

Health Technology Clinical Committee

Date: November 18, 2016

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted: January 20, 2017

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

Final HTCC Minutes

Members present: John Bramhall, MD, PhD; Gregory Brown, MD, PhD; Joann Elmore, MD, MPH; Chris Hearne, RN, DNP, MPH; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, MPH; Seth Schwartz, MD, MPH; Christopher Standaert, MD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Terence M. Quigley, MD; Christina M. Surawicz, MD.

HTCC Formal Action

- 1. Call to order:** Dr. Standaert, Chair, called the meeting to order; members present constituted a quorum.
- 2. July 8, 2016 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve July 8, 2016 minutes as written, seconded. Committee voted to accept the minutes.

Action: Six committee members approved the July 8, 2016 meeting minutes.

3. Negative pressure wound therapy for home use:

The Chair introduced committee members and the clinical expert for Negative Pressure Wound Therapy (NPWT) for Home Use, Terence M. Quigley, MD, Northwest Hospital and Medical Center.

Agency utilization and outcomes:

Dr. Shana Johnson, MD, Medical Officer, Medicaid Fee for Service, Health Care Authority, presented the state agency NPWT perspective. Find the full presentation published with the [November 18, meeting materials](#).

Scheduled and open public comments:

The chair called for public comments. Comments provided by:

- Carmen Hudson, MD, Swedish Medical Center
- William E. Struyk, Advanced Medical Technology Association.
- Alia Griffing, Washington Federation of State Employees

Final

Find public comment slide presentations published with [November 18, meeting materials](#).

Vendor report and HTCC question and answer:

Candi Wines, PhD, Hayes, Inc. presented the evidence review of *Negative Pressure Wound Therapy for Home Use*. The location of the full presentation is [November 18, meeting materials](#).

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 evaluated the available evidence. Half of the committee found the technology equivalent for safety compared to alternative treatment(s). A majority found the evidence sufficient to support NPWT as more effective in some circumstances and a majority found the cost-effectiveness of NPWT unproven. The committee discussed and voted on the evidence for use of NPWT compared to current alternative strategies. The committee considered 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 with conditions NPWT for home use.

	Not covered	Covered under certain conditions	Covered unconditionally
Negative pressure wound therapy	0	10	0

Discussion

The committee reviewed and discussed the available studies of NPWT. Details of study design, inclusion criteria and other factors affecting or potentially affecting study quality were discussed. Conditional coverage and potential criteria were discussed prior to voting on the coverage determination. All members voted to cover NPWT with conditions.

Limitations

A complete wound therapy program must have been tried or considered prior to NPWT.

Discontinuation of coverage:

- Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound
- 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound

Treatment is not covered in patients with contraindications referred to by the FDA Safety Communication from February 24, 2011.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for negative pressure wound therapy for home use.

A local coverage policy from Noridian was reviewed and discussed.

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

- International Expert Panel on Negative Pressure Wound Therapy, (2011)
- Association for the Advancement of Wound Care, (2010)
- National Pressure Ulcer Advisory Panel, (2014)
- International Working Group on the Diabetic Foot, (2016)
- Society for Vascular Surgery and the American Venous Forum, (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 negative pressure wound therapy for home use for public comment, followed by consideration for final approval at the next public meeting.

4. Fecal microbiota transplantation

Agency utilization and outcomes:

Dan Lessler, MD, MHA, Chief Medical Officer WA - Health Care Authority, presented the state agency perspective and utilization rates for the fecal microbiota transplantation topic to the committee. The presentation is found under the [November 18, meeting materials](#).

The chair introduced the clinical expert for fecal microbiota transplantation, Christina M. Surawicz, MD, Professor, University of Washington School of Medicine, Seattle, WA.

Scheduled and open public comments:

The chair called for public comments. No comments were presented.

Vendor report and HTCC question and answer:

Erika Brodt, BS, Spectrum Research, Inc., presented the evidence review addressing fecal microbiota transplantation. Find the full presentation here [November 18, meeting materials](#).

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.

	Not covered	Covered under certain conditions	Covered unconditionally
Fecal microbiota transplantation	0	10	0

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 *Clostridium 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). Medicare does not have a NCD for fecal microbiota transplantation.

The committee discussed clinical guidelines identified for fecal microbiota transplantation 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)
- Public Health England, (2013)
- National Institute for Health and Care excellence, (2013)
- Fecal Microbiota Transplantation Workgroup, (2011)
- New Zealand Society of Gastroenterology. (2015)
- Canadian Association of Gastroenterology, (2014)

The committee's cover with conditions determination is consistent with these 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.

6. Josh Morse, HTA program director presented a status update on HTA technology assessments in process and scheduled for 2017.
7. **Meeting adjourned.**