Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Dificid (fidaxomicin)

Effective: June 9, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Dificid (fidaxomicin) when **ALL** the following criteria are met:

1. BOTH of the following:
   a. Documented diagnosis of *Clostridioides difficile* infection

   AND

   b. ONE of the following:
      i. Treatment failure, contraindication, or inadequate response to vancomycin
      ii. Documentation that patient is a high risk of treatment failure with vancomycin (e.g., due to a medical condition such as compromised immunity)
      iii. Dificid is being used for treatment of a **recurrent** *C. difficile* infection

   OR

2. Treatment with Dificid was started in an inpatient facility

Limitations

None

Codes

None

References

1. 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 America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021 Sep 7;73(5):e1029-e1044. doi: 10.1093/cid/ciab549. PMID: 34164674.
2. 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 Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis 2018; 66:e1–48.

3. Dificid (fidaxomicin) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2022.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: No changes
- June 11, 2024: Effective July 1, 2024, updated criteria to allow coverage if treatment with Dificid was started in an inpatient facility.
- June 10, 2025: No changes
- June 9, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.