MEDICAL MUTUAL®

Drug Policy

Policy:	Ibsrela (tenapanor) Non-Formulary Review Criteria	Annual Review Date: 11/21/2024 Last Revised Date: 11/21/2024

OVERVIEW

Ibsrela (tenapanor) is a sodium/hydrogen exchanger 3 (NHE3) inhibitor that reduces sodium absorption in the small intestine and colon. Through this action, Ibsrela increases water secretion into the intestinal lumen, accelerating transit time and resulting in softer stool consistencies. Ibsrela has also been shown to reduce abdominal pain associated with irritable bowel syndrome (IBS) constipation. Ibsrela is minimally absorbed and has low systemic bioavailability after oral administration. Taking Ibsrela immediately before meals increases its effects. Ibsrela is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in patients 18 years of age or older. Ibsrela has the possibility to cause severe diarrhea, resulting in discontinuation of use and need for rehydration.

POLICY STATEMENT

This policy involves the use of Ibsrela. Prior authorization is recommended for pharmacy benefit coverage of Ibsrela. 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 Ibsrela as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ibsrela 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 Ibsrela is recommended in those who meet the following criteria:

1. <u>Irritable Bowel Syndrome with Constipation (IBS-C), Initial Therapy</u>
Criteria. *Patient must meet the following criteria (A, B, C, D, <u>and</u> E)*

A. The patient is 18 years of age or older; AND
B. Ibsrela 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 has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months (i, ii, iii, or iv):
   i. At least one bulk forming laxative (e.g. psyllium); OR
   ii. At least one osmotic laxative (e.g. PEG 3350); OR
   iii. At least one saline laxative (e.g. magnesium citrate); OR
   iv. At least one stimulant laxative (e.g. bisacodyl); AND
E. The patient has tried all 3 of the following [documentation requirements]: lubiprostone (Amitiza, generics), Linzess, AND Trulance; AND
F. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction.

2. Irritable Bowel Syndrome with Constipation (IBS-C), Continuation of Therapy
Criteria. *Patient must meet the following criteria (A, B, C, D, and E)*
A. The patient is 18 years of age or older; AND
B. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
C. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction
D. The patient has demonstrated a beneficial response to Ibsrela, per the prescribing physician (e.g. improved stool consistency from baseline); AND
E. The patient has tried all 3 of the following [documentation requirements]: lubiprostone (Amitiza, generics), Linzess, AND Trulance.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ibsrela 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. **Pediatric Patients Younger Than 18 Years of Age.** The safety and effectiveness of Ibsrela have not been established in patients < 18 years of age; Avoid use of Ibsrela in patients 6 years to < 12 years of age; Ibsrela is contraindicated in patients < 6 years of age due to risk of serious dehydration.

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. Ibsrela (tenapanor) [prescribing information]. Ardelyx Inc, Fremont, CA, September 2019
2. 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 Suppl 1:S2.
3. Mearin F, Lacy BE, Chang L, et al. Bowel Disorders. Gastroenterology 2016.
4. World Gastroenterology Organisation Global Guidelines Irritable Bowel Syndrome: A Global Perspective. Quigley, Eamonn M. M. Fried, Michael. Gwee, Kok-Ann et al. Journal of clinical gastroenterology 2015; 50(9):704-713.
5. Tenapanor. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 6 November 2019. Accessed on 8 October 2020.