

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

DIFICID
(fidaxomicin)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Policy

FDA APPROVED INDICATIONS

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

Clostridium difficile-Associated Diarrhea

Difacid 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

REFERENCES

1. Difacid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2015.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed December 2017.
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 February 2018.