

Fecal Microbiota Transplant

Policy MP-062

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP, Healthy U (Medicaid) and Health Choice Utah (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

Description:

Clostridium difficile infection (CDI), is a Gram-positive, spore-forming bacterium usually spread by the fecal-oral route. Patients with recurrent CDI have been observed to have reduced diversity of the intestinal microbiome and diminished numbers of bacteria relative to healthy individuals that can cause disease asymptomatic carriage, mild diarrhea, colitis, or pseudomembranous colitis.

According to the American Journal of Gastroenterology (AJG) Clostridium difficile infection is a leading cause of hospital-associated gastrointestinal illness. Patients typically have extended lengths-of-stay and CDI is a frequent cause of large hospital outbreaks of disease.

Fecal microbiota transplant (FMT) is the term used when stool is taken from a healthy individual and instilled into a sick person with certain conditions, such as recurrent CDI. Studies show that patients with recalcitrant CDI have abnormally proportioned colon microbiota and that reintroduction of normal bacteria via donor feces corrects this imbalance and breaks the cycle of CDI recurrence. The purpose of FMT treatment is based on the premise that an imbalance in the community of microorganisms residing in the gastrointestinal (GI) tract is associated with specific disease states, including susceptibility to infection. In its healthy state, intestinal microbiota performs a variety of useful functions including aiding in the digestion of carbohydrates, repressing the growth of pathogenic microbes, mediating the synthesis of certain vitamins, and stimulating the lymphoid tissue to produce antibodies to pathogens.

FMT may be administered by oral capsules, colonoscopy, retention enema, or through a nasojejunal (NJ)/nasoduodenal (ND) tube in the upper GI tract. The choice of the delivery route depends in part on patient preferences, individual risk, cost, availability of resources and expertise.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans considers fecal microbiota transplantation including capsulized, frozen and suspension (via rectal enema), medically necessary for treatment of patients with recurrent *Clostridium difficile* infection when the following criteria are met:

For Mild Disease:

- A. At least 2 episodes of recurrent mild to moderate CDI* and failure of a 6-8 week taper with vancomycin with or without an alternative antibiotic (e.g., rifaximin, nitazoxanide, metronidazole, vancomycin); **and**
- B. Persistent positive stool *C. difficile* toxin by testing

For Moderate to Severe Disease:

- A. Persistent positive stool *C. difficile* toxin by testing and
- B. At least **one** of the following:
 - i. Moderate CDI not responding to standard therapy (vancomycin) for at least 10 days.
 - ii. At least two episodes of recurrent severe CDI# resulting in hospitalization and associated significant morbidity, including renal failure.

For Fulminant Disease:

- A. Severe fulminant *C. difficile* colitis with no response to standard therapy after 48 hours.

*Patients with moderate clinical disease have frequent loose, bloody stools (>4 per day), mild anemia not requiring blood transfusions, and abdominal pain that is not severe. Patients have minimal signs of systemic toxicity, including a low-grade fever. Adequate nutrition is usually maintained, and weight loss is not associated with moderate clinical disease.

#Patients with a severe clinical presentation typically have frequent loose, bloody stools (≥6 per day) with severe cramps and evidence of systemic toxicity as demonstrated by a fever (temperature ≥37.5°C), tachycardia (HR ≥90 beats/minute), anemia (hemoglobin <10.5 g/dL), or an elevated ESR (≥30 mm/hour). Patients may have rapid weight loss.

U of U Health Plans considers fecal microbiota transplantation investigational/experimental in all other circumstances.

U of U Health Plans does NOT cover Rebyota™ suspension as current evidence is insufficient to show superiority to standard fecal microbiota preparations.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

A 2017 systematic review (Quraishi et al) investigated the effect of FMT in patients with recurrent or refractory CDI. In the pooled analysis, 92% of patients had a resolution of CDI (95% CI, 89% to 94%); heterogeneity was classified as likely moderate ($I^2=59\%$). Additionally, in the 7 trials that evaluated FMT, the intervention overall was associated with an increase in the resolution of recurrent and refractory CDI (relative risk, 0.23; 95% CI, 0.07 to 0.80). The 30 case series reported resolution rates for CDI ranged from 68% to 100%. The reviewers considered the RCTs as having a low risk of bias for adequate randomization with allocation concealment and intention-to-treat analysis. Nor did they report an assessment of bias in terms of blinding, sample size adequacy, or possible differences in baseline characteristics. However, they disputed that none of the trials demonstrated the efficacy of FMT as being truly placebo-controlled, and the case series followed patients until resolution of CDI (10 weeks to 8 years), though some had an insufficient follow-up.

In another 2018 meta-analysis (Khan et al.) researched the literature of pooled data on the use of FMT as a treatment option for recurrent CDI. Reviewers only selected randomized controlled trials that compared FMT (fresh or frozen) with medical treatment. Among the selected studies, there was a non-significant trend toward the resolution of diarrhea following a single fresh FMT infusion compared with frozen FMT or medical treatment (odds ratio, 2.45; 95% CI, 0.78 to 7.71; $p=0.12$, $I^2=69\%$), but different forms and routes of FMT administration were shown to be equally efficacious. In conclusion, FMT is a promising treatment modality for recurrent CDI. However, the authors found limited data for the variability of FMT dose usages, small trial populations and time frames to assess the success or failure of treatment.

In 2019, a third meta-analysis (Tariq et al) evaluated the efficacy of FMT as a treatment option for recurrent CDI on the basis of results from open-label studies and placebo controlled clinical trials. The authors wanted to investigate their observations on FMT cure rates for CDI being high in observational studies (e.g., >90%) but then appear to be consistently lower in open-label studies and clinical trials. Thirteen studies were included for evaluation, including six placebo-controlled RCTs and seven open-label studies. Out of 610 patients receiving FMT, 439 patients achieved clinical cure (76.1%; 95% confidence interval [CI]: 66.4% to 85.7%); study heterogeneity was significant ($I^2=91.35\%$). Cure rates were found to be lower in randomized trials (139/216, 67.7%; 95% CI: 54.2% to 81.3%) vs open-label studies (300/394, 82.7%; 95% CI: 71.1% to 94.3%; $p < 0.001$). Subgroup meta-analysis by FMT route of administration indicated lower cure rates with enema than colonoscopy (66.3% vs 87.4%; $p < 0.001$).

However, no differences between colonoscopy and oral delivery were detected (87.4% to 81.4%; $p=0.17$). Lower cure rates were observed for studies that included both recurrent and refractory CDI than those that only included patients with recurrent CDI (63.9% vs 79%; $p < 0.001$). The authors concluded that colonoscopy and oral route are more effective than enema for stool delivery and the efficacy seems to be higher for recurrent than for refractory CDI.

A recent UpToDate (2020) review summarizes FMT as an effective treatment for recurrent (≥ 3 recurrences) CDI. The authors concluded that transplantation of stool microbiota from healthy individuals to patients with recurrent CDI can break the cycle of CDI recurrence. In addition, the initial results from the FMT National Registry published in *Gastroenterology* 2021 showed a 1 month cure rate of over 90% in 200 patients who received just 1 FMT. At a 6 month follow-up, only 4% of patient had a recurrence of CDI and less than 1% had a complication of treatment includes IBS or newly diagnosed IBD. However, to minimize risk of infection, rigorous screening of potential healthy stool donors for occult pathogens must be done. The optimal approach for administration is uncertain. If feasible oral capsules should be tried first, then colonoscopy followed by enema retention and finally NJ or ND tube for patients who cannot undergo FMT via the alternate routes.

In 2022, Hayes completed a health technology assessment of fecal microbiota transplantation for the treatment of Crohn Disease (CD). The assessment determined that “A very low-quality body of evidence is insufficient to draw conclusions regarding the efficacy of FMT to help patients with CD achieve or maintain remission, but it does suggest that the procedure is safe in this population. A single comparative study evaluated FMT versus placebo transplant, which found no statistically significant benefit in efficacy with FMT. No other active- or sham-controlled trials were identified. The other 2 comparative studies in this evidence base lacked appropriate comparator or control groups and evaluated variations in FMT administration approaches and timing of treatment. Pretest-posttest studies found some improvements from baseline in efficacy outcomes. Substantial uncertainty remains regarding the extent of the benefits, which patients might benefit from the treatment, optimal treatment parameters, and whether there is long-term benefit.” In a 2024 annual review of abstracts for this report, Hayes only found 1 newly published (2022) retrospective cohort study which met the inclusion criteria. However, there was no new evidence with longer-term follow-up and no new applications of the technology since publication of the 2022 Health Technology Assessment

In 2016, the U.S. Food and Drug Administration (FDA) issued an updated draft guidance on enforcement policy regarding investigational new drug requirements for use of FMT to treat CDI not responsive to standard therapies. The draft guidance is similar to the 2013 guidance and states that the FDA is continuing to consider how to regulate FMT and that, during this interim period, the agency will use enforcement discretion regarding the use of fecal transplant to treat treatment-resistant CDI. The FDA requires that physicians obtain adequate informed consent from patients or their legal representative before performing the intervention. The document also stated that selective enforcement does not apply to the use of fecal transplant for treating conditions other than treatment-resistant CDI.

In 2019, the FDA issued a safety regarding the use of FMT due to the potential risk of serious adverse reactions or life-threatening infections caused by due to the transmission of multi-drug resistant organisms (MDROs). Two immunocompromised individuals received investigational FMT and developed invasive infections caused by the transmission of extended-spectrum beta-lactamase-producing *Escherichia coli*. One of the affected individuals died. The donor stool used in each patient's FMT procedures had not been tested for extended-spectrum beta-lactamase (ESBL)-producing gram-negative organisms prior to use. Follow-up testing verified donor stool was positive for MDROs identical to the organisms isolated from the two patients. Due to these events, the FDA has determined that the following additional protections are required for any investigational use of FMT:

- 1) Donor screening that specifically addresses risk factors for colonization with MDROs and exclusion of individuals at higher risk of colonization with MDROs such as health care workers, persons who have recently been hospitalized or discharged from long-term care facilities, persons who regularly attend outpatient medical or surgical clinics, and persons who have recently engaged in medical tourism.
- 2) MDRO testing of donor stool and exclusion of stool testing positive for MDROs. At the minimum, tests should include: extended-spectrum beta-lactamase-producing enterobacteriaceae, vancomycin-resistant enterococci, carbapenem-resistant enterobacteriaceae and methicillin-resistant *Staphylococcus aureus*.
- 3) All FMT products currently in storage for future use must be quarantined until donor MDRO carriage risk can be assessed and FMT products are tested and found negative for MDROs.
- 4) The informed consent process for FMT treatment subjects should describe the risk of MDRO transmission and infection and the measures being implemented for donor screening and stool testing.

Lastly, the American College of Gastroenterology (2021) published guidelines on diagnosis, treatment, and prevention of CDI. The guidelines addressed fecal microbiota transplant for treatment of three or more CDI recurrences, as follows: "For the treatment of one to two CDI recurrences, the guidelines recommend: tapering/pulsed-dose vancomycin for patients experiencing a first recurrence after an initial course of fidaxomicin, vancomycin, or metronidazole (strong recommendation, very low quality of evidence). In addition, Fidaxomicin for patients experiencing a first recurrence after an initial course of vancomycin or metronidazole. FMT be considered for patients with severe and fulminant CDI refractory to antibiotic therapy, in particular, when patients are deemed poor surgical candidates." In addition, fecal transplant is now recommended to be an important treatment consideration for refractory antibiotic resistant CDI for patients who have underlying ulcerative colitis (UC) given the risk of exacerbation of the patient's underlying UC and the risk of complications from fulminant CDI in this particular patient population.

The Infectious Diseases Society of America and Society for Healthcare Epidemiology of America updated their clinical practice guidelines in 2018 for the diagnosis and treatment of CDI in children and adults. For pediatric patients fecal microbiota transplantation may be used after multiple recurrences of CDI following standard antibiotic treatments, this is considered a weak recommendation with very low quality of evidence. In adult patients, fecal microbiota transplantation is strongly recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments as there is moderate quality of evidence.

No recommendations were found from the U.S. Preventive Services Task Force.

Applicable Coding

CPT Codes

Possibly Covered CPT Codes

0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
44799	Unlisted procedure, small intestine

HCPCS Codes

Possibly Covered HCPCS Codes

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

Non-Covered HCPCS Codes:

J1440 Fecal microbiota, live - jslm, 1 ml (**Rebyota™ suspension**)

ICD-10 Codes

A04.7 Enterocolitis due to *Clostridium difficile*

A04.71 Enterocolitis due to *Clostridium difficile*, recurrent

A04.72 Enterocolitis due to *Clostridium difficile*, not specified as recurrent

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