



Washington State
Health Care Authority

Program updates

Josh Morse, HTA Program Director
WA – Health Care Authority
January 20, 2017



Washington State
Health Care Authority

Today's agenda

- 1) Pharmacogenomic testing for selected conditions
- 2) Artificial disc replacement: Re-review

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2017 Committee calendar

- March 17
Extracorporeal shock wave therapy
- May 19
Treatment of chronic migraine and chronic tension-type headache
Varicose veins
- July 14
Meeting by phone
Final action on May 19, findings and decisions
- November 17, 2017
Technologies to be determined

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Update on 2016 technology selections

- ✓ Artificial disc replacement (Re-review)
- ✓ Extracorporeal shock wave therapy for musculoskeletal conditions
- ✓ Interventions for treatment of migraines/ headaches
- ✓ Varicose veins
- Skin substitutes
- Mammogram: Computer-aided detection mammography

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Questions?

More Information:
shtap@hca.wa.gov

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Health Technology Clinical Committee

Date: November 18, 2016

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

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

DRAFT 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

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

Draft

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.**

**Health Technology Clinical Committee
Draft findings and decision**

Topic: Negative pressure wound therapy for home use
Meeting date: November 18, 2016
Final adoption:

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:

20161118A – Negative pressure wound therapy for home use (NPWT)

HTCC Coverage Determination:

Negative pressure wound therapy for home use is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage:

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
- Four 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

Non-covered indicators:

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

Contraindicated for these wound types/conditions:

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed organs

Draft

Agency contact information:

Agency	Phone number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

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.

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.

Negative pressure wound therapy for home use

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Negative pressure wound therapy for home use**

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	January 5, 2015	
Public comments	January 5, to January 20, 2015	16
Selected technologies published	February 4, 2015	
Public comments	February 4, to March 6, 2015	31
Draft key questions published	May 3, 2016	
Public comments	May 4, to 17, 2016	14
Final key questions published	June 6, 2016	
Draft report published	August 16, 2016	
Public comments	August 16, to September 19, 2016	30
Final report published	October 14, 2016	
Public meeting	November 18, 2016	
Draft findings & decision published	December 6, 2016	
Public comments	December 6, to 19, 2016	15

Overview

Category	Comment Period	
	<i>December 6 - 19, 2016</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	1	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	1	0

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Gary Franklin, MD, Medical Officer	WA Labor and Industries	No

Comments of the WA Agency Medical Directors

Date: December 19, 2016

Negative Pressure Wound Therapy

Presented by Dr. Gary Franklin, Chief Medical Officer, WA State Department of Labor and Industries

1. We would like the HTCC to consider clarifying the statement “A complete wound therapy program must have been tried or considered prior to NPWT”. The word “considered” in the context is ambiguous, which is difficult to implement. We suggest the following modification: “A complete wound therapy program must have been tried and failed prior to NPWT or the complete wound therapy programs are contraindicated”.
2. An “OR” may be added between the two statements under “Discontinuation of coverage” to make it clear.

**Health Technology Clinical Committee
Draft findings and decision**

Topic: Fecal microbiota transplantation
Meeting date: November 18, 2016
Final adoption:

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:

Agency	Phone number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

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 *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)
- 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)

Draft

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:

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Fecal Microbiota Transplantation

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Fecal Microbiota Transplantation**.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	January 5, 2015	
Public comments	January 5, to January 20, 2015	16
Selected technologies published	February 4, 2015	
Public comments	February 4, to March 6, 2015	31
Draft key questions published	May 3, 2016	
Public comments	May 4, to 17, 2016	14
Final key questions published	June 6, 2016	
Draft report published	August 16, 2016	
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Public comments	December 6, to 19, 2016	15

Overview

Category	Comment Period	
	December 6, - 19, 2016	Cited Evidence
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Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	0	0