PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

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Business Unit: Utilization Management</td></tr>
<tr><td colspan="3">Policy/Procedure Title: Microbiota-Based Therapeutics (MBT)</td><td colspan="3">☒External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="2">Original Date: 05/17/2017</td><td colspan="4">Next Review Date: 06/10/2027
Last Review Date: 06/10/2026</td></tr>
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<tr><td rowspan="2">Reviewing Entities:</td><td colspan="2">☒ IQI</td><td>☐ P & T</td><td colspan="2">☒ QUAC</td></tr>
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<tr><td>☐ CEO</td><td>☐ COO</td><td>☐ CREDENTIALS</td><td colspan="2">☐ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="3">Approval Signature: Robert Moore, MD, MPH, MBA</td><td colspan="3">Approval Date: 06/10/2026</td></tr>
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I. RELATED POLICIES:

A. MCUP3041 Treatment Authorization Review (TAR) Review Process
B. MPUP3042 Technology Assessment
C. MCRP4068 Medical Benefit Medication TAR Policy

II. IMPACTED DEPTS:

A. Health Services
B. Claims
C. Member Services

III. DEFINITIONS:

A. Microbiota-Based Therapeutics (MBT) (including Fecal Microbiota Transplantation or [FMT]) – The transfer of a prepared microbial community, either derived from the processed stool of a healthy donor or synthesized from defined, lab-grown microbial consortia, to a recipient. The purpose of this therapy is to restore a healthy and diverse microbial ecosystem to the recipient's gastrointestinal tract. This procedure is also known as fecal biotherapy, fecal bacteriotherapy, stool or fecal transplant, fecal transfusion, fecal enema and human probiotic infusion.
B. *Clostridioides* (formerly *Clostridium*) *difficile* infection (CDI) - confirmed stool test positive for toxigenic *C. difficile* and patient currently has symptoms of watery diarrhea.
C. Non-severe CDI – CDI with documented White Blood Cell Count ≤15,000 cells/ml and serum creatinine <1.5 mg/dL. [E]
D. Severe CDI - CDI with WBC >15,000 cells/mL and/or serum creatinine ≥1.5 mg/dL. [E]
E. Complicated/fulminant CDI – CDI associated with hypotension or shock, ileus or megacolon. [E]
F. Recurrent or relapsing CDI (RCDI) – a second or greater episode of documented CDI.

IV. ATTACHMENTS:

A. N/A

V. PURPOSE:

The purpose of the MBT policy is to assist Utilization Management (UM) staff with decision making when reviewing Treatment Authorization Requests (TARs) for MBT to treat confirmed recurrent CDI that has failed standard CDI treatment.

VI. POLICY / PROCEDURE:

A. A Treatment Authorization Request (TAR) is required for all MBT procedures.
B. Partnership HealthPlan of California (Partnership) considers MBT medically indicated in cases of recurrent CDI as follows:
   1. Eligibility Criteria:

a. Member must be 18 years of age or older.
b. Documentation of current symptomatic recurrent CDI.
c. Documentation of at least a moderate **second or more** episode of RCDI (as defined above) which is a third episode or more of CDI, unresponsive to standard AND alternate treatments.
   1) MBT is no longer recommended as first line treatment for fulminant CDI.[E]
d. Patient is not immunocompromised (including neutropenia).
e. Severe or fulminant CDI in the hospital and the patient is not improving after completing standard antimicrobial therapy for CDI.
f. All other uses of MBT are considered experimental or investigational, including first line treatment of CDI and the treatment of inflammatory bowel disease.

2. Methodology
   a. MBT may be administered by colonoscopy, nasogastric or jejunal tube, enema, or oral route, as available from the provider performing the procedure.
   b. The provider performing the MBT and facility providing the transplant materials must comply with the U.S. Food and Drug Administration's regulations regarding MBT[A].

VII. REFERENCES:

A. U.S. FDA Vaccines, Blood and Biologics Bulletin- Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies November 2022
B. Ramrakha S, Agrawal G. Fecal microbiota transplantation for treatment of *Clostridioides difficile* infection; UpToDate. Last updated 04/09/2026.
C. Moore T, Rodriguez A, Bakken J. Fecal Microbiota Transplantation: A Practical Update for the Infectious Disease Specialist; Clin Infect Dis 2014 Feb 15; 58 (4) 541-545; doi.org/10.1093/CID/cit950
D. Cho, Janice M. *et al*. Update on Treatment of *Clostridioides difficile* Infection; Mayo Clin Proc. April 2020; 95(4): 758-769. https://www.mayoclinicproceedings.org/
E. Johnson, Stuart et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults *Clinical Infectious Diseases*, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, https://doi.org/10.1093/cid/ciab549
F. Consideration for Use of Fecal Microbiota-Based Therapies in Adults With GI Disorders. Gastroenterology, Volume 166, Issue 3, p.435. March 2024. DOI: 10.1053/S0016-5085(24)00075-1
G. Shapiro, M. (2024, February 21). AGA now recommends fecal microbiota transplant for the majority of recurrent C. diff patients. American Gastroenterological Association. https://gastro.org/press-releases/aga-recommends-fecal-transplant-for-recurrent-cdiff-patients/

VIII. DISTRIBUTION:

A. Partnership Provider Manual
B. Partnership Department Directors

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Officer

X. REVISION DATES:

Partnership Advantage (Program effective January 1, 2028)
06/11/25; 6/10/26

Medi-Cal
*06/13/18; 06/12/19; 06/10/20; 06/09/21; 06/08/22; 06/14/23; 06/12/24; (MPUP3136) 06/11/25; 6/10/26

Policy/Procedure Number: MPUP3136 (previously MCUP3136)			**Lead Department: Health Services** **Business Unit: Utilization Management**
Policy/Procedure Title: Microbiota-Based Therapeutics (MBT)			☒ **External Policy** ☐ **Internal Policy**
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*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:
N/A

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In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually
- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.

Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.