Reference number(s)
662-A

Initial Prior Authorization Dificid

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Dificid	fidaxomicin

Indications

FDA-approved Indications

Dificid is indicated in adult and pediatric patients aged 6 months and older for the treatment of C. difficile-associated diarrhea (CDAD).

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dificid and other antibacterial drugs, Dificid should be used only to treat infections that are proven or strongly suspected to be caused by C. difficile. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Coverage Criteria

C. difficile-Associated Diarrhea (CDAD)

Authorization may be granted for the requested drug when the patient has the diagnosis of C. difficile-associated diarrhea (CDAD) confirmed by a positive stool assay when ONE of the following criteria are

met:

- The patient requires additional medication to complete a 10 day course of the requested drug for therapy that was initiated in the hospital.
- The patient has experienced an inadequate treatment response to oral vancomycin.
- The patient has experienced an intolerance to vancomycin.
- The patient has a contraindication that would prohibit a trial of vancomycin.
- The requested drug is being prescribed for a pediatric patient and ONE of the following criteria are met:
    - The patient has experienced an inadequate treatment response to oral metronidazole.
    - The patient has experienced an intolerance to metronidazole.
    - The patient has a contraindication that would prohibit a trial of metronidazole.

Duration of Approval (DOA)

- 662-A: DOA: 10 days

References

1. Dificid [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 4, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/04/2024).
4. McDonald L, Gerding D, 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). *Clinical Infectious Diseases* 2018:66 (7): e1-e48. https://doi.org/10.1093/cid/cix1085. Accessed November 4, 2024.
5. Johnson S, Lavergne V, Skinner A 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, *Clinical Infectious Diseases* 2021;73 (5): e1029–e1044. https://doi.org/10.1093/cid/ciab549. Accessed Novemever 4, 2024.
6. Kelly CR, Fischer M, Allegretti JR, LaPlante K, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. *Am J Gastroenterol.* 2021 Jun 1;116(6):1124-1147.

Document History

Written by: UM Development (RP)

Reference number(s)
662-A

Date Written: 02/2012

Revised: 06/2012, 07/2012; (PL) 03/2013; (RP) 02/2014, 12/2014, 04/2015, 05/2015 (added denial reasons), 12/2015 (no clinical changes), 12/2016 (no clinical changes; MDC-1 designation); (DS) 12/2017, (SF) 12/2018 (no clinical changes), (MAC) 12/2019 (removed MDC-1 designation from title/document), 01/2020 (new indication for pediatrics); (KC) 11/2020 (no clinical changes); (EC/DW) 11/2021 (no clinical changes); (SS) 11/2022 (no clinical changes), (VLS) 11/2023 (no clinical changes), 11/2024 (no clinical changes)

Reviewed: Medical Affairs (DR) 03/2012; (WF) 06/2012; (DC) 07/2012; (LMS) 03/2013; (KP) 02/2014; (LCB) 12/2014; (KRU) 04/2015; (ME) 03/2018, (CHART) 01/02/20, (CHART) 12/03/20, (CHART) 12/02/2021, 12/01/2022, 11/30/2023, 11/21/2024

External Review: 05/2012, 06/2012, 06/2013, 04/2014, 04/2015, 04/2016, 04/2017, 04/2018, 04/2019, 04/2020, 04/2021, 02/2022, 02/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

1	Does the patient have the diagnosis of C. difficile-associated diarrhea (CDAD) confirmed by a positive stool assay? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Does the patient require additional medication to complete a 10 day course of the requested drug for therapy that was initiated in the hospital? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Has the patient experienced an inadequate treatment response to oral vancomycin? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	Has the patient experienced an intolerance to vancomycin? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of vancomycin? [If Yes, then no further questions. If No, then go to 6.]	Yes	No
6	Is the requested drug being prescribed for a pediatric patient? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has the patient experienced an inadequate treatment response to oral metronidazole? [If Yes, then no further questions. If No, then go to 8.]	Yes	No

8	Has the patient experienced an intolerance to metronidazole? [If Yes, then no further questions. If No, then go to 9.]	Yes	No
9	Does the patient have a contraindication that would prohibit a trial of metronidazole? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for diarrhea caused by a specific bacteria that has been confirmed with a positive stool test. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Approve, 10 Days	Go to 3	
3.	Approve, 10 Days	Go to 4	
4.	Approve, 10 Days	Go to 5	
5.	Approve, 10 Days	Go to 6	
6.	Go to 7	Deny	Your plan only covers this drug if you have tried oral vancomycin, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your

			request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review [Short Description: Step Therapy - Oral Vancomycin]
7.	Approve, 10 Days	Go to 8	
8.	Approve, 10 Days	Go to 9	
9.	Approve, 10 Days	Deny	Your plan only covers this drug if you have tried oral vancomycin OR you are a pediatric patient and have tried oral metronidazole, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review [Short Description: Step Therapy - Oral Metronidazole]