

Fidaxomicin (DIFICID)

Criteria for Use

November 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vawww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive fidaxomicin.*

- Fidaxomicin prescribed for the treatment of systemic infections.
- Patient with a history of hypersensitivity reaction to fidaxomicin or another macrolide antibiotic
- Patient with asymptomatic *Clostridioides difficile* colonization
- Patient with fulminant *Clostridioides difficile* infection (CDI) (e.g., life-threatening CDI or toxic megacolon) or ileus

Inclusion Criteria *The answers to the first item PLUS at least one additional item must be fulfilled in order to meet criteria.*

- Patient with clinical symptom onset (e.g. 3 or more unformed stools in 24 hours after discontinuation of laxatives) and laboratory confirmation of CDI

AND one of the following:

- Patient with an initial episode of CDI who is at increased risk of CDI recurrence (e.g. age \geq 65 years old, concomitant antibiotic use during CDI treatment, and/or immunosuppression).
- Patient with a recurrent episode of CDI*

Dosage and Administration

Standard regimen: 200 mg orally twice daily for 10 days with or without food

Extended-pulse regimen: 200mg orally twice daily for 5 days, then 200mg orally every other day for 20 days with or without food

Supplemental Information

**Recurrence is typically defined as a repeated symptomatic, laboratory-confirmed case of CDI within 12 weeks after a prior episode*

- Patients at high risk of CDI recurrence include age \geq 65 years old, concomitant antibiotic use during CDI treatment, immunosuppression
- Vancomycin 125mg PO QID x 10 days is also an acceptable treatment regimen for a first episode of CDI
- Either a repeat standard course of vancomycin or vancomycin as a tapered and pulse regimen are acceptable alternative options for the first recurrent episode of CDI (vancomycin taper / pulsed regimen is also acceptable treatment for subsequent recurrences)
- Infectious Diseases and/or Gastroenterology consults should be considered for patients with multiple CDI recurrences or fulminant CDI.
- The SHEA/IDSA Clinical Practice Guidelines for CDI recommend the following:
 - Discontinue therapy with the inciting antimicrobial as soon as possible, as this may influence the risk of CDI recurrence

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