Fecal Microbiota Transplantation (for North Carolina Only)

Policy Number: CSNCT0368.01
Effective Date: September 1, 2023

Instructions for Use

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Related Policies

- Fecal Calprotectin Testing
- Outpatient Surgical Procedures – Site of Service (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Fecal Microbiota Transplantation

For medical necessity clinical coverage criteria, refer to the North Carolina Medicaid Clinical Coverage Policy for Fecal Microbiota Transplantation, 1A-40.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

Description of Services

Fecal Microbiota Transplantation (FMT) involves introducing saline-diluted fecal matter (i.e., fecal suspension) from a donor into the gastrointestinal tract of an individual with recurrent Clostridium Difficile Infection (rCDI) with the intent of reestablishing a more normal fecal composition and increased microbial diversity.

The treatment has been used extensively for treating rCDI with success, likely because the donated gut microbial ecosystem can substitute the microbiota lost through antibiotic use and consequently suppress Clostridioides difficile overgrowth, promoting recovery. Donor strains introduced into the gastrointestinal tract via FMT robustly colonize and create themselves in conjunction with or in place of the pre-existing microbiota (Carlucci et al., 2016).

REBYOTA® (fecal microbiota, live-jslm; formerly RBX2660) is a standardized FMT product approved by the FDA for the prevention of rCDI and is not indicated for the treatment of CDI. The treatment is administered rectally as a single dose, prepared from stool donated by qualified individuals. The donors and the donated stool are tested for a panel of transmissible pathogens; however, as REBYOTA® is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. In addition, the stool may contain food allergens; the potential for the product to cause adverse reactions due to food allergens is unknown. The manufacturer recommends not administering REBYOTA® if the patient has a history of a severe allergic reaction (e.g., anaphylaxis) to REBYOTA® or any of its components (REBYOTA, 2022).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

On November 30, 2022, the U.S. Food and Drug Administration approved REBYOTA®, the first fecal microbiota product approved by the agency. REBYOTA® is approved for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older. It is for use after an individual has completed antibiotic treatment for recurrent CDI. For more information, refer to: https://www.fda.gov/vaccines-blood-biologics/vaccines/rebyota. (Accessed December 28, 2022)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Fecal Microbiota Transplantation 1A-40 https://medicaid.ncdhhs.gov/media/12314/open. Accessed February 6, 2023.

Policy History/Revision Information

Date	Summary of Changes
09/01/2023	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.