CLINICAL MEDICAL POLICY	
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
10/01/2025	Provider Effective date
08/12/2025	PARP Approval
06/18/2025	QI/UM Committee review
06/18/2025	Annual Review: No changes to clinical criteria. Updated 'Reference Sources' section.
09/01/2024	Provider Effective date
07/22/2024	PARP Approval
06/19/2024	QI/UM Committee review
06/19/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and
12/01/2023	Provider Effective date
08/08/2023	PARP Approval
06/21/2023	QI/UM Committee review
06/21/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2022	Provider Effective date
07/20/2022	PARP Approval
06/15/2022	QI/UM Committee review
06/15/2022	Annual Review: No changes to clinical criteria. Reformatted Procedure section numbering. Added TAG determination information. Added additional FDA COVID-19 information. Updated Summary of Literature and Reference Sources sections.
09/20/2021	Provider effective date

08/02/2021	PARP approval
06/16/2021	QI/UM Committee review
06/16/2021	Annual Review: Revised the wording of the coverage and medical necessity guidelines.
09/07/2020	Provider effective date
08/04/2017	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary fecal microbiota transplants in patients with recurrent Clostridium difficile infections.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.

Definitions

Prior Authorization Review Panel (PARP)– A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval, and denial of all PH-MCO Prior Authorization policies and procedures.

Clostridium Difficile Infection (CDI) – 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 (e.g., in soil, in water, and in animal feces).

Fecal Microbiota Transplantation (FMT) – A procedure that involves the instillation of a solution derived from a healthy donor's fecal matter. The instillation occurs via nasogastric tube, retention enema, colonoscope, and oral capsules.

Procedures

1. Fecal microbiota transplant (FMT) is considered medically necessary for individuals with current or relapsing Clostridium difficile infection (CDI) when ALL of the following criteria are met:
    A. There is documentation which confirms CDI by a positive stool test; AND
    B. An appropriate donor screening following the FDA guidelines for biologic donors has been completed; AND
    C. The individual has experienced ANY ONE of the following conditions:
        a) At least three (3) episodes of mild to moderate CDI; OR
        b) Recurrent or relapsing CDI with ONE of the following:
            i. Documented failure of a 6- to 8-week taper with vancomycin, with or without an alternative antibiotic (e.g., rifaximin, nitrazoxaide); OR
            ii. At least two episodes of severe CDI resulting in hospitalization and associated significant morbidity; OR
        c) Moderate CDI that is not responding to standard therapy for at least one week; OR
        d) Severe fulminant C. difficile colitis with no response to standard therapy after 48 hours.

    Note: HCPCS code G0455 (*preparation with instillation of fecal microbiota by any method, including assessment of donor specimen*) requires a Program Exception. The ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

    Note: A second FMT may be considered medically necessary when the provider indicates the initial FMT was unsuccessful.

2. Contraindications
   Healthcare providers should exercise caution in utilizing FMT in patients with ANY of the following:
   - Suppressed immune system
   - Currently receiving chemotherapy
   - Decompensated liver cirrhosis, advanced HIV/AIDS, recent bone marrow transplants
   - Toxic megacolon
   - Pregnancy

3. Fecal microbiota transplants are considered not medically necessary for any other condition than those listed above including but not limited to: inflammatory bowel disease, autoimmune disorders, allergic diseases, and hepatic steatosis, and hepatic encephalopathy, neurological and metabolic disorders.

   Any requests for FMT approval that does not meet the guidelines listed above will require a review by a Medical Director on a case-by-case basis.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The proper place of service for FMT is in the outpatient setting.

Governing Bodies Approval

In May 2013, the FDA classified FMT as an Investigational New Drug (IND). Using this classification, the FDA would regulate fecal microbiota, which would require every provider to file an IND application. Physicians must also obtain an adequate informed consent from the patient or legal representative. The legal consent must contain, at a minimum, a statement that the use of FMT products to treat CDI is investigational and a discussion of the therapy's potential risks and alternative options.

In July 2013, the FDA issued guidance stating that it would exercise "enforcement discretion." This would allow physicians to provide FMT (for patients with C. difficile infections not responding to standard therapies) without filing an IND application. Until FMT is formally approved, the use of this procedure is restricted to the treatment of recurring Clostridium difficile. If the provider wishes to utilize FMT for any other indication, an IND application must be filed with the FDA.

In March 2014, the FDA released draft guidance, for public feedback only, concerning two proposed changes to the current approval. The first change is that the donor be "known" to the patient or physician and second, that all donor and stool screening be conducted under the supervision of the physician performing the FMT. Medical professional societies raised concerns regarding the potential to compromise access and safety. In March 2016, the FDA revised draft guidance to propose that enforcement discretion be narrowed so that physicians who obtain material from stool banks to treat CDI that is nonresponsive to standard therapy would need to do an IND application. The FDA requested

feedback on how to implement this proposal so that guidance does not create undue burdens for physicians. There has not been any further published guidance by the FDA.

On March 23, 2020, the FDA issued a safety alert to inform health care providers and patients of the potential risk of transmission of SARS-CoV-2 by FMT. SARS-CoV-2 is the virus that causes the respiratory disease, COVID-19. The following additional protection guidelines have been issued by the FDA:

- No clinical use of FMT product manufactured from stool donated on or after December 1, 2019, until additional screening and testing procedures and changes to the informed consent process are implemented for such stool donations as described below:
    - Stool donor screening, including an assessment of whether, since December 1, 2019, the donor was diagnosed with laboratory-confirmed SARS-CoV-2 infection, experienced symptoms of COVID-19 (e.g., fever, cough, shortness of breath) not explained by another diagnosis, or was exposed to a suspected or confirmed case of COVID-19 or SARS-CoV-2 infection.
        - In any instances of suspected or confirmed SARS-CoV-2 infection or exposure as described above, exclusion of the donor from further donations and exclusion from clinical use of any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the suspected or confirmed SARS-CoV-2 infection or exposure.
    - Testing of the stool donation or stool donor for SARS-CoV-2 virus or RNA
        - Testing approaches might include testing upper respiratory specimens (e.g., nasal swabs) or other specimens (e.g., rectal swabs or stool donations).
        - If SARS-CoV-2 is detected, exclusion of the donor from further donations and exclusion from clinical use of any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the first positive test.
    - As part of the informed consent process, conveying to the FMT recipient that healthy, asymptomatic stool donors may potentially be infected with SARS-CoV-2, describing the testing approach and other strategies used to mitigate the risk of SARS-CoV-2 transmission, and advising the FMT recipient of the limitations of testing and risk mitigation strategies (FDA, 2020).

CMS

There are no CMS National Coverage Determinations (NCD), or Local Coverage Determinations (LCD) located during the development of this medical policy.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

On March 2013, the TAG workgroup assigned fecal microbiota transplant an Option # 3, specifically for HCPCS code G0455.

Program Exception
HCPCS code G0455 requires a Program Exception. The ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

Clostridium difficile is an anaerobic, spore-forming bacillus that is responsible for a spectrum of gastrointestinal illnesses ranging from asymptomatic carriage to toxic megacolon and death. Clostridium difficile infection (CDI) is a disease defined as the acute onset of diarrhea in a patient with documented toxigenic C. difficile or C. difficile toxin, without any other clear cause of diarrhea. The prevalence of CDI is increasing in both hospitalized and community-based inflammatory bowel disease patients.

The incidence of CDI remained static until the mid- to late-1990s. Since 2000, several reports have been issued on the increased incidence and severity of this disease (Warny, 2005). It has been noted that there is an increase in the community-acquired CDI, but reports suggest that this is likely due to underdiagnosed conditions due to the lack of awareness of CDI outside the hospital setting.

It is not clear what causes the C. difficile overgrowth. It appears that there is a disruption of the normal colonic flora, which occurs most often following the administration of oral, parenteral, or topical antibiotics. CDI is treated with antibiotic therapy, but symptoms recur in up to 35% of patients, and up to 65% of patients with recurrence develop a chronic recurrent pattern of CDI (Gough et al., 2011).

According to the Centers for Disease Control and Prevention, C. difficile was estimated to cause nearly half a million infections in the United States, and 29,000 people died within 30 days of the initial diagnosis. Those at more risk for acquiring C. difficile are the elderly, young children, and those who have illnesses or conditions that require prolonged use of antibiotics. CDI is a costly bacterial illness in hospitalized patients, involving 1% of hospital stays in the United States. The aggregate cost is $8.2 billion annually (Lucado et al., 2013).

The American College of Gastroenterology (ACG) recommends that FMT should be considered second-line therapy for a third recurrence of CDI. The ACG published a guideline on diagnosis, treatment, and prevention of CDIs. The guideline addressed FMT for treatment of three or more CDI recurrences, as follows:

- For treatment of one to two CDI recurrences, the guideline recommended that the first recurrence of CDI can be treated with the same regimen that was used for the initial episode. If severe, however, vancomycin should be used. The second recurrence should be treated with a pulsed vancomycin regimen. (Conditional recommendation, low-quality evidence).
- If there is a third recurrence after a pulsed vancomycin regimen, FMT should be considered. (Conditional recommendation, moderate-quality evidence) (Surawicz et al., 2013).

The American Gastroenterology Association (AGA) refers physicians to working group guidelines that also recommend consideration of FMT following three failed rounds of antibiotic (Kelly et al. 2015).

The Infectious Diseases Society of America (IDSA) has stated that FMT has been shown to be a superior therapeutic modality for the treatment of recurrent CDI and recommends the procedure in patients with

mild to moderate recurrent CDI (Moore, Rodriguez and Bakken, 2013).

The IDSA & the Society for Healthcare Epidemiology of America (SHEA) has provided published recommendations on the best treatment for recurrent CDI:

1. Treat a first recurrence of CDI with oral vancomycin as a tapered and pulsed regimen rather than a second standard 10-day course of vancomycin, OR
2. Treat a first recurrence of CDI with a 10-day course of fidaxomicin rather than a standard 10-day course of vancomycin, OR
3. Treat a first recurrence of CDI with a standard 10-day course of vancomycin rather than a second course of metronidazole if metronidazole was used for the primary episode.
4. Antibiotic treatment options for patients with >1 recurrence of CDI include oral vancomycin therapy using a tapered and pulsed regimen, a standard course of oral vancomycin followed by rifaximin, or fidaxomicin.
5. Fecal microbiota transplantation is recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments.
6. There are insufficient data at this time to recommend extending the length of anti–*C. difficile* treatment beyond the recommended treatment course or restarting an anti–*C. difficile* agent empirically for patients who require continued antibiotic therapy directed against the underlying infection or who require retreatment with antibiotics shortly after completion of CDI treatment, respectively.

Patients who have failed to resolve recurrent CDI despite repeated antibiotic treatment attempts present a particularly difficult challenge. Clinical investigations of patients with recurrent CDI have shown significant disruption of the intestinal microbiome diversity as well as relative bacterial population numbers. Instillation of processed stool collected from a healthy donor into the intestinal tract of patients with recurrent CDI has been used with a high degree of success to correct the intestinal dysbiosis brought about by repeated courses of antibiotic administration. Anecdotal treatment success rates of fecal microbiota transplantation (FMT) for recurrent CDI have been high regardless of route of instillation of feces, and have ranged between 77% and 94% with administration via the proximal small bowel; the highest success rates (80%–100%) have been associated with instillation of feces via the colon (IDSA & SHEA, 2018).

Research revealed that there are several relative contraindications and risks associated with FMT.
Relative contraindications include:

- History of major gastrointestinal surgery
- Metabolic syndrome
- Systemic autoimmune disorders (e.g., multiple sclerosis, connective tissue disease)
- Atopic diseases (e.g., eczema, eosinophilic disorders of the GI tract)

Risks in Fecal Microbiota Transplants:

- Transmission of infectious organisms contained in donor stool
- Allergic reaction to antigens in donor stool
- Enhanced colitis activity in patients with underlying irritable bowel disease
- Perforation with instillation (colonoscopy, nasogastric tube, or enema)
- Blood loss
- Theoretical increased risk of developing disease which may be related to donor gut bacteria (obesity/metabolic syndrome, autoimmune conditions, allergic/atopic disorders, neurologic

disorders, and malignancy).

Overall, FMT is extremely safe with no long-term side effects. There are few adverse events with FMT such as bloating, gas, cramping, and fever that may develop on the first night due to an immune response. Among adults with CDI that is recurrent or not responsive to treatment, the use of frozen compared with fresh FMT material did not result in a significantly lower rate of resolution of diarrhea, indicating that the use of frozen FMT material may be a reasonable treatment option for these patients, according to a study (Malani and Rao, 2016).

Donor screening is one of the most important steps for FMT. Stool can be obtained from a patient's related donor or an unrelated donor (universal healthy donor). All donors should be approved for stool donation and this process should be done voluntarily. Donor candidates should be fully informed of the benefits and harms of the donation and complete a written consent form. Donor's infectious, metabolic, and other pathologic conditions can be transferred to recipients (Gweon et al, 2022).

COVID-19 arising from the emergence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has rapidly progressed into a global pandemic. Emerging evidence shows that SARS-CoV-2 RNA and/or SARS-CoV-2 virus may be found in stools of infected individuals and viral RNA may remain positive in stools even when viral RNA in the respiratory tract is no longer detectable. These results suggest the possibility of transmission of SARS-CoV-2 via a fecal-oral route. International expert panels recommend that at least a nasopharyngeal swab and serology should be considered in potential FMT donors. Another expert opinion recommends that FMT should be delayed until COVID-19 is better controlled and may be performed only in cases of fulminant CDI without response to maximal combination therapy (Gweon et al, 2022).

Rationale
Van Nood et al. reported on a trial involving 43 patients that were 18 years of age and older who received FMT for recurrent CDI. The patients were randomized into one of three treatment groups:
1) FMT; 2) antibiotic therapy (Vancomycin); and 3) antibiotic (Vancomycin) and bowel lavage. There were a total of 16 patients in the FMT group, of which fifteen (94%) were cured. Thirteen were cured after a single infusion, two after a second infusion from a different stool donor. These patients showed increased fecal bacterial diversity, similar to that in the healthy donors. There was an increase in the Bacteroidetes species and Clostridium clusters IV and XIVa and a decrease in Proteobacteria species. For those patients that were assigned to antibiotics only (13 patients), only 4 (31%) were deemed cured. For those patients assigned to the antibiotics and bowel lavage, only 3 (23%) of the thirteen patients were cured.

An additional systematic review concluded results that found lower cure rates in randomized trials than in open-label and in observational studies (Tariq, R; et al, 2019). According to the systematic review, colonoscopies and oral route are more effective than enema for stool delivery and the efficacy seems to be higher for recurrent than for refractory CDI.

There is insufficient published evidence on the safety and efficacy of fecal transplant for treating conditions other than CDI. Thus, FMT is considered investigational and not medically necessary for all conditions other than recurrent CDI. The FMT has shown promise for Crohn's disease and ulcerative coloitis but modifying our intestinal microbiome could help address a broad variety of other conditions (Citroner, 2018).

Multiple clinical trials have reported the safety and efficacy of FMT for recurrent and refractory CDI. In a

recent systematic and meta-analysis of seven random controlled trials and 30 case series, FMT was superior to vancomycin therapy with resolution rates as high as 92% (Quraishi et al. 2017). The authors noted that there is no agreement as to acceptable donor characteristics /selection or the routes of delivery of FMT (via colonoscopy, retention enemas, oral capsules, NG tube instillation).

The C Diff Foundation has developed recommendations of the best treatments for recurrent CDI. FMT was given a strong recommendation with moderate quality of evidence for adult patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. The Foundation indicates that the use of FMT in pediatric patients with multiple recurrences of CDI following antibiotic treatments as a weak recommendation with very low quality of evidence.

A study published by the American Gastroenterological Association found that FMT cures nearly 80% of patients with severe or fulminant CDI (SFCDI) when utilized in a sequential manner. The study compared outcomes of hospitalized patients before and after implementation of an FMT program for SFCDI and investigated whether the changes could be directly attributed to the FMT program. A retrospective analysis of characteristics and outcomes of patients hospitalized for SFCDI (430 hospitalizations) at a single center was performed, from January 2009 through December 2016. The study compared CDI-related mortality within 30 days of hospitalization, CDI-related colectomy, length of hospital stay, and readmission to the hospital within 30 days before (2009–2012) vs after (2013–2016) implementation of the inpatient FMT program. The result was CDI-related mortality and colectomy were lower after implementation of the FMT program. Overall, CDI-related mortality was 10.2% before the FMT program was implemented vs 4.4% after. The FMT program significantly reduced CDI-related colectomy in patients with SFCDI (6.8% before vs 2.7% after; P = .041), in patients with fulminant CDI (15.7% before vs 5.5% after; P = .017), and patients with refractory SFCDI (31.8% vs 7.6%; P = .001) (Cheng, Phelps, Nemes, et al., 2020).

Vinta and colleagues (2017) reported the findings of a clinical trial involving 20 patients with ulcerative colitis who received FMT via colonoscopic delivery of 2-donor concentrate. No serious adverse events were noted. Seven patients achieved the primary outcome of clinical response by week 4. Three patients were in remission at week 1, and two of these patients achieved mucosal healing. There were three patients who required escalation of care. The authors concluded that colonoscopic FMT using a 20-donor fecal microbiota preparation (FMP) is safe and effective in achieving clinical response by week 4 in patients with active ulcerative colitis. It was noted that longer-term follow up and correlation with microbial parameters are needed to provide insight into factors influencing clinical outcomes.

Few studies have been reported on the efficacy of fecal transplant among pediatric patients. In 2018, the results of a prospective observational pilot study of 15 children, ages 21 months to 18 years, treated by fecal transplant for recurrent CDI (Fareed et al). The authors reported that fecal transplant successfully treated rCDI in all 15 children. There were three patients that received the transplant that continued to experience GI bleeding, however these patients had been diagnosed with underlying inflammatory bowel disease. While the remaining participants showed significantly increased Bacteroidetes levels, the three with underlying disease showed no difference.

One study from the Mayo Clinic looked at C. difficile infections, specifically in children. Of the estimated 13.7 million Children hospitalized from 2005 to 2009, the researchers found 46,176 children – 0.34 percent– had the infection. Children with the infection were of an average age of 3 years old. The researchers found children with C. difficile were hospitalized on average for six days compared to two days for children without the bacteria. Children with the infection were five times more likely to need a surgical procedure on their colon, called a colectomy, than were other hospitalized children. Children with

C. difficile were also more than twice as likely to need to be discharged to a long-term care facility and were more than 2.5 times as likely to die as were other hospitalized children.

Coding Requirements

Procedure Codes

CPT Code	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
44799	Unlisted procedure, small intestine
HCPCS Code	**Description**
*G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

***Requires a Program Exception with approval from a Medical Director on a case-by-case basis.*

Diagnosis Codes

ICD-10 Code	Description
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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