



Fecal Bacteriotherapy

Origination: 01/24/13	Revised: 06/04/13	Annual Review: 10/05/23
------------------------------	--------------------------	--------------------------------

Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *Fecal Bacteriotherapy* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

- *Fecal Bacteriotherapy* is approved as a covered benefit on a case-by-case basis and when the following criteria has been met:
 - Member must have severe recalcitrant C. Difficile infection that failed standard treatment;
 - Procedure must be performed by a provider (Gastroenterologist) with experience in the collection, testing, and application of the fecal material.
 - The FDA announced 5/13/13 that fecal bacteria are a biological product not approved by the agency for any therapeutic use. Therefore, physicians wanting to perform the procedure for any indication must file an Emergency Use Investigational New Drug Application (IND).
 - Otherwise, Fecal Bacteriotherapy is considered to be investigational/experimental and not a covered benefit.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.