

**Dificid (fidaxomicin) oral tablet**  
**Dificid (fidaxomicin) oral suspension**  
**Effective 03/01/2021**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <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 has the diagnosis of Clostridium difficile-associated diarrhea (CDAD) 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.; December 2015.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed December 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2018.
4. 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](http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Gastrointestinal/Clostridium_difficile/#recommendations). Accessed December 2018.

### **Review History**

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

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