Health Technology Clinical Committee
Final findings and decision

Topic: Fecal microbiota transplantation (FMT)
Meeting date: November 18, 2016
Final adoption: January 20, 2017

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:
20161118B – Fecal microbiota transplantation (FMT)

HTCC Coverage Determination:
Fecal microbiota transplantation is a covered benefit with conditions.

HTCC reimbursement determination:
Limitations of coverage:
Covered for patients with c. difficile infection who have failed an appropriate course of antibiotic therapy.

Non-covered indicators:
Not covered for treatment of inflammatory bowel disease.

Agency contact information:

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<thead>
<tr>
<th>Agency</th>
<th>Phone number</th>
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<tbody>
<tr>
<td>Labor and Industries</td>
<td>1-800-547-8367</td>
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<td>Public Employees Health Plan</td>
<td>1-800-200-1004</td>
</tr>
<tr>
<td>Washington State Medicaid</td>
<td>1-800-562-3022</td>
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**HTCC coverage vote and formal action:**

**Committee decision**

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on fecal microbiota transplantation (FMT) for conditions including *Clostridium difficile* infection and inflammatory bowel disease (i.e. ulcerative colitis and Crohn’s disease). There is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of FMT for these conditions compared to current alternative strategies. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover FMT with conditions.

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<tr>
<th>Fecal microbiota transplantation</th>
<th>Not covered</th>
<th>Covered under certain conditions</th>
<th>Covered unconditionally</th>
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**Discussion**

The committee reviewed and discussed the available studies of FMT. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine FMT at least equivalent for safety and effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. Prior to the second voting question addressing coverage the committee discussed potential criteria for coverage. A majority of the committee voted to cover FMT with conditions.

**Limitations**

Patients with *c. difficile* infection who have failed an appropriate course of antibiotic therapy.

Not covered for treatment of inflammatory bowel disease.

**Action**

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for fecal microbiota transplantation.

The committee discussed clinical guidelines identified for FMT from the following organizations:

- American College of Gastroenterology, (2013)
- European Society of Clinical Microbiology and Infectious Diseases, (2014)
- The Ohio State University Wexner Medical Center, (2014)
- Fecal Microbiota Transplantation Workgroup, (2011)
- Canadian Association of Gastroenterology, (2014)
The committee’s cover with conditions determination is consistent with the guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on FMT for public comment followed by consideration for final approval at the next public meeting.

Health technology clinical committee authority:

Washington State’s legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology’s safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.