MEDICAL MUTUAL®

Drug Policy

Policy:	Motegrity (prucalopride)	Annual Review Date: 01/20/2022 Last Revised Date: 01/20/2022

OVERVIEW

Motegrity is a serotonin-4 (5HT4) receptor agonist indicated for the treatment of chronic idiopathic constipation in adults. The safety and effectiveness of Motegrity have not been established in pediatric patients. In clinical trials, suicide attempts and suicidal ideation have been reported. A causal association between treatment with Motegrity and an increased risk of suicidal ideation and behavior have not been established.

POLICY STATEMENT

This policy involves the use of Motegrity. Prior authorization is recommended for pharmacy benefit coverage of Motegrity. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Motegrity as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Motegrity be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Motegrity is recommended in those who meet the following criteria:

1. **Chronic Idiopathic Constipation (CIC)**
   Criteria. *Patient must meet the following criteria (A, B, C, D, E, and F):*
   - **A.** The patient is 18 years of age or older; AND
   - **B.** Motegrity is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
   - **C.** The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
   - **D.** The patient failed on or is intolerant to at least 2 of the following, with or without a stool softener, in the past 3 months:
     - **a.** At least one stimulant laxative (e.g. bisacodyl); OR

b. At least one osmotic laxative (e.g. PEG 3350); OR
c. At least one saline laxative (e.g. magnesium citrate); AND

E. The patient does not have intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, or severe inflammatory conditions of the intestinal tract (e.g. Crohn's Disease, ulcerative colitis, toxic megacolon/megarectum); AND

F. The patient will be monitored appropriately for the emergence of suicidal thoughts and behaviors and/or worsening of existing depression

2. <u>Continuation of Therapy</u>
Criteria. *Approve if the patient has demonstrated a beneficial response to Motegrity, per the prescribing physician (e.g. increased number of bowel movements from baseline) AND the patient has no contraindications to Motegrity.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Motegrity has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended in patients with a history of suicidal ideation and behavior.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Motegrity [prescribing information]. Shire US Inc. Lexington, MA. December 2018.

2. Prucalopride. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 19 December 2018. Accessed on 14 January 2020.