

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> <i>Clostridium difficile</i> -associated diarrhea (CDAD) <input type="checkbox"/> Other (please state): _____ _____
Clinical Consideration	<input type="checkbox"/> Patient failed or is intolerant to standard therapy for CDAD per clinical practice guidelines. This includes metronidazole, vancomycin, and/or Alinia. ( <i>Documentation required</i> ) <input type="checkbox"/> Standard therapy contraindicated due to allergy. List related allergy: _____ <input type="checkbox"/> Other _____
Note:	<b><i>IV vancomycin can be compounded into an oral solution for a significant cost savings compared to oral vancomycin. The cost for a 10 day course of Dificid is approximately \$3,300 compared to compounded vancomycin which will cost approximately 98% less.</i></b>
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):
	Please attach a copy of the prescription or provide ALL of the information below: Dificid <sup>®</sup> (fidaxomicin) Strength _____ Sig _____ Qty _____ Refills _____
	<b><i>*Please attach all relevant medical records and test results*</i></b> <b>We will not process incomplete forms.</b> <b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)**

\_\_\_\_\_  
 Prescriber Signature

\_\_\_\_\_  
 Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 11/10/11

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Fidaxomicin (Dificid™)

#### CLASSIFICATION

- Macrolide, antibacterial

#### DESCRIPTION

- Fidaxomicin is a locally-acting macrolide antibacterial drug that is bactericidal against Clostridia species, including *Clostridium difficile* via inhibition of RNA synthesis by RNA polymerases.
- It is indicated in adults for the treatment of *Clostridium difficile*-associated diarrhea (CDAD).
- Safety and effectiveness have not been studied in patients < 18 years of age.
- In 2 randomized, double-blind, parallel-group trials (n=1138), oral fidaxomicin was noninferior to oral vancomycin in effecting clinical cure of CDAD; additionally, it was superior in reducing recurrence of acute symptoms of CDAD. There was no significant difference between fidaxomicin and vancomycin in the rate of recurrence in patients infected with the hypervirulent baseline *C difficile* isolates.
- Adverse events associated with the use of fidaxomicin with greater frequency compared with vancomycin include nausea, vomiting, abdominal pain, gastrointestinal hemorrhage, anemia, and neutropenia.

#### FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 3 (non-preferred brand)
Commercial Formulary:	Tier 3 (non-preferred brand)
Medicare Part D coverage:	Tier 4 (non-preferred brand)

#### COVERAGE CRITERIA

**Dificid (fidaxomicin)** meets the definition of **medical necessity** for the following:

- Adults with confirmed or strongly suspected *Clostridium difficile*-associated diarrhea.
- Documentation required if:
  - Failure of an adequate trial of 10 days of *metronidazole* or 7 days of oral Vancocin (*vancomycin hydrochloride*)
  - Intolerance to standard therapy for CDAD per clinical practice guidelines. This includes metronidazole, vancomycin, and/or Alinia.
  - Contraindication to use of standard therapy due to allergy.

Dificid (fidaxomicin) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.

Required Provider Specialty:

- None required

## DOSAGE/ADMINISTRATION:

### Clostridium difficile infection

- Difucid (fidaxomicin) 200mg orally twice daily with or without food for 10 days

### Dosage in Renal Failure

- No dose adjustment is needed based on renal function

## PRECAUTIONS:

- Increased risk of bacterial drug resistance if there is a lack of confirmation or strongly suspected Clostridium difficile-associated diarrhea.
- Difucid should not be used for systemic infections.

## Billing/Coding information

### Associated HCPCS Codes:

J8499	Prescription drug, oral, non-chemotherapeutic

### Associated CPT Coding:


### Associated ICD-9 Coding:

008.45	Clostridium difficile Pseudomembranous colitis
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## COST

- AWP (September 2011): 10 day course: \$3273.60
- COMMITTEE APPROVAL: September 28, 2011

## GUIDELINE UPDATE INFORMATION:

September 2011	Policy created

## REFERENCES:

- DRUGDEX®, accessed 09/29/11.
- Product Information: DIFICID(TM) tablet, fidaxomicin tablet. Optimer Pharmaceuticals, Inc. San Diego, CA 92121.
- SH Cohen 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; 31:431.