Pharmacy Medical Necessity Guidelines: Dificid (fidaxomicin)

Effective: February 15, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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. The Member has a diagnosis of *Clostridioides difficile*

AND

2. The Member had an inadequate response, intolerance, or contraindication to oral vancomycin

LIMITATIONS

1. Approval of Dificid tablets will be limited to 20 tablets per fill.
2. Approval of Dificid will be limited to 1 treatment course (10 days)

CODES

None

REFERENCES

1. Dificid (fidaxomicin) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc; April 2020.
2. Kelly CP, Lamont LT, Bakken JS. Clostridioides (formerly Clostridium) difficile infection in adults: treatment and prevention. UpToDate. Available at: uptodate.com. Accessed 4 January 2021.
3. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for *Clostridium difficile* infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA). *CID*. 2018;66:e1-e48.

APPROVAL HISTORY

April 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 9, 2021: Updated MNG to include Dificid oral suspension. Updated "Clostridium" to "Clostridioides."

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.