Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization       Number: 07.095

Title: *fidaxomicin* (*Dificid*)                 Page 1 of 3

<table>
<thead>
<tr>
<th>Approval: Robert Bonnell, M.D., Med. Dir.</th>
<th>DATES - Origination: 10/01/11</th>
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<tr>
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<td>Annual Review: 08/23/17</td>
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Implementation Information:**

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 Medical Department staff has access to the *Medical Department Procedure Manual* and receives notice from management when procedures are developed, updated and/or revised, or archived:

   3.1 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

**Background Information:**

**Reference Statement**

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
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Background Information, continued:

Medication Summary

• Dificid (fidaxomicin) is an oral macrolide antibiotic which is bactericidal against Clostridium difficile. Dificid inhibits the sigma-dependent transcription of bacterial RNA polymerases which inhibits RNA synthesis. It has little effect on normal fecal flora. Dificid does not exhibit cross resistance with other classes of antibiotics due to its distinct site of action. Clinical response is similar to vancomycin, but sustained clinical response may be greater.

• Dificid is available as a 200 mg tablet administered by mouth twice daily for 10 days for the treatment of Clostridium difficile-associated diarrhea.

Coverage Guidelines

• Member must be eligible and have applicable benefits.

• Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

• Members less than 18 years of age, as safety and efficacy have not been established.

• Members with a history of hypersensitivity to Dificid or any of its ingredients.

Additional Information

• AvMed’s Clinical Pharmacists are licensed by the State of Florida.

• AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
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Procedure:

1.0 Request for *initial therapy* with **Dificid** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Diagnosis of pseudomembranous colitis due to *Clostridium difficile* or *clostridium-difficile* associated diarrhea (CDAD); **AND**

1.2 Member shows inadequate response or experiences intolerance to an adequate trial of Vancocin (oral vancomycin);

1.3 If criteria are met, initial therapy for Dificid may be approved for up to 10 days.

References: