PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

DIFICID
(fidaxomicin)

Status: CVS Caremark Criteria ***REG***
Type: Initial Prior Authorization ***Ref # 2753-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
Dificid 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 Dificid and other antibacterial drugs, Dificid 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.

COVERAGE CRITERIA
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

RATIONALE
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 indicated in adult and pediatric patients aged 6 months and older for the treatment of C difficile-associated diarrhea (CDAD).

The recommended dose for adults is 200 mg orally twice daily for 10 days. The recommended dosing for pediatric patients, who weigh at least 12.5 kg and are able to swallow tablets, is 200 mg orally twice daily for 10 days. If unable to swallow tablets or weigh less than 12.5 kg, Dificid oral suspension is available for use. The recommended dosing for pediatric patients is based on body weight and administered via oral syringe twice daily for 10 days.

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

In two randomized, double blinded trials in adult patients, 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 to oral vancomycin, defined as clinical response at the end of treatment and survival without proven or suspected CDAD recurrence through 25 days beyond the end of treatment. 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.

The safety and efficacy of Dificid in pediatric patients 6 months to less than 18 years was investigated in a Phase 3, multicenter, investigator-blinded, randomized, comparative trial.

Since the recommended duration of treatment with Dificid for C difficile-associated diarrhea is 10 days, the duration of approval will be 10 days if coverage criteria is met.

REFERENCES

1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2019
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2019.
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 2019.

Written by:	UM Development (DS)
Date Written:	10/2018
Revised:	(SF) 12/2018 (no clinical changes), (MAC) 12/2019 (no clinical changes), 01/2020 (new indication for pediatrics)
Reviewed:	Medical Affairs (ME) 10/2018, (CHART) 01/02/2020 External Review: 10/2018, 04/2019, 04/2020

CRITERIA FOR APPROVAL

1.	Does the patient have the diagnosis of *C difficile*-associated diarrhea (CDAD) confirmed by a positive stool assay?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 10 days	Deny	You do not meet the requirements of your plan. Your plan covers this drug when all of these conditions apply: - You have bacteria certain type of bacterial infection that is causing diarrhea - The type of bacteria has been confirmed by a stool test Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no confirmation of diagnosis]