

Clinical Pharmacy Program Guidelines for Dificid

Program	Prior Authorization
Medication	Dificid (fidaxomicin)
Issue Date	9/2011
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Clostridium difficile-Associated Diarrhea

Dificid is indicated in adults (greater than or equal to 18 years of age) for treatment of *Clostridium difficile*-associated diarrhea (CDAD). 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*.

2. Coverage Criteria:

<p>A. <u>Authorization Criteria</u></p> <p>1. Diagnosis of <i>Clostridium difficile</i>-associated diarrhea (CDAD), also known as <i>C. difficile</i> pseudomembranous colitis</p> <p style="text-align: center;">-AND-</p> <p>2. <u>One</u> of the following:</p> <p style="padding-left: 20px;">a. <u>Both</u> of the following:</p> <p style="padding-left: 40px;">(1) Patient has mild-moderate CDAD</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(2) History of failure, contraindication, or intolerance to oral Vancocin (vancomycin)</p> <p style="text-align: center;">-OR-</p> <p style="padding-left: 20px;">b. Patient has severe CDAD</p>

-OR-

c. For continuation of prior Difucid therapy

Authorization will be issued for 10 days.

3. References:

1. Difucid Prescribing Information. Optimer Pharmaceuticals, Inc., December 2015.
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4. Maroo S, Lamont JT. Recurrent *Clostridium difficile*. *Gastroenterology.* 2006;130:1311-16.
5. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol.* 2010;31(5):431-55.
6. Per clinical consult with infectious disease specialist, June 29, 2011.
7. Crook D, Weiss K, Cornely O, et al (April 10-13, 2010). Randomized clinical trial (RCT) in *Clostridium difficile* infection (CDI) confirms equivalent cure rate and lower recurrence rate of fidaxomicin (FDX) versus vancomycin (VCN). Poster presented at the 20th European Congress of Clinical Microbiology and Infectious Diseases, Vienna, Austria.
8. Per clinical consult with infectious disease, pediatric infectious disease, and gastroenterology and internal medicine specialists, August 23, 2011.
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11. Hu MY, Katchar K, Kyne L, et al. Prospective derivation and validation of a clinical prediction rule for recurrent *C. difficile* infection. *Gastroenterology.* 2009;136:1206-1214.
12. Garey KW, Sethi S, DuPont HL. Meta-analysis to assess risk factors for recurrent *Clostridium difficile* infection. *J Hosp Infect.* 2008;70:298-304.
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14. Johnson S. Recurrent *Clostridium difficile* infection: a review of risk factors, treatments, and outcomes. *J Infect.* 2009;58(6):403-10.
15. Kim JW, Lee KL, Jeong JB, et al. Proton pump inhibitors as a risk factor for recurrence of *Clostridium difficile*- associated diarrhea. *World J Gastroenterol.* 2010;16(28): 3573-7.
16. McFarland LV, Surawicz CM, Rubin M, et al. Recurrent *Clostridium difficile* disease: epidemiology and clinical characteristics. *Infect Control Hosp Epidemiol.* 1999;20(1):43-50.
17. Kelsen JR, Kim J, Latta D, et al. Recurrence rate of *Clostridium difficile* infection in hospitalized pediatric patients with inflammatory bowel disease. *Inflamm Bowel Dis.* 2011;17(1):50-5.

18. DuPont HL. The search for effective treatment of Clostridium difficile infection. N Engl J Med. 2011;364:473-5.
19. Zar FA, Bakkanagari SR, Moorthi KMLST, Davis MB. A comparison of vancomycin and metronidazole for the treatment of Clostridium difficile-associated diarrhea, stratified by disease severity. Clin Infect Dis. 2007;45:302-7.

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.