

Reference number(s) 7164-A

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	V
Advanced Control Formulary Chart (ACFC)	\square
Advanced Control - Choice (ACCF)	Ø
Basic Control (BC)	
Basic Control Chart (BCC)	
Standard Control (SF)	Ø
Standard Control Formulary Chart (SFC)	Ø
Standard Control - Choice (SCCF)	Ø
Value (VF)	Ø
Value Formulary Chart (VFC)	V

Formulary	Applies
Managed Medicaid Template (MMT)	
Marketplace (MF)	
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	
Aetna Individual Lives (IVL)	
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	Ø
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	Ø
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	

Exception Criteria Ibsrela

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ibsrela	tenapanor

Indications

FDA-approved Indications

Ibsrela is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

Ibsrela Exception (ACCF, ACF, ACFC, Aetna FI ACF, Aetna FI ACFC, SCCF, SF, SFC, VF, VFC) 7164-A P09-2025.docx © 2025 CVS Caremark. All rights reserved.

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Coverage Criteria

Irritable Bowel Syndrome with Constipation (IBS-C)

Authorization may be granted when the requested drug is being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in an adult patient when ALL of the following criteria are met:

- The patient cannot be treated with a formulary alternative [Available Formulary Alternatives: Linzess, Amitiza (lubiprostone)].
- The patient has experienced an inadequate treatment response, intolerance, or has a clinical reason to avoid Linzess AND Amitiza (lubiprostone). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has recurrent abdominal pain on average at least one day per week in the last 3
 months with symptom onset at least 6 months prior to diagnosis. [ACTION REQUIRED:
 Documentation is required for approval.]
- The patient's recurrent abdominal pain is associated with at least TWO of the following: related to defecation, associated with a change in frequency of stool, associated with a change in form (appearance) of stool. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has experienced greater than 25 percent of bowel movements with Bristol stool types 1 or 2. [ACTION REQUIRED: Documentation is required for approval.] [NOTE: Bowel habit subtypes should be based only on days with abnormal bowel movements.]
- The patient has experienced less than 25 percent of bowel movements with Bristol stool types 6 or 7. [ACTION REQUIRED: Documentation is required for approval.] [NOTE: Bowel habit subtypes should be based only on days with abnormal bowel movements.]

Duration of Approval (DOA)

7164-A: DOA: 12 months

References

- 1. Ibsrela [package insert]. Waltham, MA: Ardelyx, Inc.; May 2025.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed September 10, 2025.
- 3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/10/2025).
- 4. ROME IV Diagnostic Criteria for Disorders of Gut-Brain Interaction (DGBI). January 2016. Available at: https://theromefoundation.org/rome-iv/rome-iv-criteria/. Accessed on September 10, 2025.

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