

Washington State
Health Care Authority
Health Technology Assessment

Program Overview

Josh Morse, Director
Health Technology Assessment Program
May 15, 2015

WA - Health Technology Assessment


Program Updates

Today:

- Imaging for Rhinosinitus
- Bariatric Surgery

November 20, 2015:

- Tympanostomy Tubes
- Lumbar Fusion – Re-review



WA - Health Technology Assessment

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

Washington State Health Care Authority

WA - Health Technology Assessment

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.

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Washington State Health Care Authority

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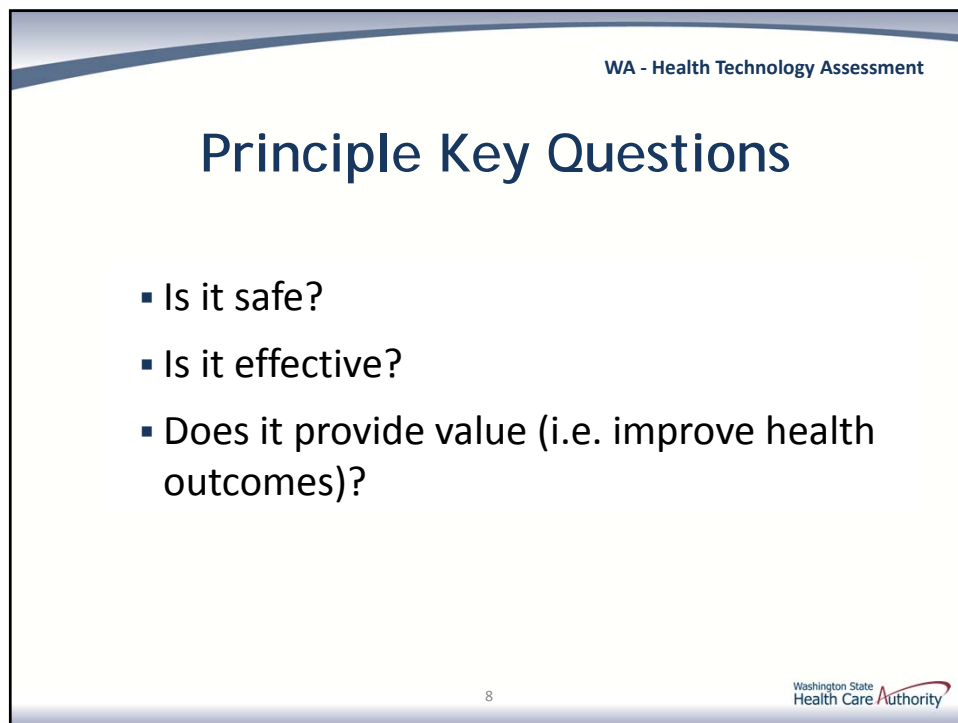
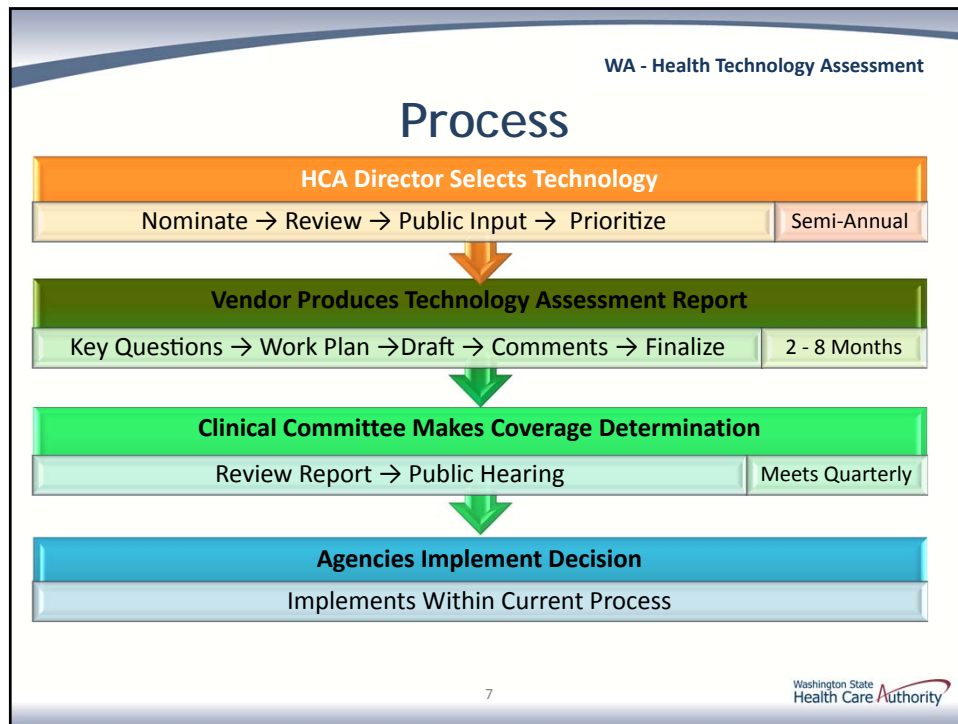
Purpose: Pay for What Works

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.

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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.

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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)

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Technology Topics 2015

- Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment
- Appropriate Imaging for Breast Cancer Screening in Special Populations
- Testosterone Testing
- ★ Imaging for Rhinosinusitis
- ★ Bariatric Surgery for Overweight and Obese
- Tympanostomy Tubes
- Lumbar Fusion (Re-review)

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How To Participate

- Visit the HTA Web site: <http://www.hca.wa.gov/hta>
- Join the HTA stakeholder distribution list: shtap@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.

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Meeting Reminders

- Meeting is being recorded.
- Transcript will be made available on HTA website:
www.hca.wa.gov/hta.
- When participating in discussions, please:
 - State your name; and
 - Use the microphone.
- To provide public comment during today's meeting:
 - Sign-up on clipboard located on table outside this meeting room; and
 - Complete a Participant Conflict Disclosure form.

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Contact Information

Josh Morse, Program Director
(360) 725-0839
Josh.Morse@hca.wa.gov

HTA web address: hca.wa.gov/hta
HTA program email: shtap@hca.wa.gov

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Washington State
Health Care Authority

Health Technology Clinical Committee

Date: March 20, 2015

Time: 8:00 am – 12:30 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the HTA website at:

www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

HTCC DRAFT MINUTES

Members Present: C. Craig Blackmore, MD, MPH; Marie-Annette Brown, PhD, RN, ARNP, FAAN; Joann Elmore, MD MPH; David K. McCulloch, MD, FRCP; Richard C. Phillips, MD, MS, MPH, FACS; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Christopher Standaert, MD; Kevin Walsh, 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. January 16, 2015 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

Action: Seven committee members approved the January 16, 2015 meeting minutes. One member abstained.

- 3. Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. Two comments were received on the draft decision. Committee added a clarifying footnote to decision language based on public comment received.

Action: Seven committee members voted to approve the Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment Draft Findings & Decision document. One member abstained.

- 4. Appropriate Imaging for Breast Cancer Screening in Special Populations:** Chair referred members to the draft findings and decision and called for further discussion. Five comments were received on the draft decision.

Action: Seven committee members voted to approve the Appropriate Imaging for Breast Cancer Screening in Special Populations Draft Findings & Decision document. One member abstained.

Draft

5. Testosterone Testing:

Agency Utilization and Outcomes:

G. Steven Hammond, MD, PhD, MHA, Medical Director, Washington Department of Labor and Industries presented the state agency utilization rates for Testosterone Testing for Adult Males to the committee. The full presentation is published with [March 20 meeting materials](#).

Scheduled and Open Public Comments:

The Chair called for public comments. Open public comments were presented by:

- Bruce Smith, MD, Regence/ Blue Shield

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert for Testosterone Testing, Alvin M. Matsumoto, MD, FACP, Professor, Department of Medicine, University of Washington School of Medicine.

Teresa L. Rogstad, MPH, Hayes, Inc. presented the evidence review addressing Testosterone Testing. The full presentation is published with [March 20 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 Testosterone Testing 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 Testosterone Testing. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote:

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Testosterone Testing	0	9	0

Discussion

The chair called for discussion of conditions and evidence related to testosterone testing. The committee identified potential conditions and moved to vote. The committee voted to cover with the following conditions:

- Suspected or known primary hypogonadism
- Suspected or known secondary hypogonadism with organic cause, e.g.:
 - Pituitary disorders
 - Suprasellar tumor
 - Medications suspected to cause hypogonadism
 - HIV with weight loss
 - Osteoporosis
- Signs of hypogonadism or symptoms of sexual dysfunction (all three criteria from European male aging study)
- Monitoring of testosterone therapy

Action

The committee checked for availability of Medicare national coverage decisions (NCDs). There are no NCDs for testosterone testing.

The committee discussed identified guidelines and recommendations for testosterone treatment. The Chair noted consistency with the guidelines with differences due to interpretation of the evidence.

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

6. Josh Morse, HTA Program Director presented information regarding the four HTA evidence reviews currently in progress.
7. **Meeting adjourned.**

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

Topic: Testosterone Testing
Meeting Date: March 20, 2015
Final Adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

Number and Coverage Topic:

20150320A – Testosterone Testing

HTCC Coverage Determination:

Testosterone testing is a **covered benefit with conditions**.

HTCC Reimbursement Determination:

Limitations of Coverage:

- Suspected or known primary hypogonadism
- Suspected or known secondary hypogonadism with organic cause, e.g.:
 - Pituitary disorders
 - Suprasellar tumor
 - Medications suspected to cause hypogonadism
 - HIV with weight loss
 - Osteoporosis
- Signs of hypogonadism or symptoms of sexual dysfunction (all three criteria from European male aging study)
- Monitoring of testosterone therapy

Non-covered Indicators: N/A

This decision does not apply to females, males under age 18, or transgender persons.

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 demonstrates that there is sufficient evidence to cover Testosterone Testing.

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 Testosterone Testing under certain conditions**.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Testosterone Testing	0	9	0

Discussion

The chair called for discussion of conditions and evidence related to testosterone testing. The committee identified potential conditions and moved to vote. Based on review of the information provided in the evidence report, in comments and state agency utilization information, the following conditions were discussed and approved by the majority of the clinical committee:

Limitations of Coverage

- Suspected or known primary hypogonadism
- Suspected or known secondary hypogonadism with organic cause, e.g.:
 - Pituitary disorders
 - Suprasellar tumor
 - Medications suspected to cause hypogonadism
 - HIV with weight loss
 - Osteoporosis
- Signs of hypogonadism or symptoms of sexual dysfunction (all three criteria from European male aging study)
- Monitoring of testosterone therapy

Non-Covered Indicators: N/A

This decision does not apply to females, males under age 18, or transgender persons.

Action

The committee checked for availability of Medicare national coverage decisions (NCDs). There are no NCDs for testosterone testing.

The committee discussed identified guidelines and recommendations for testosterone treatment.

Draft

The committee Chair directed HTA staff to prepare a Findings and Decision document on Testosterone Testing reflective of the majority vote 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.

Testosterone Testing

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 Testosterone Testing.

Timeline

Phase	Date	Public Comment Days
Technology Recommendations published	November 19, 2012	
Public comments	November 19 - December 3, 2012	15
Selected Technologies published	December 6, 2012	
Public comments	December 6, 2012 - January 7, 2013	32
Draft Key Questions published	July 15, 2014	
Public comments	July 15 – 29, 2014	14
Final Key Questions published	August 8, 2014	
Draft Report published	December 17, 2014	
Public comments	December 17 – January 19, 2015	34
Final Report published	February 11, 2015	
Public Meeting	March 20, 2015	
Draft Findings & Decision published	April 9, 2015	
Public comments	April 9 – 23, 2015	14
	Total	109

Overview

Category	Comment Period	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	1	1
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	1	1

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. G. Steven Hammond, Phd, MD, MHA	WA Dept of Corrections	Yes



STATE OF WASHINGTON
DEPARTMENT OF CORRECTIONS
Health Services Division
P. O. Box 41123 • Olympia, Washington 98501-1123

Memorandum

Date: April 17, 2015

To: Health Technology Clinical Committee

From: G. Steven Hammond, PhD, MD, MHA

Re: Testosterone Testing Findings and Decision

I have a few suggestions to clarify the HTCC reimbursement determination limitations of coverage statement for testosterone testing. The draft reads:

- Suspected or known primary hypogonadism
- Suspected or known secondary hypogonadism with organic cause, e.g.:
 - Pituitary disorders
 - Suprasellar tumor
 - Medications suspected to cause hypogonadism
 - HIV with weight loss
 - Osteoporosis
- Signs of hypogonadism or symptoms of sexual dysfunction (all three criteria from European male aging study)
- Monitoring of testosterone therapy

I suggest the following version (changes highlighted):

Limitations of Coverage:

- Known primary hypogonadism (hypogonadism with elevated gonadotropins)
- Suspected or known secondary hypogonadism with organic cause, e.g.:
 - Pituitary disorders
 - Suprasellar tumor
 - Medications suspected to cause hypogonadism

Testosterone Testing Findings and Decision

April 17, 2015

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- HIV with weight loss
- Osteoporosis
- Physical examination signs of hypogonadism (e.g., gynecomastia or absent or atrophic testes)
- Symptoms of sexual dysfunction (all three criteria from European male aging study present¹)
- Monitoring of testosterone therapy

Listing “suspected primary hypogonadism” without qualification is too vague to allow adequate implementation; instead I list physical examination signs and sexual dysfunction symptoms as the clinical findings that would raise clinical suspicion of hypogonadism.

I specify “hypogonadism with elevated gonadotropins” to clearly state what is meant by the term “primary hypogonadism.” Primary hypogonadism typically refers to a disease of the testes; in the setting of primary hypogonadism, pituitary gonadotropin levels are above normal.

I also include a reference to the European Male Aging Study paper that reports the three symptoms of sexual dysfunction that correlate with low testosterone levels in older men.

These suggestions are offered with the intention of clarifying and further specifying conditions of coverage for testosterone testing in adult men. I believe the suggested edits are in accord with the intent of the HTCC.

I would like to thank the HTCC for their work reviewing the HTA assessment on testosterone testing in adult men.

GSH:sb

¹ N Engl J Med 2010;363:123-35