Fecal Bacteriotherapy for Treatment of Recurrent Clostridium Difficile Infection

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Policy

The Medical Management Department reviews referral requests for authorization of fecal bacteriotherapy for the treatment of recurrent *Clostridium difficile* infection not responsive to standard antibiotic therapies.

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

To facilitate the authorization process referral requests for fecal bacteriotherapy (FBT) must include the following:

1. Documentation of initial diagnosis of CDI confirmed through stool testing.

2. Documentation of recurrence of CDI, including detailed history of previous episodes of infection and courses of treatment.

3. Documentation that care is being managed by a specialist in infectious disease or gastroenterology.

B. Criteria for Medical Necessity:

Fecal Bacteriotherapy (FBT) is considered medically necessary for the treatment of recurrent *Clostridium Difficile* infection (CDI) if **ALL** the following criteria are met:

1. Patient has diagnosis of CDI confirmed by positive stool testing; **AND**

2. Patient has recurrent CDI, with three or more episodes of CDI and recurrent or persistent diarrhea despite antibiotic treatment for each CDI episode (Repeat testing for CDI is not necessary or recommended to prove treatment failure. Recurrence or persistence of diarrhea is indicative of treatment failure.), **AND**

3. Patient is not currently on any other anti-infective therapy, except related to the CDI.

Note: Requests for **repeat** FBT treatment of recurrent CDI must be reviewed by the Medical Director.

C. Indications Considered Investigational or not of Medical Necessity: (*Not an all-inclusive list*)

1. FBT given as first line treatment for initial CDI.
2. FBT for indications other than recurrent CDI.

CPT/HCPCS Codes:

44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen.

References:

Department of Health and Human Services, U.S. Food and Drug Administration. Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies. March 2016. Accessed January 21, 2019.

Kao D, Roach B, Silva M, et al. Effect of oral capsule– vs colonoscopy-delivered fecal microbiota transplantation on recurrent Clostridium difficile infection: a randomized clinical trial. J Am Med Assoc. 2017; 318:1985-1993.

McDonald LC, et al. Clinical practice guideline 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 Inf Dis. 2018;66(7): e1-e48.

UW Health. *Clostridium Difficile* Infection: Prevention, Diagnosis, Treatment and Management -Adult/Pediatric-Inpatient/Ambulatory/Emergency Department Guideline. Effective August 24, 2017. Last revised June 2018. Accessed January 21, 2019.