tenapanor (Ibsrela®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO170

Description

Tenapanor (Ibsrela) is an orally administered sodium/hydrogen exchange 3 inhibitor.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
tenapanor (Ibsrela)	50 mg tablets	Irritable bowel syndrome with constipation (IBS-C)	60 tablets/30 days

Initial Evaluation

I. Tenapanor (Ibsrela) may be considered medically necessary when the following criteria below are met:
   A. The condition being treated is a covered line according to the Oregon Health Plan List of Prioritized Services; **AND**
   B. The member is 18 years of age or older; **AND**
   C. The medication is prescribed by, or in consultation with, a gastroenterologist; **AND**
   D. A diagnosis of **irritable bowel syndrome with constipation (IBS-C)** when the following are met:
      1. The provider attests the member has less than three complete spontaneous bowel movements per week on average (defined as bowel movements without aid of laxatives that provide a sense of complete evacuation); **AND**
      2. The member experiences pain from the condition AND a pain score has been documented; **AND**
      3. The member has had an inadequate response to, intolerance of, or has a contraindication to the ALL of the following:
         i. Dietary and lifestyle modifications (e.g., removal of offending foods, increased fiber intake) AND increased physical activity; **AND**
         ii. At least one osmotic laxative (e.g., polyethylene glycol); **AND**
         iii. lubiprostone (Amitiza); **AND**
         iv. One of the following: linaclotide (Linzess) OR plecanatide (Trulance).

II. Tenapanor (Ibsrela) is considered investigational when used for all other conditions, including but not limited to:
   A. Hyperphosphatemia
   B. Chronic kidney disease
   C. Irritable bowel syndrome with diarrhea
   D. Mixed irritable bowel syndrome
   E. Chronic idiopathic constipation
   F. Opioid-induced constipation

Renewal Evaluation

I. Member has not been established on therapy by the use of free samples, manufacturer coupons, or otherwise; **AND**
II. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
III. The medication is prescribed by, or in consultation with, a gastroenterologist; **AND**
IV. Provider attests the member has exhibited improvement in disease symptoms as indicated by **BOTH** of the following:
   1. An increase of at least one complete spontaneous bowel movement per week; **AND**
   2. A reduction in abdominal pain.

Supporting Evidence

I. Tenapanor (Ibsrela) was evaluated in two double-blind, placebo-controlled, randomized trials in adult patients –T3MPO-2 and T3MPO-1. The majority of subjects were female, white, and all met Rome III criteria for IBS-C. This requires a pain score of at least three on a 0-10 scale, less than three complete spontaneous bowel movements (CSBMs) per week and less than five spontaneous bowel movements (SBMs) per week. Tenapanor (Ibsrela) has a Black Box Warning for serious dehydration in pediatric patients, and has not been evaluated in any pediatric population to date. It is contraindicated in those less than six years of age, and comes with a recommendation to avoid use in those less than 12 years of age. It should be avoided as animal studies showed cause of death to be dehydration in young juvenile rats.
   - The primary outcome was proportion of responders, defined as achieving both of the following for at least six of the first 12 weeks of the trials: an increase of at least one CSBM per week on average and a reduction of 30% in weekly average abdominal pain score compared to baseline.

- T3MPO-2: 620 subjects were evaluated for 26 weeks of treatment. Responders active vs. placebo: 37% vs. 24% (CI 6-20%). Difference from placebo 13%.
- T3MPO-1: 606 subjects were evaluated for 12 weeks and then were re-randomized to active drug or placebo for a 4-week withdrawal period. Responders active vs. placebo: 27% vs. 19% (CI: 2-15%). Difference from placebo 8%.

II. The quality of the evidence is considered low given the invalidated subjective endpoints used to determine efficacy and the short duration of therapy evaluated for safety and efficacy. Additionally, given the limited treatment effect and lack of place in therapy information, usability is uncertain at this time; thus, use of non pharmacologic agents and other established therapies are required prior to payment consideration.

Investigational or Not Medically Necessary Uses

I. Safety and efficacy have not yet been sufficiently established and/or clinical trials are currently underway for the following indications:
   A. Hyperphosphatemia
   B. Chronic kidney disease

References

1. Ibsrela [Prescribing Information]. Ardelyx, Inc. Fremont, CA. 2019.
2. Zelnorm [Prescribing Information]. Sloan Pharma/WorldMeds LLC. Louisville, KY. 2019.
3. Moayyedi P, Mearin F, Azpiroz F, et al. Irritable bowel syndrome diagnosis and management: A simplified algorithm for clinical practice. United European Gastroenterol J. 2017;5(6):773-788.
4. U.S. National Library of Medicine. A 26-week study to evaluate the efficacy and safety of tenapanor in IBS-C (T3MPO-2). clinicaltrials.gov. Available at https://clinicaltrials.gov/ct2/show/NCT02686138.
5. U.S. National Library of Medicine. A 12-week study with a 4-week randomized withdrawal period to evaluate the efficacy and safety of tenapanor for the treatment of IBS-C (T3MPO-1). clinicaltrials.gov. Available at https://clinicaltrials.gov/ct2/show/NCT02621892.

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	02/2020