MEDICATION POLICY:
Dificid (fidaxomicin)

Applicable Drugs: Dificid (fidaxomicin)

Preferred: fidaxomicin (generic)

Non-preferred: Dificid tab (brand) and Dificid suspension (brand)

Date of Origin: 12/13/2023

Date Last Reviewed / Revised: 10/27/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documented presence of clinically significant diarrhea caused by *Clostridioides difficile* infection that is confirmed by positive stool assay.

II. Minimum age requirement: 6 months of age.

III. Documentation of treatment failure or contraindication to a course of oral vancomycin.

IV. Treatment must be prescribed by or in consultation with a gastroenterologist or infectious disease specialist.

V. Medication is prescribed in accordance with FDA labeling and is supported by current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults and pediatric patients weighing at least 12.5 kg: twenty 200 mg tablets per 10 days.
    - Patients weighing more than 12.5 kg with documented inability to swallow pills may be approved for one bottle of 40 mg/mL oral suspension per 10 days instead.
- Pediatric patients weighing at least 4 kg: one bottle of 40 mg/mL oral suspension per 10 days.

APPROVAL LENGTH

- **Authorization:** One course of treatment (10 days).
- **Re-Authorization:** N/A

APPENDIX

Table 1. Recommended Dosage of DIFICID Oral Suspension in Pediatric Patients, Based on Weight.

Body Weight	Dose Administered Twice Daily	Volume of 40 mg/mL Suspension to be Administered Orally Twice Daily
4 kg to less than 7 kg	80 mg	2 mL
7 kg to less than 9 kg	120 mg	3 mL
9 kg to less than 12.5 kg	160 mg	4 mL
12.5 kg and above	200 mg	5 mL

REFERENCES

1. Dificid (fidaxomicin) tablets and oral suspension. Package insert. Merck Sharp & Dohme LLC; 2024. Accessed October 27, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/201699sXXXlbl.pdf
2. Infectious Diseases Society of America and Society for Healthcare Epidemiology of America. 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Accessed October 27, 2026. https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/
3. Fischer M, Vaughn BP, Peery AF, Kelly CR. AGA clinical practice update on management of Clostridioides difficile infection in adults: expert review. Clin Gastroenterol Hepatol. 2026;24(9):2359-2369. doi:10.1016/j.cgh.2026.05.007
4. Kelly CR, Fischer M, Allegretti JR, LaPlante K, Stewart DB, Limketkai BN, Stollman NH. ACG clinical guidelines: prevention, diagnosis, and treatment of Clostridioides difficile infections. Am J Gastroenterol. 2021;116(6):1124-1147. doi:10.14309/AJG.0000000000001278.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.