

Federal Employee Program® 1310 G Street, N.W. Washington, D.C. 20005 202.942.1000 Fax 202.942.1125

# 5.50.024

Section: Prescription Drugs Effective Date: July 1, 2023

Subsection: Gastrointestinal Agents Original Policy Date: December 28, 2018

Subject: Motegrity Page: 1 of 5

Last Review Date: June 15, 2023

## Motegrity

#### Description

### Motegrity (prucalopride)

#### **Background**

Motegrity (prucalopride) is a selective serotonin type 4 (5-HT4) receptor agonist. It is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis (high-amplitude propagating contractions), which increases bowel motility (1).

#### **Regulatory Status**

FDA-approved indication: Motegrity is indicated for the treatment of chronic idiopathic constipation (CIC) in adults (1).

The use of this medication is contraindicated in patients with 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 (1).

Motegrity may cause an increase in suicidal ideation and behavior. All patients should be monitored for persistent worsening of depression or the emergence of suicidal thoughts and behaviors. Patients, caregivers, and family members of patients should be counseled to be aware of any unusual changes in mood or behavior and alert the healthcare provider (1).

The safety and effectiveness of Motegrity in pediatric patients less than 18 years of age have not been established (1).

Section: Prescription Drugs Effective Date: July 1, 2023

Subsection: Gastrointestinal Agents Original Policy Date: December 28. 2018

Subject: Motegrity Page: 2 of 5

#### Related policies

Amitiza, Ibsrela, Linzess, Opioid Antagonist Drug Class, Trulance

#### **Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Motegrity may be considered **medically necessary** if the conditions indicated below are met.

Motegrity may be considered **investigational** for all other indications.

## **Prior-Approval Requirements**

Age 18 years of age or older

#### **Diagnosis**

Patient must have the following:

Chronic Idiopathic Constipation (CIC)

#### **AND ALL** of the following:

- a. Inadequate response to **ALL** of the following laxative therapies:
  - i. Bulk-forming laxative (e.g., psyllium (Metamucil))
  - ii. Stimulant laxative (e.g., senna (Senokot)
  - iii. Osmotic laxative (e.g., polyethylene glycol 3350 (Miralax))
- b. Absence of gastrointestinal obstruction
- c. **NO** dual therapy with other legend constipation medications (see Appendix 1)

## Prior - Approval Renewal Requirements

**Age** 18 years of age or older

#### **Diagnosis**

Patient must have the following:

Section: Prescription Drugs Effective Date: July 1, 2023

Subsection: Gastrointestinal Agents Original Policy Date: December 28. 2018

Subject: Motegrity Page: 3 of 5

Chronic Idiopathic Constipation (CIC)

#### AND ALL of the following:

- a. Improvement in constipation symptoms
- b. Absence of gastrointestinal obstruction
- c. NO dual therapy with other legend constipation medications (see Appendix 1)

#### **Policy Guidelines**

#### **Pre - PA Allowance**

None

### **Prior - Approval Limits**

**Quantity** 90 tablets per 90 days

**Duration** 12 months

## Prior - Approval Renewal Limits

Same as above

#### Rationale

#### Summary

Motegrity (prucalopride) is a selective serotonin type 4 (5-HT4) receptor agonist. It is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis (high-amplitude propagating contractions), which increases bowel motility. The safety and effectiveness of Motegrity in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Motegrity while maintaining optimal therapeutic outcomes.

#### References

 Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.

# 5.50.024

Section: Prescription Drugs Effective Date: July 1, 2023

Subsection: Gastrointestinal Agents Original Policy Date: December 28. 2018

Subject: Motegrity Page: 4 of 5

Policy History	
Date	Action
December 2018 March 2019 June 2019 December 2019	Addition to PA Annual review Annual review Annual review
March 2020	Annual review. Added "absence of gastrointestinal obstruction" to renewal requirements
June 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review
July 2022	Addition of Ibsrela to Appendix 1
September 2022	Annual review
June 2023	Annual review
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.

# 5.50.024

Section: Prescription Drugs Effective Date: July 1, 2023

Subsection: Gastrointestinal Agents Original Policy Date: December 28. 2018

Subject: Motegrity Page: 5 of 5

## **Appendix 1 - List of Legend Constipation Medications**

Generic Name	Brand Name
linaclotide	Linzess
lubiprostone	Amitiza
methylnaltrexone	Relistor
naldemedine	Symproic
naloxegol	Movantik
plecanatide	Trulance
prucalopride	Motegrity
tenapanor	Ibsrela