CareSource

MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Policy Name	Policy Number	Date Effective
Fecal Microbiota Installation	MM-1066	12/01/2021-07/31/2022

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Fecal Microbiota for Installation, Including Assessment of Donor Specimen

B. Background

Fecal Microbiota Transplantation is the transplantation of fecal bacteria from a healthy donor into the gastrointestinal tract of an individual recipient for the treatment of recurrent Clostridium difficile infection. It can result in mild diarrhea to life threatening fulminant pseudomembranous colitis. Often it affects older adults and may occur because of antibiotic therapy which disrupts the normal bacterial flora in a health gastrointestinal tract. It the cessation of antibiotic therapy does not restore normal colonic flora, the introduction of healthy bacterial flora via FMT is suggested.

FMT is typically performed by a gastroenterologist. The procedure involves the instillation of a solution from a healthy donor's fecal matter and is delivered via a nasogastric tube, retention enema, or colonoscope. The clinical goal of FMT is to replenish the healthy gut microflora to reconstitute natural intestinal defenses against C. difficile.

C. Definitions

Clostridium Difficile – (C-diff), a bacterium that causes diarrhea and more serious intestinal conditions. It is a part of the normal balance of bacteria living in the intestines and is also present in the environment.

- **Fecal Microbiota Transplant (FMT)** A procedure that involves the instillation of a solution derived from a health donor's fecal matter.

D. Policy

I. Fecal Microbiota for Installation is covered without prior authorization when
   A. There has been three or more episodes of recurrent c-diff infection as confirmed by positive stool cultures.
   B. The episode of diarrhea is refractory to appropriate antibiotic treatment protocol, including at least one regimen of pulsed vancomycin.

   C. Procedure should be performed in a tertiary care center

II. FMT is considered not medically necessary for any condition other than those listed above. Specific examples of conditions that are excluded include, but are not limited to:
   A. Colon cancer
   B. Crohn's disease
   C. Graft-versus-host disease of the gut
   D. Inflammatory Bowel Diseases
   E. Insulin resistance

F. Metabolic Sclerosis
G. Obesity
H. Parkinson's Disease
I. Pouchitis
J. Ulcerative Colitis

E. Conditions of Coverage-N/A

F. Related Policies/Rules-N/A

G. Review/Revision History

DATE		ACTION
Date Issued	08/19/2020	
Date Revised	07/07/2021	Reviewed ref erences
Date Effective	12/01/2021	
Date Archived	07/31/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Indiana Health Coverage Programs, IHCP Banner Page BR202021. 26 May 2020 Retrieved May 18, 2021 from www.in.gov
2. Center for Disease Control and Prevention (CDC). Healthcare Associated infections: Clostridium Difficile. 23 September 2015. Retrieved June 22, 2021 from www.cdc.gov
3. Wang JW, Kuo FC, Wang YK, Hsu WH, Yu FJ, Hu HM, Hsu PI, C.Fecal Microbiota Transplantation: Review and Update. Journal of Formosan Medical Assoc. 1181 (1) March 2019, 523-531. Retrieved May 24, 2021.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

IN-MED-P-764100 Issue Date 09/19/2020 Approved OMPP 09/27/2021