



Health Technology Assessment

Program Overview

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Health Technology Assessment
May 17, 2013



Presentation Overview

Today's Topics:

- Cochlear Implants: Bilateral versus Unilateral
- Catheter Ablation Procedures for Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation (SVTA)
- HTA Program Overview



HTA Background

- The Health Technology Assessment Program (HTA) is located within the Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
 - Safety
 - Efficacy/ Effectiveness
 - Cost-Effectiveness

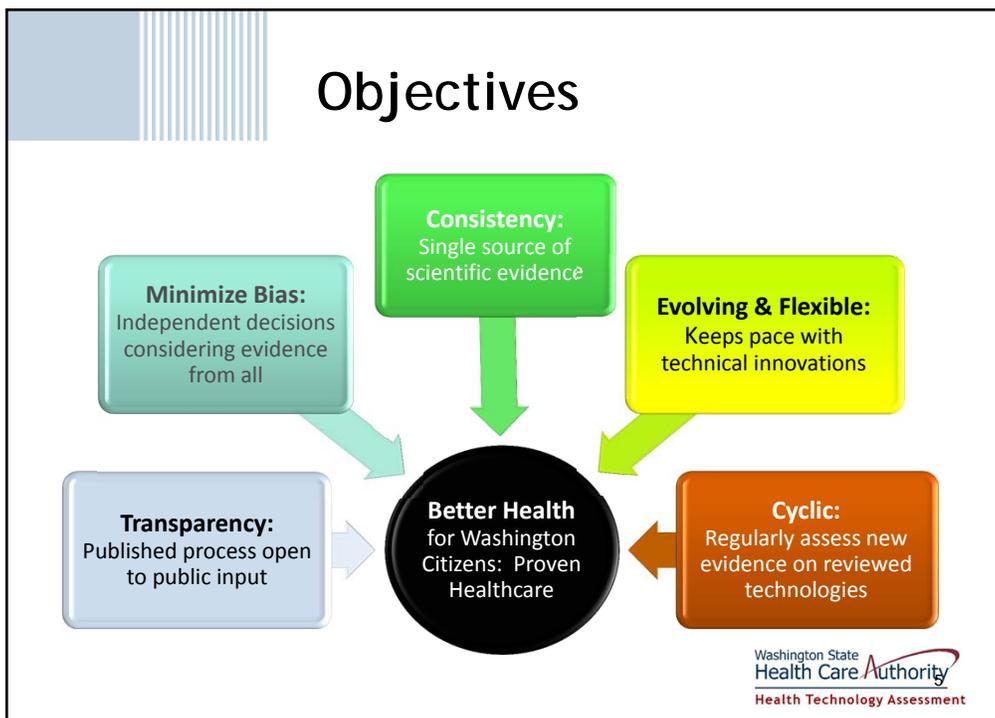
HTA Background

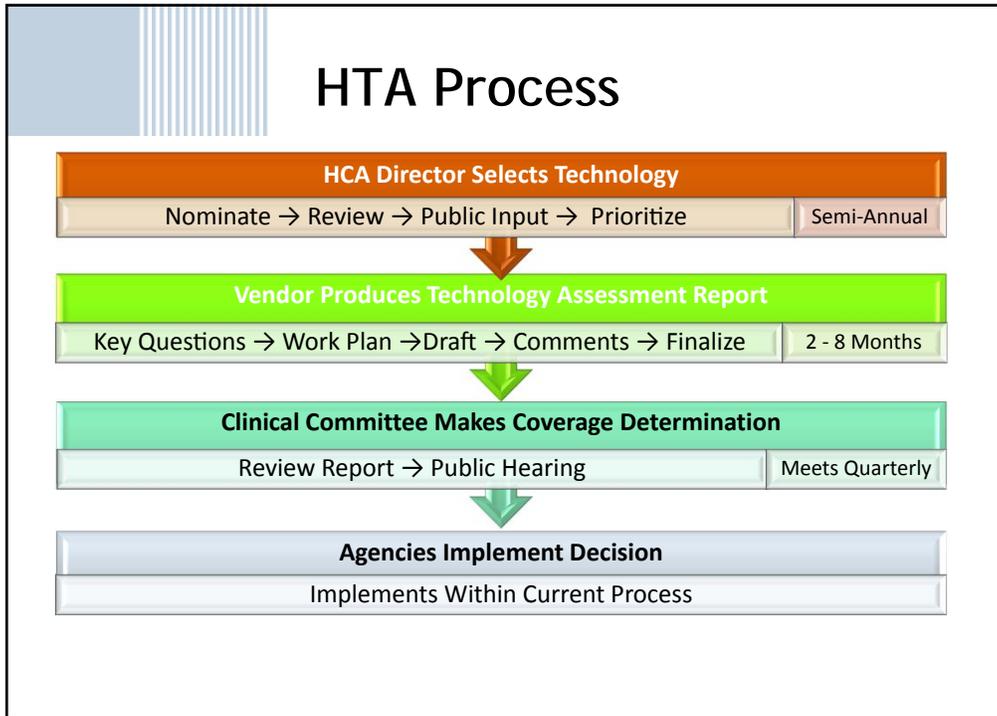
- Multiple state agency programs participate to identify topics and implement policy decisions:
 - Health Care Authority
 - Uniform Medical Plan
 - Medicaid
 - Labor and Industries
 - Corrections
- Implementation:
 - Agencies implement determinations of the HTA program within their existing statutory framework.

Purpose: Pay for What Works

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners to determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.





Key Questions

- Is it safe?
- Is it effective?
- Does it provide value (i.e. improve health outcomes)?



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HTA Values

Transparency: Publish topics, criteria, reports, conduct open meetings

Best Evidence: Formal, systematic process for review of selected health care technologies.

Independent Decisions: Committee of practicing clinicians make decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.

HTCC Decision Basis

Clinical Committee decisions must give greatest weight to most valid and reliable evidence.

- Objective Factors for evidence consideration
 - Nature and source of evidence
 - Empirical characteristics of the studies or trials upon which evidence is based
 - Consistency of outcomes with comparable studies
- Additional evaluation factors
 - **Recency** (date of information)
 - **Relevance** (applicability of information to the key questions presented or participating agency programs and clients)
 - **Bias** (conflict of interest or political considerations)

Technology Topics 2013

- ❖ Cochlear Implants: Bi- versus Unilateral
- ❖ Ablation Procedures for Supraventricular Tachyarrhythmia
- Carotid Artery Stenting
- Cardiac Nuclear Imaging
- Hyaluronic Acid/Viscosupplementation (update)
- Hip Resurfacing (update)
- Facet Neurotomy (update)

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How To Participate

- **Visit** the HTA Web site: www.hta.wa.gov
- **Join** the HTA stakeholder distribution list: shtap@hta.hca.wa.gov
Stakeholders notified of all program publications and meetings
- **Comment** on:
 - Proposed topics
 - Key questions
 - Draft & final reports
 - Draft decisions
- **Attend** HTCC public meetings
All meeting materials posted on the web
- **Present** comments at Clinical Committee meetings
- **Nominate** health technologies for review

Washington State
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HTA Contact Information

Email: shtap@hca.wa.gov

Website: hta.hca.wa.gov/

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Thank you!



Health Technology Clinical Committee

Date: March 22, 2013

Time: 8:00 am – 5:00 pm

Location: SeaTac Airport Conference Center

Adopted:

Meeting materials and transcript are available on the HTA website at:
http://hta.hca.wa.gov/past_materials.html

HTCC MINUTES

Members Present: C. Craig Blackmore MD, MPH; Marie-Annette Brown PhD, RN; Joann Elmore, MD MPH; Carson E. Odegard DC, MPH; Richard C. Phillips MD, MS, MPH; Seth Schwartz MD, MPH; Michelle Simon PhD, ND; Michael Souter MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh MD

Members Absent: David McCulloch, MD

HTCC FORMAL ACTION

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. November 16, 2012, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
Action: Eight committee members approved the November 16, 2012 meeting minutes. Three members were absent.
- 3. Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection.
Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Draft Findings & Decision was approved and adopted by the committee.
Action: Nine committee members approved the Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Findings & Decision document. Two members were absent.
- 4. Vitamin D Screening and Testing Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection.
Vitamin D Screening and Testing Draft Findings & Decision was approved and adopted by the committee.
Action: Nine committee members approved the Vitamin D Screening and Testing Findings & Decision document. Two members were absent.

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5. Hyperbaric Oxygen Therapy (HBOT) for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions.

Scheduled and Open Public Comments:

The Chair called for public comments. One individual scheduled time for public comments:

- Karen Stanek, MD, Northwest Medical Rehabilitation

Presentation materials and conflict of interest form are available with [March 22 meeting materials](#).

No open public comments were presented.

Agency Utilization and Outcomes:

Kerilyn Nobuhara MD, MHA, Senior Medical Consultant, Health Care Authority, presented the state agency utilization rates for Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions to the committee. The full presentation is published with [March 22 meeting materials](#).

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Neil Hampson, MD, Past-President, Undersea and Hyperbaric Medical Society, Physician Emeritus, Virginia Mason Medical Center, Seattle, WA.

Karen Crotty, PhD, MPH of Hayes, Inc, presented the evidence review addressing Hyperbaric Oxygen Therapy. The full presentation is published with [March 22 meeting materials](#).

Committee Discussion and Decision:

The HTCC reviewed and considered the Hyperbaric Oxygen Therapy technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

- *Discussion:* The Chair called for discussion of conditions of coverage for Hyperbaric Oxygen Therapy following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:
- *Limitations of Coverage:*
 - Hyperbaric Oxygen Therapy is a covered benefit for:
 - Crush injuries and suturing of severed limbs. HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened;
 - Compromised skin grafts and flaps (not for primary management of wounds);
 - Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management;
 - Osteoradionecrosis as an adjunct to conventional treatment;

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- For prevention of osteoradionecrosis associated with tooth extraction in a radiated field;
- Soft tissue radionecrosis as an adjunct to conventional treatment;
- Diabetic wounds in patients who meet the following three criteria:
 - Patient has type I or type II diabetes and has a wound that is due to diabetes;
 - Patient has a wound classified as Wagner grade III or higher; and
 - Patient has failed an adequate course of standard wound therapy.

Non-covered Indications:

- Brain injury including traumatic (TBI) and brain injury chronic (excluding stroke)
- Cerebral Palsy
- Multiple Sclerosis
- Headache/migraine
- Sensorineural hearing loss
- Thermal burns
- Other non-healing wounds

The committee checked for availability of a Medicare decision. The Centers for Medicare & Medicaid Services (CMS) cover Hyperbaric Oxygen Therapy in either a mono-place or multi-chamber for a number of indications. For conditions addressed by the CMS National Coverage Determination and the HTA review, the HTCC findings agree with the CMS policy.

Chair directed HTA staff to prepare a draft coverage determination document for the topic.

6. Spinal Cervical Fusion for Degenerative Disc Disease:

Scheduled and Open Public Comments: The Chair called for public comments. Three individuals scheduled time for public comments:

- Joseph Cheng, MD, American Association of Neurological Surgeons/ Congress of Neurological Surgeons
- Jason Lerner, Director Marketing Access, De Puy Synthes
- David Flum, MD, Spine Surgical Care and Outcomes Assessment Program (Spine SCOAP)

One organization submitted a letter in lieu of a scheduled presentation:

- Deana SCearce, JD, Director, State Government Affairs, Medtronic, Inc.

Presentation materials and conflict of interest forms are available with [March 22 meeting materials..](#)

No open public comments were presented.

Agency Utilization and Outcomes:

Gary Franklin, MD, MPH, Medical Director, Department of Labor and Industries, presented the state agency utilization rates for Cervical Spinal Fusion to the committee. The full presentation is published with [March 22 meeting materials.](#)

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Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Trent Tredway, MD, Director, Minimally Invasive Spine Surgery, Department of Neurological Surgery, and Associate Professor University of Washington School of Medicine.

Daniel A. Ollendorf, MPH, ARM, of the Institute for Clinical and Economic Review, presented the evidence review addressing Cervical Spinal Fusion. The full presentation is published with [March 22 meeting materials](#).

Committee Discussion and Decision

The HTCC reviewed and considered the Cervical Spinal Fusion technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Cervical Spinal Fusion	0	0	10

- *Discussion:* The Chair called for discussion of conditions of coverage for Cervical Spinal Fusion following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

- *Limitations of Coverage:*

Cervical Spinal Fusion is a covered benefit for patients with signs and symptoms of radiculopathy and advanced imaging evidence of corresponding nerve root compression and failure of conservative (non-operative) care.

Cervical Spinal Fusion is not a covered benefit for neck pain without evidence of radiculopathy or myelopathy.

The committee checked for availability of a Medicare coverage decision. There is no national coverage determination (NCD) for any form of fusion surgery. Local coverage decisions (LCDs) are limited to spinal fusion for *lumbar* degenerative disc disease.

Chair directed HTA staff to prepare a draft coverage determination document for the topic.

The Chair called for further comments. No further comments on review of Cervical Spinal Fusion.

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7. The Chair called for committee review of draft key questions open for public comment: Cardiac Nuclear Imaging; and Hyaluronic Acid / Viscosupplementation (re-review). HTA staff reminded committee members of the open comment period for key questions; committee reviewed draft key questions.
8. Meeting adjourned.

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**Health Technology Clinical Committee
Draft Findings and Decision**

Topic: Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions
Meeting Date: March 22, 2013
Final Adoption:

Number and Coverage Topic:

20130322A – Hyperbaric Oxygen Therapy (HBOT) for Tissue damage, Including Wound Care and Treatment of Central Nervous System Conditions

HTCC Coverage Determination:

Hyperbaric Oxygen Therapy is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination:

Limitations of Coverage

1. Crush injuries and suturing of severed limbs; as an adjunct when loss of function, limb, or life is threatened.
2. Compromised skin grafts and flaps (not for primary management of wounds).
3. Chronic refractory osteomyelitis unresponsive to conventional medical and surgical management.
4. Osteoradionecrosis; as an adjunct to conventional treatment.
5. For prevention of osteoradionecrosis associated with tooth extraction in a radiated field.
6. Soft tissue radionecrosis; as an adjunct to conventional treatment.
7. Diabetic wounds in patients who meet the following three criteria:
 - a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - b. Patient has a wound classified as Wagner grade III or higher; and
 - c. Patient has failed an adequate course of standard wound therapy.

Non-Covered Indicators

1. Brain injury including traumatic (TBI) and chronic brain injury
2. Cerebral Palsy
3. Multiple Sclerosis
4. Migraine or cluster headaches
5. Acute and chronic sensorineural hearing loss
6. Thermal burns
7. Non-healing venous, arterial and pressure ulcers

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

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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 agency and state utilization information. The committee concluded that the current evidence on Hyperbaric Oxygen Therapy demonstrates that there is sufficient evidence to cover with conditions. The committee considered all 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 with conditions Vitamin D Screening and Testing.

Hyperbaric Oxygen Therapy Coverage Vote

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Hyperbaric Oxygen Therapy	0	0	10

Discussion

The Chair called for discussion on conditions for use of Intensity Hyperbaric Oxygen Therapy due to the majority voting for coverage with conditions. The following conditions were discussed and approved by a majority:

Limitations of Coverage

Covered Conditions

1. Crush injuries and suturing of severed limbs. HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
2. Compromised skin grafts and flaps (not for primary management of wounds).
3. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
4. Osteoradionecrosis as an adjunct to conventional treatment.
5. For prevention of osteoradionecrosis associated with tooth extraction in a radiated field.
6. Soft tissue radionecrosis as an adjunct to conventional treatment.
7. Diabetic wounds in patients who meet the following three criteria:
 - a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - b. Patient has a wound classified as Wagner grade III or higher; and
 - c. Patient has failed an adequate course of standard wound therapy.

Non-Covered Conditions

1. Brain injury including traumatic (TBI) and chronic brain injury
2. Cerebral Palsy
3. Multiple Sclerosis

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4. Migraine or cluster headaches
5. Acute and chronic sensorineural hearing loss
6. Thermal burns
7. Non-healing venous, arterial and pressure ulcers

Action

The committee Chair directed HTA staff to prepare a Findings and Decision document on Hyperbaric Oxygen Therapy reflective of the majority vote for final approval at the next public meeting.

The committee reviewed the evidence report for existing clinical guidelines and Centers for Medicare & Medicaid Services (CMS) decisions. CMS does not have a national coverage determination (NCD) for Hyperbaric Oxygen Therapy.

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.

Meeting materials and transcript are available on the HTA website at:
http://www.hta.hca.wa.gov/past_materials.html

Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions

Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions.

Category	Comment Period <i>April 17 – May 1, 2013</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	0	0

Comments with Evidence:

None.

Comments without Evidence:

None.

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 1, 2011	
Public comments due	November 15, 2011	15
Selected technologies published	November 29, 2011	
Public comments due	December 29, 2011	30
Draft Key Questions published	May 23, 2012	

WA - Health Technology Assessment

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Public comments due	June 8, 2012	17
Final Key Questions published	July 20, 2012	
Draft report published	January 4, 2013	
Public comments due	February 7, 2013	35
Final report published	February 15, 2013	
Public meeting date	March 22, 2013	
Findings & decision published	April 17, 2013	
Public comments due	May 1, 2013	15

**Health Technology Clinical Committee
Draft Findings and Decision**

Topic: Cervical Spinal Fusion for Degenerative Disc Disease
Meeting Date: March 22, 2013
Final Adoption:

Number and Coverage Topic:

20130322B – Cervical Spinal Fusion for Degenerative Disc Disease

HTCC Coverage Determination:

Cervical Spinal Fusion for Degenerative Disc Disease is a **covered benefit with conditions**.

HTCC Reimbursement Determination:

Limitations of Coverage

Cervical Spinal Fusion is covered for when the following conditions are met:

1. Patients with signs and symptoms of radiculopathy; and
2. Advanced imaging evidence of corresponding nerve root compression; and
3. Failure of conservative (non-operative) care.

Non-Covered Indicators

Cervical Spinal Fusion is not a covered benefit for neck pain without evidence of radiculopathy or myelopathy.

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 agency and state utilization information. The committee concluded that the current evidence on Cervical Spinal Fusion for Degenerative Disc Disease demonstrates that there is sufficient evidence to cover with conditions. The committee considered all 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 with conditions Cervical Spinal Fusion for Degenerative Disc Disease.

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Cervical Spinal Fusion Coverage Vote

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Cervical Spinal Fusion	0	0	10

Discussion

The Chair called for discussion on conditions for use of Intensity Cervical Spinal Fusion for Degenerative Disc Disease due to the majority voting for coverage with conditions. The following conditions were discussed and approved by a majority:

Limitations of Coverage

Covered Conditions

Patients with signs and symptoms of radiculopathy
 And advanced imaging evidence of corresponding nerve root compression
 And failure of conservative (non-operative) care

Non-Covered Conditions

Non-covered for neck pain without evidence of radiculopathy or myelopathy

Action

The committee Chair directed HTA staff to prepare a Findings and Decision document on Cervical Spinal Fusion for Degenerative Disc Disease reflective of the majority vote for final approval at the next public meeting.

The committee checked for availability of a Medicare coverage decision. There is no national coverage determination (NCD) for cervical spinal fusion surgery. Local coverage decisions (LCDs) are limited to spinal fusion for lumbar degenerative disc disease.

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.

Draft

Meeting materials and transcript are available on the HTA website at:
http://www.hta.hca.wa.gov/past_materials.html

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Cervical Spinal Fusion for Degenerative Disc Disease

Findings & Decision

Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Cervical Spinal Fusion for Degenerative Disc Disease.

Category	Comment Period <i>April 17 – May 1, 2013</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	0	0

Comments with Evidence:

None.

Comments without Evidence:

None.

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 1, 2011	
Public comments due	November 15, 2011	15
Selected technologies published	November 29, 2011	
Public comments due	December 29, 2011	30
Draft Key Questions published	September 21, 2012	
Public comments due	October 5, 2012	15

WA - Health Technology Assessment

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Final Key Questions published	October 30, 2012	
Draft report published	January 8, 2013	
Public comments due	February 14, 2013	38
Final report published	February 21, 2013	
Public meeting date	March 22, 2013	
Findings & decision published	April 17, 2013	
Public comments due	May 1, 2013	15