIPATION (CIC), INITIAL:
1. Documented diagnosis of chronic idiopathic constipation
   AND
2. Documentation of a minimum of TWO of the following symptoms for the last 3 months: (a) Straining during at least 25% of defecations, (b) Sensation of anorectal obstruction/blockage for at least 25% of defecations, (c) Lumpy or hard stools in at least 25% of defecations, (d) Manual

maneuvers to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor) (e) Sensation of incomplete evacuation for at least 25% of defecations OR (f) Fewer than three spontaneous bowel movements per week
AND

3. Prescriber attests to ruling out secondary causes of chronic constipation (drug- induced, IBS-C, Inflammatory bowel disease, colorectal cancer, hypothyroidism,electrolyte imbalances)
AND
4. The member has tried and failed (2 week trial for each agent) or is intolerant to at least 2of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); ORAt least one saline laxative (e.g. magnesium citrate) OR bulk-forming laxative (e.g. psyllium or methylcellulose)
AND
5. Prescriber attests to appropriate monitoring for suicidal ideation and behavior as well as self-injurious ideation and new-onset or worsening of depression
AND
6. Motegrity (prucalopride), will not be used in combination with other functional gastro- intestinal disorder drugs [Linzess (linaclotide), Amitiza (lubiprostone), Trulance (plecanatide), Movantik (naloxegol oxalate), Symproic (naldemedine tosylate), Relistor(methylnaltrexone) orZelnorm (tegserod maleate)]
AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Motegrity (prucalopride), include: Hypersensitivity to MOTEGRITY AND 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.]
AND
8. IF NON-FORMULARY/NON-PREFERRED: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. CHRONIC IDIOPATHIC CONSTIPATION (CIC):

1. Documentation of a positive response to therapy using qualitative measures (≥ 3 bowel movements per week, improvement in quality of life, less straining during defecation, less incidences of incomplete evacuation)
AND
2. Prescriber attests to continued appropriate monitoring for worsening of depression or emergence of suicidal thoughts and behavior
AND
3. Documentation of no intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 months, continuing authorization: 12 months

PRESCRIBER REQUIREMENTS:

NA

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

CIC: 2 mg tablet daily

Max of #30 tablets per 30 days

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Serotonin-4-receptor (5HT-4) agonist

FDA-APPROVED USES:
Motegrity is indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Rome IV Diagnostic Criteria for Constipation

Must include two or more of the following criteria for diagnosis:
*Criteria should be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

- Straining during at least 25% of defecations
- Sensation of anorectal obstruction/blockage for at least 25% of defecations
- Lumpy or hard stools in at least 25% of defecations
- Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of thepelvic floor)
- Sensation of incomplete evacuation for at least 25% of defecations
- Fewer than three spontaneous bowel movements per week.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Chronic idiopathic constipation (CIC), defined as constipation in which the underlying cause is unknown, is a common and debilitating disease. First-line treatment consists of lifestyle modifications such as increasing fiber and fluid intake and exercise. Patients are then recommended to try varied over-the-counter stool softeners, bulking agents, or stimulants. If treatment failure persists, then pro-secretory agents (i.e., Linzess, Amitiza, Trulance) can be initiated. Historically, there have been no drug options beyond the pro-secretory agents.
The FDA approved Motegrity based on data from 6 individual trials. Clinical trials were varied in geographic region and timeframe, with some conducted in Europe, Asia, or the United States eitherbefore or after the 21st century. 5 out of 6 trials demonstrated superiority of Motegrity over placebo in primary response rate (increase to > 3 bowel movements per week) and lasted 12 weeks. The trial that failed to demonstrate superiority was conducted in Europe and lasted 24 weeks. Motegrityis a selective agonist of the 5HT-4 receptor and, unlike previously recalled predecessor Zelnorm®, does not show an increase in cardiovascular events due to increased selectivity for the 5HT-4 receptor.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Motegrity (prucalopride) are considered experimental/investigational and therefore, will

follow Molina's Off-Label policy. Contraindications include hypersensitivity to Motegrity, intestinal perforation or obstruction, obstructive ileus, severe inflammatory conditions such as Crohn's disease and ulcerative colitis. Discontinuation is advised if a patient experiences any unusual changes in mood or behavior.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Motegrity Tablets: 1 mg, 2 mg

REFERENCES

1. Motegrity (prucalopride) [package insert]. Lexington, MA: Shire Pharmaceuticals, Inc; November 2020
2. Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. Gastroenterology 2013;144:218–238.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy Quantity Appendix	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file