Pharmacy Medical Necessity Guidelines:
Dificid (fidaxomicin)

Effective: March 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Clostridioides difficile is a common hospital-acquired infection. *C. difficile* colonizes the human intestinal tract after normal gut flora is altered by antibiotic therapy. *C. difficile* is the cause of antibiotic-associated pseudomembranous colitis. Initial treatment of *C. difficile* should include cessation of the causative antibiotic as soon as possible. Patients with symptoms of *C. difficile* infection (e.g., abdominal pain, diarrhea, nausea and vomiting) who have a positive diagnostic assay should be treated with antibiotics for the *C. difficile* infection. Treatment is not indicated for patients who test positive but do not have symptoms. Options for the treatment of *C. difficile* include oral vancomycin and fidaxomicin.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Dificid (fidaxomicin) is a macrolide antibiotic indicated in adults and pediatric patients 6 months of age and older for the treatment of *Clostridioides difficile*-associated diarrhea. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dificid (as well as that of other antibacterial drugs), Dificid should only be used to treat infections that are proven or strongly suspected to be caused by *Clostridioides difficile.*

Dificid is available as tablets and oral suspension.

COVERAGE GUIDELINES

The plan may authorize coverage of Dificid tablets or oral suspension for Members when the following criteria are met:

1. Treatment with Dificid was started in an inpatient facility

OR

1. Member meets ALL of the following:
    a. Member has a diagnosis of *Clostridioides difficile* infection

    AND

    b. Member meets ONE of the following:
        i. Member had an inadequate response, intolerance, or contraindication to oral vancomycin

        OR

        ii. Clinical rationale why the member cannot be treated with vancomycin (e.g., Dificid is being requested for treatment of recurrent *C. difficile* infection, member has high risk of treatment failure such a compromised immunity)

LIMITATIONS

1. Approval of Dificid tablets will be limited to 20 tablets per fill.
2. Approval of Dificid suspension will be limited to 1 bottle (136 mL) per fill.
3. Approval of Dificid will be limited to 1 treatment course (10 days)
4. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Dificid (fidaxomicin) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc; October 2024.
2. Johnson S, Lavergne V, Skinner AM, et al. Clinical practice guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of American (SHEA): 2021

focused update guidelines on management of *Clostridioides difficile* infection in adults. *CID.* 2021;ciab549, https://doi.org/10.1093/cid/ciab549.
3. Kelly CR, Fischer M, Allegretti JR, et al. ACG clinical guidelines: prevention, diagnosis, and treatment of *Clostridioides difficile* infections. *Am J Gastroenterol*. 2021;116:1124-1147.

APPROVAL HISTORY

October 1, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective June 1, 2023: administrative update, updated *Clostridium* to *Clostridioides.*
2. February 13, 2024: Effective March 1, 2024, updated fax number for RxUM.
3. February 11, 2025: No changes
4. February 10, 2026: Effective March 1, 2026, updated limitations section to add language that requests for brand-name products with AB-rated generics will be reviewed according to the Brand Name criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services