

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

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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:

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

## References

1. Difucid [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
3. 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](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 Difucid 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.

