Prior Authorization Approval Criteria

Dificid (fidaxomicin)

Generic name: fidaxomicin

Brand name: Dificid

Medication class: Antibiotic

FDA-approved use: Indicated for adults ≥ 18 years of age for the treatment of Clostridium difficile-associated diarrhea.

Available dosage forms: 200 mg film-coated tablet

Usual dose: One 200 mg tablet by mouth twice daily for 10 days with or without food.

Approximate monthly cost: (based on AWP 2011) $3,600 for 20 tablets

Duration of therapy: 10 days

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records.
- Prescriber must be a gastroenterologist or an infectious disease specialist.
- Diagnosed with Clostridium difficile-associated diarrhea.
- ≥ 18 years of age.
- Failed or intolerant to a 10 to 14 day treatment course with metronidazole.
- Failed or intolerant to a 10 to 14 day treatment course with vancomycin.

Criteria for continuation of therapy:

- Recurrence of *Clostridium difficile*-associated diarrhea following an initial treatment with fidaxomicin.
- The first recurrent episode should be treated with the same medication used during the initial episode. This recommendation is based on the clinical practice guidelines published by SHEA and IDSA.

Caution:

- The safety and efficacy of fidaxomicin in patients younger than 18 years of age have not been established.
- Fidaxomicin is classified as a pregnancy category B antibiotic. It is not known if fidaxomicin is excreted in breast milk.

Monitoring:

- Resolution of symptoms following the initiation of treatment with fidaxomicin.

Contraindication:

- None documented at this time.

Not approved if:

- Patient does not meet the above stated criteria.

Special considerations:

- Fidaxomicin has minimal systemic absorption and should not be used to treat systemic infections.
- Fidaxomicin is no more effective than vancomycin in treating Clostridium difficile-associated diarrhea. A double-blind, randomized controlled trial showed the clinical cure rate was 88.2% in the fidaxomicin group and 85.8% in the vancomycin group.
- Fidaxomicin is more effective than vancomycin in sustaining a clinical response and preventing recurrent infections with Clostridium difficile. A double-blind, randomized controlled trial showed the recurrence rate was 15.4% in the fidaxomicin group and 25.3% in the vancomycin group ($p = 0.005$).
- Fidaxomicin may be a suitable option for a patient who is at a high risk for recurrent infections (age > 65 years, on long-term dialysis, previous history of a stroke, nosocomial acquisition of the Clostridium difficile infection, proton pump inhibitor and/or fluoroquinolone use, previous intravenous glycopeptide (vancomycin) use).

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/11