TUFTS Health Plan

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

<table>
<tr><td>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</td><td>Fax Numbers:

RXUM: 617.673.0988</td></tr>
</table>

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Dificid (fidaxomicin) is a macrolide antibacterial drug indicated in adult and pediatric patients aged 6 months and older for the treatment of C. 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 (fidaxomicin) for Members, when **all** the following criteria are met:

1. Documented diagnosis of *Clostridioides difficile* infection

AND

2. Treatment failure, contraindication, or inadequate response to vancomycin

LIMITATIONS

None

CODES

None

REFERENCES

1. Ananthakrishnan AN. Clostridium difficile infection: epidemiology, risk factors and management. *Nat Rev Gastroenterol Hepatol*. 2011;8:17-26.
2. Bartlett JG. Clostridium difficile: progress and challenges. *Ann NY Acad Sci*. 2010;1213:62-9.
3. Centers for Disease Control and Prevention. Frequently asked questions about Clostridium difficile for healthcare providers. Revised 2012 March. URL: cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html. Available from Internet. Accessed 2016 August 19.
4. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol*. 2010;31(5):431-55.

5. Cornely, OA, Crook, DW, Esposito, R, et al. Fidaxomicin versus vancomycin for infection with Clostridium difficile in Europe, Canada, and the USA: a double-blind, non-inferiority, randomized controlled trial. Lancet Infect Dis. 2012;12(4):281-9.
6. Crawford T, Huesgen E, Danziger T. Fidaxomicin: a novel macrocyclic antibiotic for the treatment of Clostridium difficile infection. Am J Health Syst Pharm. 2012 Jun 1;69(11):933-43.
7. Crook D, Miller M, Louie T, et al. Efficacy and safety of fidaxomicin vs. vancomycin in Clostridium difficile infection in two randomized controlled trials with 1,105 patients. Infectious Diseases Society of America 2010 48th Annual Scientific Session, presented October 23, 2010.
8. Dificid (fidaxomicin) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2020.
9. Lancaster, JW, Matthews, SJ Fidaxomicin: the newest addition to the armamentariumagainst Clostridium difficile infections. *Clin Ther.* 2012;34(1):1-13.
10. Salkind AR. Clostridium difficile: an update for the primary care clinician. *Southern Medical Journal*. 2010;103(9):896-900.
11. Zhanel GG, Walkty AJ, Karlowsky JA. Fidaxomicin: a novel agent for the treatment of Clostridium difficile infection. Can J Infect Dis Med Microbiol. 2015 Nov-Dec;26(6):305-12.

APPROVAL HISTORY

December 9, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 6, 2012: No changes
- October 15, 2013: No changes
- October 7, 2014: No changes
- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct
- September 13, 2016: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template
- September 12, 2017: No changes
- August 7, 2018: No changes
- April 9, 2019: No changes
- April 14, 2020: Effective July 1, 2020, criteria requires treatment failure or inadequate response to vancomycin instead of metronidazole or vancomycin.
- February 9, 2021: Updated overview section to include Dificid oral suspension and to reflect expanded indication for pediatric patients. Updated criteria to list "contraindication to vancomycin". 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.