BENEFIT COVERAGE POLICY

Title: BCP-69 Fecal Bacteriotherapy

Effective Date: 01/01/2022

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials including coverage policies.
- The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan covers fecal bacteriotherapy (fecal microbiota transplantation and capsulized fecal microbiota transplantation).

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

2.0 Background:

Fecal bacteriotherapy (FB), also known as fecal microbiota transplantation (FMT), fecal transplant, fecal transfusion, and probiotic infusion, is the transfer of a liquid suspension of stool from a healthy donor to the patient and is proposed for the treatment of Clostridium difficile infection (CDI), which can result in mild diarrhea to life-threatening fulminant pseudomembraneous colitis. Treatment involves discontinuation of the offending antibody and oral administration of metronidazole or vancomycin. In some cases, patients non-responsive to medical management are treated by surgical colectomy, which has a mortality rate of 35% to 57%. One of the risks with FMT is the transfer of contagious agents (e.g., fungi, parasites, and viruses) from the donor.

Approximately 20% of patients with CDI will have multiple recurrences; persistent CDI causes chronic debilitating symptoms, including toxic megacolon, septic shock, and death. One of the more controversial of such alternative treatments is FMT. Although the notion of FMT is foreign -- even startling -- and not esthetic to most people, the concept has been around for many decades. Its benefit and effectiveness dates back more than 50 years to its use for staphylococcal pseudomembranous colitis, and now FMT is showing great promise as an inexpensive, safe, and highly efficient treatment for recurrent and refractory CDI.

Fecal bacteriotherapy is currently being used as a last resort therapy for patients with severe recurrent and refractory C. difficile-associated disease (CDAD). The procedure involves the instillation of a solution derived from a healthy donor's fecal matter via a nasogastric tube, retention enema, or

colonoscope. The clinical goal of fecal bacteriotherapy is to replenish the healthy gut microflora to reconstitute natural intestinal defenses against C. difficile.

The fecal bacteriotherapy procedure involves collection of fecal samples from a healthy donor, usually a family member. Immunological matching is not necessary as it is with blood transfusion or organ transplant. Only recently have donor screening protocols been implemented. However, donor health history and screening of donor's blood and fecal samples are necessary. Donors must not have a history of gastrointestinal problems, colon polyps or malignancy, recent antibiotic treatment, bowel surgery, systemic autoimmunity, metabolic syndrome, or extensive travel. Laboratory screening of donor fecal samples includes intestinal pathogens, ova and parasites, and C. difficile. Donor blood is tested for chronic viral infections (e.g., hepatitis, HIV, cytomegalovirus, Epstein-Barr).

Although the impact of the recent FDA approval of Dificid (fidaxomicin) as a treatment for CDAD is not yet known, fecal bacteriotherapy is expected to continue to be investigated and applied as a therapy for patients with recurrent and severe CDAD.

A. Covered for the following:
    1. Diagnostic testing confirms diagnosis of Clostridium difficile; AND
    2. Recurrent or relapsing C. difficile infection (CDI) defined as one of the following:
        a. At least three episodes of mild to moderate CDI and failure of a six to eight-week taper with vancomycin; OR
        b. At least two episodes of severe CDI resulting in hospitalization and associated with significant morbidity; OR
    3. Moderate CDI not responding to standard therapy (vancomycin) for at least a week; OR
    4. Severe or fulminant C. difficile colitis with no response to standard therapy after 48 hours.
B. Cost of testing donor specimen is included in the CPT code for procedure.
C. Fecal bacteriotherapy for all indications not defined above is considered experimental, investigational or unproven. This includes, but is not limited:
    1. Crohn's disease.
    2. Idiopathic thrombocytopenic purpura.
    3. Inflammatory bowel diseases.
    4. Insulin resistance.
    5. Irritable bowel syndrome.
    6. Metabolic syndrome.
    7. Multiple sclerosis.
    8. Ulcerative colitis.

3.0 Clinical Determination Guidelines:

None.

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union Only; 8 = ASO group L0002184.

COVERED CODES

Code	Description	Prior Approval	Benefit Plan Cost Share Reference
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen	N	Professional fees for surgical and medical services.
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen	N	Professional fees for surgical and medical services

COVERED PRIMARY ICD-10 DIAGNOSIS CODES	
Code	**Description**
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent
Fecal bacteriotherapy is considered experimental and investigational for all other diagnoses and not a covered benefit.	

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 Terms & Definitions:

Clostridium difficile – Bacterium in the gut, with overgrowth releases toxins that attack the lining of the intestines, causing a condition called Clostridium difficile colitis. C. diff is one of the most important causes of infectious diarrhea in the U.S. Symptoms can be mild with watery diarrhea three or more times a day for several days, with abdominal pain or tenderness. More severe cases can cause watery diarrhea up to 15 times a day, severe abdominal pain, loss of appetite, fever, blood or pus in the stool, and weight loss. Risk factors for C. diff. infection include:

- Surgery of the gastrointestinal (GI) tract.
- History of CDI within the previous six months.
- CDI with hyper-virulent strain: ribotypes 027, 078, 244
- Severe CDI at presentation: Shock, megacolon, perforation, acute renal failure
- Diseases of the colon such as inflammatory bowel disease or colorectal cancer.
- A weakened immune system.
- Use of chemotherapy drugs.
- Previous C. diff. infection.
- Age 65 or older.
- Kidney disease.
- Use of proton-pump inhibitors, which lessen amount of stomach acid.

7.0 References, Citations & Resources:

1. Infectious Disease Society of America (ISDA). Fecal microbiota transplantation. Investigational new drug protocol. 2016. Accessed Sep 18, 2019. Available at URL address: http://www.idsociety.org/FMT/.

2. U.S. Food and Drug Administration (FDA). Enforcement policy regarding investigational new drug requirements for use of fecal microbiota for transplantation to treat Clostridium difficile infection not

responsive to standard therapies. Mar 1, 2016. Accessed Sep 18, 2019. Available at URL address: http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM488223.pdf.

8.0 Associated Documents [For internal use only]:

None.

9.0 Revision History:

Original Effective Date: 08/01/2016

Next Review Date: 01/01/2023

Revision Date	Reason for Revision
July 2016	Policy created
July 2017	Annual review – converted from Medical Policy 035 to Benefit Coverage Policy format; added ICD-10 diagnoses which this procedure is considered Experimental/Investigational
April 2018	Annual review by QI/MRM due Aug. 2018. Initial review by BCC. Recommend removal of PA due to low utilization. Reformatted criteria from Sec. 3.0 to Sec.1.0. References updated.
9/19	Annual review; citations updated.
10/20	Annual review, no changes, approved at BCC 3/1/21
10/21	Annual review,no changes approved at BCC 12/6/2021