UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Dificid

Program	Prior Authorization
Medication	Dificid (fidaxomicin)
Markets in Scope	Arizona, California, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2011
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Clostridioides difficile*-Associated Diarrhea (previously known as *Clostridium difficile)

Dificid is indicated in adults and pediatric patients 6 months of age and older for treatment of *Clostridioides difficile*- associated diarrhea (previously known as *Clostridium difficile*- associated diarrhea). 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 *Clostridioides difficile*.

2. Coverage Criteria:

A. <u>Authorization Criteria</u>

1. Diagnosis of *Clostridioides difficile*-associated diarrhea (CDAD) [previously known as *Clostridium difficile*- associated diarrhea]

-AND-

2. **<u>One</u>** of the following:

   a. History of failure, contraindication, or intolerance to Firvanq (vancomycin) oral solution

   -OR-

   b. History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution (NOT Firvanq) if the prescriber provides a reason or special circumstance the patient cannot use Firvanq

-OR-

c. For continuation of prior Dificid therapy

Authorization will be issued for 10 days.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2020
2. McDonald, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), *Clin Infect Dis. 2018* April *19;66(7):e1-48.*
3. Kelly C. Clostridioides (formerly Clostridium) difficile infection in adults: Treatment and prevention. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 18, 2020.)

Program	Prior Authorization- Dificid (fidaxomicin)
Change Control	
Date	Change
9/2011	New Guideline
12/2011	Revised indications section II.A. Clarified the precursor use of vancomycin must be the oral formulation in section III.A.3 of guideline.
9/2012	Criteria have been revised to allow patients diagnosed with CDAD to receive Dificid if they are “at high risk for CDAD recurrence.” Removed criteria under patients with severe CDAD: “History of failure (as defined by unresolved CDAD infection), contraindication, or intolerance to oral Vancocin (vancomycin)”

6/2014	Annual Review
12/2015	Full revision to Dificid clinical criteria. Removed the following requirements: New CDAD infection, previous metronidazole therapy requirement for mild-moderate CDAD, and high risk of recurrence. Also updated criteria to align with current template.
10/2016	Annual review. Updated policy template.
11/2016	Added the word “severe” at step 2b. This was mistakenly removed during the last policy update.
11/2017	Updated background and references. Removed end notes.
10/2018	Updated criteria to require step through Firvanq for all disease severities. Updated references.
4/2019	Annual Review. Updated references
4/2020	Updated background to include new indication for pediatric patients. Renamed *Clostridum difficile* to *Clostridioides difficile*.