PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

DIFICID
(fidaxomicin)

Status: CVS Caremark Criteria ***MDC-1***
Type: Initial Prior Authorization ***Ref # 662-A***

* *Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA APPROVED INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dificid and other antibacterial drugs, Dificid should be used only to treat infections that are proven or strongly suspected to be caused by *Clostridium difficile (CDI)*.

Clostridium difficile-Associated Diarrhea

Dificid is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of *Clostridium difficile*-associated diarrhea (CDAD).

COVERAGE CRITERIA

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

- The patient has the diagnosis of *Clostridium 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 after a trial of at least 7 days, OR has intolerance or contraindication to vancomycin

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Dificid is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of *Clostridium difficile*-associated diarrhea (CDAD). The recommended dose is 200 mg orally twice daily for 10 days with or without food.

A case of *Clostridium difficile* (CDI) is defined by the presence of symptoms (usually diarrhea) and either a stool test positive for *C. difficile* toxins or toxigenic *C. difficile,* or colonoscopic or histopathologic findings revealing pseudomembranous colitis.[4]

In two large Phase 3 clinical studies Dificid had a clinical response rate at the end of the 10-day treatment period that was non-inferior to oral vancomycin. Dificid demonstrated superior sustained clinical response, defined as clinical response that was maintained without proven or suspected CDAD recurrence through 25 days beyond the end of treatment, compared to oral vancomycin. This difference was due to lower rates of proven or suspected CDAD during the follow-up period in

Dificid-treated patients. Similar rates of clinical response at the end of treatment and proven or suspected CDAD during the follow-up period were seen in Dificid-treated and vancomycin-treated patients infected with a BI isolate.

According to the most recent Infectious Disease Society of America (IDSA) Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children, either vancomycin or fidaxomicin is recommended over metronidazole for an initial episode of CDI. The dosage is vancomycin 125 mg orally 4 times per day or fidaxomicin 200 mg twice daily for 10 days. For fulminant CDI, oral vancomycin dosed at 500 mg 4 times per day is the regimen of choice. The options to treat a first recurrence of CDI include oral vancomycin as a tapered and pulsed regimen rather than a second standard 10-day course, a 10-day course of fidaxomicin, or a standard 10-day course of oral vancomycin rather than a second course of metronidazole if metronidazole was used for the primary episode. The recommended treatment options for patients with more than one recurrence are oral vancomycin using a tapered and pulsed regimen, a standard course of oral vancomycin followed by rifaximin, or fidaxomicin.[4]

REFERENCES

1. Dificid [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. Accessed December 2018.

Written by:	UM Development (RP)
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Reviewed:	Medical Affairs (DR) 03/2012; (WF) 06/2012; (DC) 07/2012; (LMS) 03/2013; (KP) 02/2014; (LCB) 12/2014; (KRU) 04/2015; (ME) 03/2018 External Review: 05/2012, 06/2012, 06/2013, 04/2014, 04/2015, 04/2016, 04/2017, 04/2018, 04/2019

CRITERIA FOR APPROVAL

1	Does the patient have the diagnosis of *Clostridium difficile*-associated diarrhea (CDAD) confirmed by a positive stool assay?	Yes	No
2	Does the patient require additional medication to complete a 10-day course of the requested drug for therapy that was initiated in the hospital? [If yes, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response to oral vancomycin after a trial of at least 7 days, OR has intolerance or contraindication to vancomycin?	Yes	No

Guidelines for Approval			
Duration of Approval		**10 Days**	
Set 1		**Set 2**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	1	2
2		3	

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have these conditions: - You have an infection that tests show is caused by a specific bacteria - The bacteria are susceptible to the drug Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no confirmation of diagnosis]
2.	Approve, 10 days	Go to 3	
3.	Approve, 10 days	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had poor response to a trial of at least 7 days of oral vancomycin or you cannot take it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to oral vancomycin]