

Fecal Microbiota Transplantation SRG-007

Iowa Medicaid Program:	Prior Authorization	Effective Date:	3/21/2018
Revision Number:	7	Last Rev Date:	1/19/2024
Reviewed By:	Medicaid Medical Director	Next Rev Date:	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	Approved Date:	6/21/2019

Descriptive Narrative

Recurrent *Clostridioides* (formerly *Clostridium*) *difficile* infection (CDI) is defined by complete abatement of symptoms while on appropriate therapy, followed by reappearance of symptoms within 2 to 8 weeks after treatment has been stopped. Recurrent CDI occurs in 10 to 25 percent of members treated with antimicrobial therapy.

Recurrence of CDI is an increasing problem following antimicrobial therapy. Members with recurrent CDI have been observed to have reduced diversity of the intestinal microbiome and diminished numbers of bacteria relative to healthy individuals. Transplantation of stool microbiota from healthy individuals to members with recurrent *C. difficile* can restore these missing strains and break the cycle of CDI recurrence.

Fecal microbiota transplantation (FMT) (instillation of processed stool collected from a healthy donor into the intestinal tract of a member with recurrent CDI) is effective for treatment of recurrent CDI. FMT protocols may vary between institutions.

FMT may be administered via any of the following methods:

- Oral capsules,
- Lower gastrointestinal (GI) tract procedure (colonoscopy, retention enema), or
- Upper GI tract procedure (nasojunal/nasoduodenal tube).

The optimal approach to FMT administration is uncertain.

Criteria

Prior authorization is required.

Fecal transplantation may be medically necessary when **ALL** the following are met:

1. Infection confirmed by a positive stool test for CID; **AND**
2. There have been at least three episodes of recurrent CID and associated diarrhea refractory to antibiotic therapy; **AND**
3. Member is not immunocompromised, including:
 - a. Members on major immunosuppressive agents such as high-dose corticosteroids or chemotherapeutic antineoplastic agents; **AND**
 - b. Members with decompensated liver cirrhosis, advanced HIV/acquired immune deficiency syndrome, recent bone marrow transplant, or other cause of severe immunodeficiency

Repeat fecal transplantation may be considered medically necessary if the member continues to meet the above criteria.

Fecal transplantation is considered **investigational** for any other indication not listed above.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen.
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen.
44799	Unlisted procedure, small intestine (for instillation of specimen by nasogastric tube).

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. 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. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

Fecal microbiota transplantation for treatment of recurrent Clostridioides (formerly Clostridium) difficile infection, UpToDate.

Guidelines for Diagnosis, Treatment, and Prevention of Clostridium difficile Infections, American College of Gastroenterology, 2013.

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) 2/15/2018.


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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) CID 2018:66 (1 April).


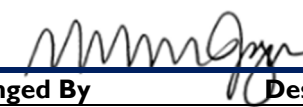

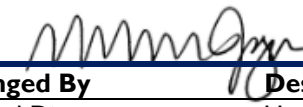
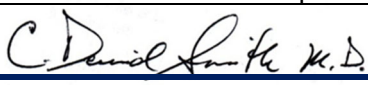
Krishna Rao and Vincent B. Young, Fecal Microbiota Transplantation for the Management of Clostridium difficile Infection Infect Dis Clin North Am. 2015 March ; 29(1): 109–122. doi:10.1016/j.idc.2014.11.009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			
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Signature			
Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual review.	7
Signature			
William (Bill) Jagiello, DO			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/20/2023	CAC	Annual review – added codes 44705 and 44799.	6
Signature William (Bill) Jagiello, DO 			
1/21/2022	CAC	Annual review. Formatting changes.	5
Signature William (Bill) Jagiello, DO 			
1/15/2021	CAC	Annual review.	4
Signature William (Bill) Jagiello, DO 			
5/15/2020	CAC	Narrative Description was rewritten, criteria was amended, repeat treatment criteria added.	3
Signature William (Bill) Jagiello, DO 			
3/7/2019	Medical Director	Updated treatment.	2
Signature C. David Smith, MD 			
7/17/2015	CAC	Added paragraph in References.	1
Signature			