Pharmacy Policy Bulletin: J-0222 Dificid (fidaxomicin) – Commercial and Healthcare Reform	
Number: J-0222	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0222-010	**Original Date:** 05/01/2019
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Dificid (fidaxomicin) tablets and oral suspension
FDA-Approved Indication(s):	• Adult and pediatric patients 6 months of age and older for the treatment of *Clostridium difficile*-associated diarrhea (CDAD).

Background:	• Dificid, a locally-acting macrolide antibiotic, is bactericidal via inhibition of RNA polymerases primarily against Clostridia species including *Clostridium difficile*. • A 2021 focused update to the Infectious Diseases Society of America (IDSA) guidelines for the treatment of *Clostridium difficile* infection recommends fidaxomicin rather than a standard course of vancomycin for the treatment of an initial *C. difficile* episode. • Per the Centers for Disease Control and Prevention (CDC), laboratory tests that are commonly used to diagnose *C. difficile* infection include molecular tests (nucleic acid amplification tests [NAAT] or polymerase chain reaction [PCR] tests), the glutamate dehydrogenase (GDH) test, enzyme immunoassay (EIA) tests (for detection of toxin A and/or B produced by *C. difficile*), and a positive stool culture. • Prior authorization is utilized to ensure appropriate use in *C. difficile* infection. • Prescribing considerations: ○ To prevent the development of drug-resistant bacteria, Dificid should only be used for infections proven or strongly suspected to be caused by *C. difficile*.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Dificid (fidaxomicin) tablets or Dificid oral suspension may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member has a diagnosis of CDAD (ICD-10: A04.7), confirmed by all of the following **(1. and 2.)**:
   1. The member has ≥ 3 unexplained and new-onset loose bowel movements in < 24 hours
   2. The member has one (1) of the following **(a. through d.)**:
      a. A positive nucleic acid amplification test (NAAT) or polymerase chain reaction (PCR) result for *C. difficile*
      b. A positive glutamate dehydrogenase (GDH) test result
      c. A positive enzyme immunoassay (EIA) for *C. difficile* toxin
      d. A positive stool culture for *C. difficile*

B. If the request is for brand Dificid tablets, the member has experienced therapeutic failure or intolerance to generic fidaxomicin tablets.

C. If the request is for Dificid oral suspension, the member meets one (1) the following **(1. or 2.):**
   1. The member has an inability to swallow capsules/tablets.
   2. The member has experienced therapeutic failure or intolerance to generic plan-preferred fidaxomicin tablets.

II. Reauthorization

When a benefit, coverage of Dificid (fidaxomicin) tablets or Dificid oral suspension may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member has a recurrence of CDAD (ICD-10: A04.71, A04.72), confirmed by all of the following **(1. and 2.)**:
   1. The member has experienced an episode of symptom onset (for example, unexplained or new onset loose bowel movements).
   2. The member has one (1) of the following **(a. through d.)**:
      a. A positive nucleic acid amplification test (NAAT) or polymerase chain reaction (PCR) result for *C. difficile*
      b. A positive glutamate dehydrogenase (GDH) test result
      c. A positive enzyme immunoassay (EIA) for *C. difficile* toxin
      d. A positive stool culture for *C. difficile*

B. If the request is for brand Dificid tablets, the member has experienced therapeutic failure or intolerance to generic fidaxomicin tablets.

C. If the request is for Dificid oral suspension, the member meets one (1) the following **(1. or 2.):**
   1. The member has an inability to swallow capsules/tablets.
   2. The member has experienced therapeutic failure or intolerance to generic plan-preferred fidaxomicin tablets.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 10 day authorization may be granted.

Reauthorization:

- Commercial and HCR Plans: If approved, up to a 1 month authorization will be granted.

At the time of authorization, Dificid may be authorized in quantities as follows:

Product	Indication	Approvable quantity
Dificid	Recurrence of CDAD	20 tablets per 10 days 150 mL bottle per 10 days per occurrence

Automatic Approval Criteria

None

For previous versions of the Commercial and HCR policy, please see policy J-0358.

References:

1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2020.
2. Johnson S, Lavergne V, Skinner AM, et al. Clinical practice guidelines by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 focused update guidelines on management of *Clostridioides difficile* infection in adults. *Clin Infect Dis.* 2021. doi: https://doi.org/10.1093/cid/ciab549.
3. Centers for Disease Control and Prevention. FAQs for Clinicians about *C. diff.* Available at: https://www.cdc.gov/cdiff/clinicians/faq.html#diagnosis. Accessed September 7, 2024.