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Policy Number: C23725-A

Ibsrela (tenapanor)

PRODUCTS AFFECTED

Ibsrela (tenapanor)

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:
Irritable bowel syndrome with 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. IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C)
1. Documented diagnosis of IBS-C
   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 [DOCUMENTATION REQUIRED]
AND

3. Documentation ruling out IBS-C organic disease (alarm symptoms), dys-synergic defecation, IBS-D or slow colonic transit.
AND
4. The member has tried and failed (2-week trial for each agent) or is intolerant to at least 2 of 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); OR at least one saline laxative (e.g. magnesium citrate)
AND
5. Ibsrela (tenapanor) will not be used in combination with other functional gastro- intestinal disorder drugs [Amitiza (lubriprostone), Linzess (linaclotide), Motegrity(prucalopride), Trulance (plecanatide), Movantik(naloxegol oxalate), Symproic(naldemedine tosylate),Relistor (methylnaltrexone) or Zelnorm(tegserod maleate)]
AND
6. 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 Ibsrela (tenapanor) include: Members less than 6 years of age due to the risk of serious dehydration]
AND
7. 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. FOR ALL INDICATIONS:

1. Documentation that the member has demonstrated a beneficial response to Ibsrela, per the prescribing physician (e.g. increased number of bowel movements from baseline)
AND
2. Documentation of no intolerable adverse effects or drug toxicity.

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
N/A

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
IBS-C: 50 mg twice daily
Max of #60 capsules 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:
Sodium/Hydrogen Exchanger 3 (NHE3) Inhibitor

FDA-APPROVED USES:
Treatment of irritable bowel syndrome with constipation (IBS-C) 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 the pelvic floor)
- Sensation of incomplete evacuation for at least 25% of defecations
- Fewer than three spontaneous bowel movements per week.

Rome IV Diagnostic Criteria for IBS-C
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

- Recurrent abdominal pain on average at least 1 day/week in the last 3 months- Related to defecation
- Associated with a change in the frequency of stool
- Associated with a change in the form (appearance) of stool

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Irritable Bowel Syndrome-Constipation is a chronic functional gastrointestinal (GI) disorder that arises from an abnormal functioning of the GI tract, not from structural or biochemical abnormalities and it is characterized by chronic abdominal pain, bloating and altered appearance or frequency of bowel movements. First-line treatment consists of lifestyle modifications such as dietary modification (increasing fiber and fluid intake, gluten and lactose avoidance) and physical activity. Patients are then recommended to try various over-the-counter stool softeners, bulking agents, or stimulants. If treatment failure persists, then pro-secretory agents (i.e., Ibsrela, Linzess, Amitiza, Trulance) can be initiated.

Tenapanor is a sodium/hydrogen exchanger 3 inhibitor, which acts locally to reduce sodium absorption from the small intestine and colon. Reduced sodium absorption results in increased intestinal lumen water secretion, accelerating intestinal transit time, and softening stool consistency. Tenapanor also decreases intestinal permeability and visceral hypersensitivity in animal models, which may reduce abdominal pain.

The FDA approved Ibsrela based on data from two phase 3 trials for IBS-C. Two randomized controlled trials of tenapanor in patients with IBS-C showed a modest beneficial effect with a combined improvement in abdominal pain and an increase in the number of complete spontaneous bowel movements.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Ibsrela (tenapanor) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications include patients less than 6 years of age. Discontinuation is advised if a patient experiences diarrhea requiring hospitalization.

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:

Ibsrela 50 mg tablets

REFERENCES

1. Ibsrela (tenapanor) [prescribing information]. Waltham, MA: Ardelyx Inc; April 2022.
2. Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. Diseases of the Colon & Rectum. 2016;59(6):479-492. doi:10.1097/dcr.0000000000000599.
3. Weinberg DS, Smalley W, Heidelbaugh JJ, Sultan S. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology. 2014;147(5):1146-1148. doi:10.1053/j.gastro.2014.09.001.
4. Drossman DA, Hasler WL. Rome IV-Functional GI Disorders: Disorders of Gut-Brain Interaction. Gastroenterology. 2016;150(6):1257-61.
5. Palsson OS, Whitehead WE, Van tilburg MA, et al. Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians. Gastroenterology 2016.

SUMMARY OF REVIEW/REVISIONS	DATE
Initial version created	Q2 2022