

Dificid (fidaxomicin) oral tablet
Dificid (fidaxomicin) oral suspension
Effective 10/01/2021

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|-----------------------|--|--|--|--|
| Plan | <input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange | | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit | | | <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Specialty Limitations | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | | |
| Contact Information | Medical Benefit Pharmacy Benefit | Phone: 833-895-2611 Phone: 800-711-4555 | Fax: 888-656-6671 Fax: 844-403-1029 | |
| Exceptions | N/A | | | |

Overview

Fidaxomicin is an antibacterial drug that acts locally in the gastrointestinal tract on *C. difficile*. It is a fermentation product obtained from the Actinomycete *Dactylosporangium aurantiacum*. Fidaxomicin is a macrolide antibacterial drug that inhibits RNA synthesis by binding to RNA polymerases.

Coverage Guidelines

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member is diagnosed with *Clostridioides* (formerly *Clostridium*) *difficile* infection confirmed by a positive stool assay
2. The member meets ONE of the following:
 - a. The patient requires additional medication to complete a 10-day course of the requested drug for therapy that was initiated in the hospital
 - b. The patient has experienced an inadequate treatment response to oral vancomycin after a trial of at least 7 days, OR has intolerance or contraindication to vancomycin

Limitations

1. Initial approvals will be granted for 10 days.
2. The following quantity limits apply:

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|---------------------------------|------------------------|
| Dificid 200mg oral tablet | 20 tablets per 10 days |
| Dificid 40mg/mL oral suspension | 136mL per 10 days |

References

1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2020
2. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections. *Am J Gastroenterol* 2021; 116:1124. McDonald LC, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA). Available online at:

http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Gastrointestinal/Clostridium_difficile/#recommendations. Accessed December 2018.

4. Nwachuku E, Shan Y, Senthil-Kumar P, et al. Toxic Clostridioides (formerly Clostridium) difficile colitis: No longer a diarrhea associated infection. Am J Surg 2021; 221:240

Review History

01/23/2020 – Transitioned from SGM to Custom Criteria; added Difcid oral suspension. Effective 3/1/21.

07/21/2021- Reviewed July P&T; changed diagnosis name; removed “diarrhea-associated” and added “infection. Effective 10/01/2021.

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

