Fecal Microbiota Transplantation
SRG-007

Iowa Medicaid Program	Prior Authorization	**Effective Date**	03/21/2018
Revision Number	8	**Last Reviewed**	01/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	01/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	06/21/2019

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.

The efficacy for one FMT is approximately 50 percent. increases to 75 percent for two FMT administrations and approximately 90 percent for more than two FMT administrations. However, despite this, the US Food and Drug Administration generally recommends only a single administration.

Alteration of the colonic microbiota following FMT appears to be durable. Two studies demonstrated durable cure around 80% in 1-2 years following treatment.

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 (nasojejunal/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; **OR**
   b. Members with decompensated liver cirrhosis, advanced HIV/acquired immune deficiency syndrome, recent bone marrow transplant, or other cause of severe immunodeficiency; **OR**
   c. Presence of inflammatory bowel disease

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/CPT code is inappropriate.

HCPCS/CPT	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

Borody T. Ramrakha S. Fecal microbiota transplantation for treatment of Clostridioides difficile (formerly Clostridium) infection. UpTodate. Topic last updated: March 19, 2024. Accessed November 8, 2024.

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Clostridioides difficile: Facts for Clinicians. Center for Disease Control and Prevention. March 5, 2024.

McDonald LC. Gerding DN. Johnson S. et al. Clinical Practice Gudelines foe Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Disease Society of America ((IDSA) and the Society for Healthcare Epidemiology of America (SHEA). ISDA Guideline for Clinical Infectious Diseases. Clinical Infectious Diseasers 2018:66 (1 April).

Kelly CR. Monika F. Allegretti JR et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. American Journal of Gastroenterology 116(6): p 112401147, June 2021.

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
[mm/dd/yyyy]			[#]
Signature			

Change Date	Changed By	Description of Change	Version
01/17/2025	CAC	Annual Review. Updated Descriptive Narrative and References sections. Added 3c and “OR” to 3 a & b in Criteria section.	8
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/19/2024	CAC	Annual Review.	7
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/20/2023	CAC	Annual review – added codes 44705 and 44799.	6
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/21/2022	CAC	Annual review. Formatting changes.	5
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Change Date	**Changed By**	**Description of Change**	**Version**
01/15/2021	CAC	Annual Review.	4
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
05/15/2020	CAC	Narrative Description was rewritten, criteria was amended, repeat treatment criteria added.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
03/07/2019	Medical Director	Updated treatment.	2
Signature C. David Smith, MD			
Change Date	**Changed By**	**Description of Change**	**Version**
07/17/2015	CAC	Added paragraph in References.	1
Signature			

CAC = Medicaid Clinical Advisory Committee