

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for fidaxomicin oral tablet and Dificid oral suspension under the patient's prescription drug benefit.

Description:

fidaxomicin oral tablet and Dificid oral suspension is indicated in adult and pediatric patients aged 6 months and older for the treatment of C. difficile-associated diarrhea (CDAD).

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of fidaxomicin oral tablet and Dificid oral suspension, and other antibacterial drugs, fidaxomicin oral tablet and Dificid oral suspension should be used only to treat infections that are proven or strongly suspected to be caused by *C. difficile*. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Applicable Drug List:

fidaxomicin 200mg tablet Dificid 40mg/mL suspension

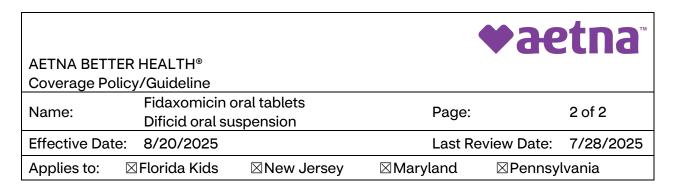
Policy/Guideline:

The requested drug will be covered with prior authorization when the following criteria are met:

 The patient has the diagnosis of C. difficile-associated diarrhea (CDAD) confirmed by a positive stool assay

AND

- The patient requires additional medication to complete a 10-day course of the requested drug for therapy that was initiated in the hospital
 OR
- The patient has experienced an inadequate treatment response to oral vancomycin
- The patient has experienced an intolerance to vancomycin
- The patient has a contraindication that would prohibit a trial of vancomycin
 OR
- The requested drug is being prescribed for a pediatric patient AND
 - The patient has experienced an inadequate treatment response to oral metronidazole



OR

- The patient has experienced an intolerance to metronidazole
 OR
- The patient has a contraindication that would prohibit a trial of metronidazole

Approval Duration and Quantity Restrictions:

Approval: 10 days

References:

- 1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2022.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 4, 2024.
- 3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/04/2024).
- 4. McDonald L, Gerding D, Johnson S, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clinical Infectious Diseases* 2018:66 (7): e1-e48. https://doi.org/10.1093/cid/cix1085. Accessed November 4, 2024.
- Johnson S, Lavergne V, Skinner A et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases 2021;73 (5): e1029–e1044. https://doi.org/10.1093/cid/ciab549. Accessed Novemever 4, 2024.
- 6. Kelly CR, Fischer M, Allegretti JR, LaPlante K, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. *Am J Gastroenterol.* 2021 Jun 1;116(6):1124-1147.