

Initial Prior Authorization

Trulance

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
Trulance	plecanatide

Indications

FDA-approved Indications

Trulance is indicated in adults for the treatment of:

- chronic idiopathic constipation (CIC).
- irritable bowel syndrome with constipation (IBS-C).

Coverage Criteria

Chronic Idiopathic Constipation (CIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient.

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.

Duration of Approval (DOA)

- 1578-A: DOA: 36 months
- 1582-A: DOA: 12 months

References

1. Trulance [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; March 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed August 1, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/01/2024).

Document History

Written by: UM Development (KM)

Date Written: 01/2017

Revised: 09/2017 (no clinical changes), 01/2018 (new indication); JK 09/2018 (updated indication question to include for adults); (DS) 09/2019 (no clinical changes; combined criteria; removed MDC); (KC) 09/2020 (no clinical changes); (DS) 09/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (DMH) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (AN) 01/2017; (GAD) 02/2018; (MES) 09/2018; (CHART) 09/26/19, 09/24/20, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 02/2017, 12/2017, 02/2018, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

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|---|---|-----|----|
| 1 | Is the requested drug being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient?
[If Yes, then no further questions. If No, then go to 2.] | Yes | No |
| 2 | Is the requested drug being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in an adult patient?
[No further questions] | Yes | No |

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Approve, 12 Months	Go to 2	
2.	Approve, 12 Months	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Chronic idiopathic constipation (CIC) in an adult and B) Irritable bowel syndrome with constipation (IBS-C) in an adult. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>