



Program Overview

Josh Morse, Program Director
Health Technology Assessment
March 21, 2014

Presentation Overview

Today's Topics:

- HTA Program Overview
- Nonpharmacological Treatments for Treatment-resistant Depression
- Facet Neurotomy

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:

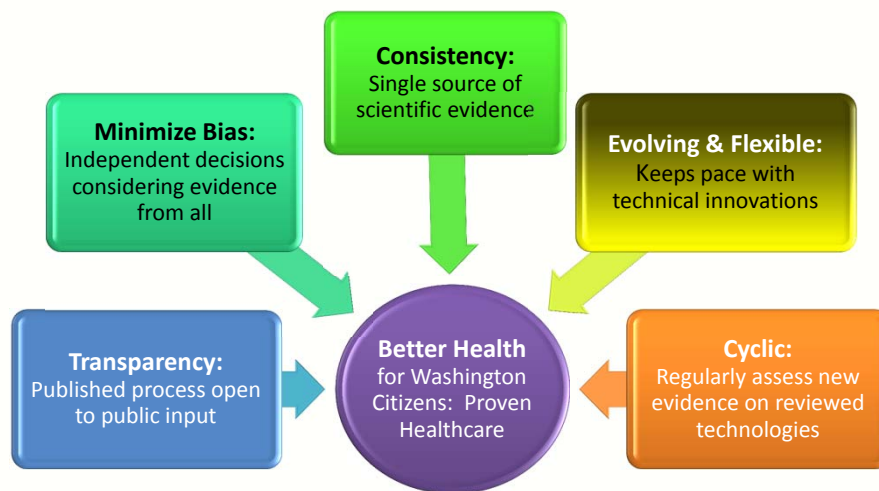
Agencies implement determinations of the HTA program within their existing statutory framework.

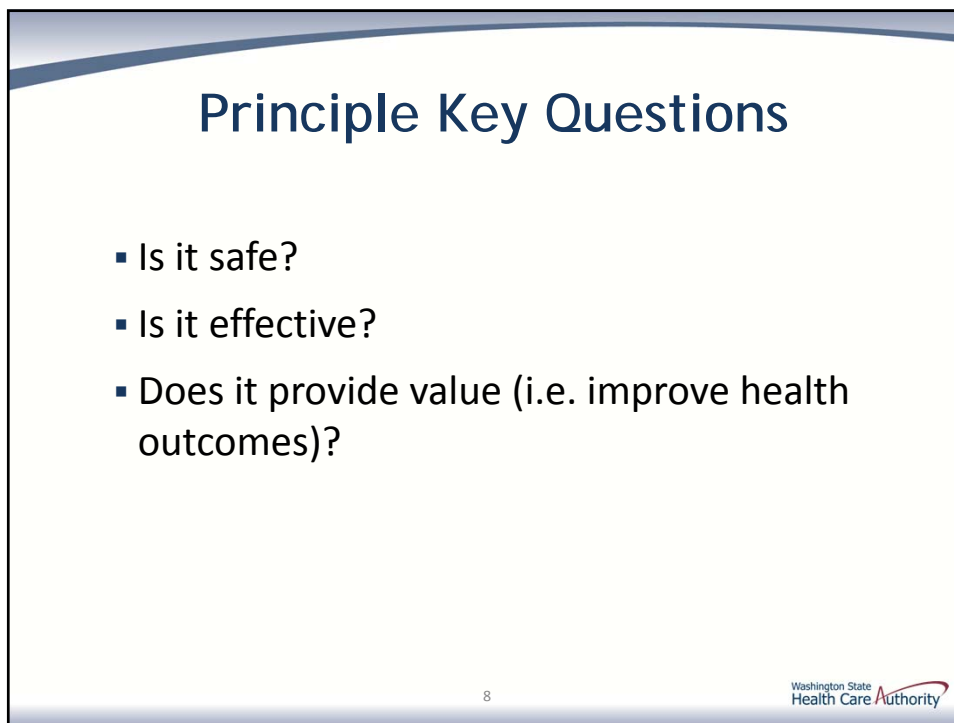
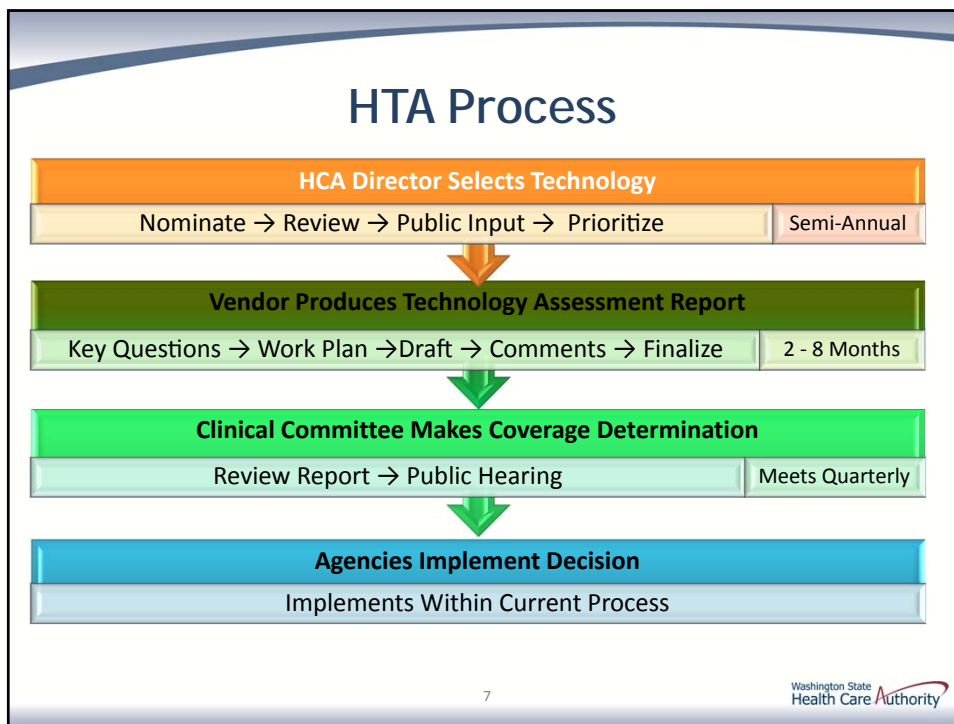
Purpose: Pay for What Works

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.

Objectives






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.

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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)

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Technology Topics 2013-14

- Hyperbaric Oxygen (HBO2) Treatment
- Cervical Spinal Fusion for Degenerative Disc Disease
- Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation
- Cochlear Implants: Bi- versus Unilateral
- Cardiac Nuclear Imaging
- Carotid Artery Stenting
- Hyaluronic Acid/Viscosupplementation (Update)
- Hip Resurfacing (Update)
- **Facet Neurotomy for Treatment of Facet Joint Pain**
- **Nonpharmacological Treatments for Treatment-resistant Depression**
- Proton Beam Therapy
- Thyroid Ultrasound for Screening and Assessment of Goiter
- Neuroimaging for Primary Degenerative Dementia & Mild Cognitive Impairment

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Washington State
Health Care Authority

How To Participate

- Visit the HTA Web site: <http://www.hca.wa.gov/hta> (**NEW URL!**)
- 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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Washington State
Health Care Authority

HTA Contact Information

Josh Morse, Program Director

(360) 725-0839

Josh.Morse@hca.wa.gov

New 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: November 15, 2013

Time: 8:00 a.m. – 5:00 p.m.

Location: SeaTac Airport Conference Center

Adopted:

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

<http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx>

HTCC DRAFT MINUTES

Members Present: C. Craig Blackmore, MD, MPH; Marie-Annette Brown, PhD, RN; Joann Elmore, MD MPH; David McCulloch, MD; 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

HTCC FORMAL ACTION

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. September 20, 2013, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

Action: Ten committee members approved the September 20, 2013 meeting minutes. One member was absent.

Carotid Artery Stenting Draft Findings & Decision: Chair referred members to the draft findings and decision and called for further discussion. One comment was received on the draft decision. Committee discussed and determined to make wording changes to the draft to address possible typographical errors in the draft determination.

- On page four of draft Findings and Decision and under Action heading, the third sentence was modified to read, 'cover symptomatic extracranial CAS without a requirement of study participation for patients at high risk for CEA with a stenosis of 50% or greater.'
- On page four under Action in the second paragraph, an incomplete sentence was corrected to read, 'the committee determined noncoverage for intracranial stents based on evidence indicating serious safety concerns and recognizing that state agency programs may provide coverage in the context of research'.

Carotid Artery Stenting Draft Findings & Decision was approved and adopted by the committee.

Action: Eleven committee members approved the Carotid Artery Stenting Findings & Decision document.

Draft

- 3. Cardiac Nuclear Imaging:** Chair referred members to the draft findings and decision and called for discussion. No comments were received on the draft Findings and Decision document.

Cardiac Nuclear Imaging Draft Findings & Decision was approved and adopted by the committee.

Action: Eleven committee members approved the Cardiac Nuclear Imaging Draft Findings & Decision document.

5. Hyaluronic Acid/ Viscosupplementation

Scheduled and Open Public Comments:

The Chair called for public comments. Five individuals had scheduled time for public comments and one submitted a letter:

- Ghislaine Robert, MD – Fidia Pharma USA Inc
- Vinod Dasa, MD – Department of Orthopaedic Surgery, Louisiana State University Health Sciences Center
- Michael W Schucker, MS, PAS, PA-C – Rockwood Clinic Bone & Joint Center
- Jon E Block, PhD – The Jon Block Group
- Samir K Bhattacharyya, PhD – Mitek Sports Medicine/ DePuy Synthes
- Greg Devereux, Executive Director – WA Federation of State Employees (Letter)

Presentation materials and conflict of interest forms are available with [November 15, meeting materials](#).

Open public comments were presented by:

- Lynn McRoy, MD – Sanofi Biosurgery
- Brad Bisson – DePuy/Synthes Mitek

Agency Utilization and Outcomes:

Robert Mootz, DC, Associate Medical Director, WA Department of Labor and Industries presented the state agency utilization rates for Hyaluronic Acid/ Viscosupplementation to the committee. The full presentation is published with [November 15, meeting materials](#).

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert for both of the November meeting's topics, Howard A Chansky, MD, Professor and Vice Chair, Orthopaedics and Sports Medicine, University of Washington.

Teresa L Rogstad, MPH, of Hayes, Inc, presented the evidence re-review addressing Hyaluronic Acid/Viscosupplementation. The full presentation is published with [November 15, meeting materials](#).

Committee Discussion and Decision:

The HTCC reviewed and considered the Hyaluronic Acid/Viscosupplementation 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. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Hyaluronic Acid/Viscosupplementation	3	0	8

Covered Conditions

Discussion: The Chair called for discussion of conditions of coverage for Hyaluronic Acid/Viscosupplementation following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

- Restricted to patients who have a medical contraindication to other forms of non-surgical care;
- Is limited to two courses per year with at least four months between courses; and
- Documented evidence of clinical benefit in terms of pain and function from the prior course of treatment is required for subsequent treatment courses.

Limitations of Coverage

The committee checked for availability of a Medicare decision. CMS does not have a national coverage determination (NCD) for Hyaluronic Acid/Viscosupplementation. The committee also reviewed practice guidelines from The American Academy of Orthopaedic Surgeons, American College of Rheumatology; National Institute for Health and Care Excellence; and Osteoarthritis Research Society International. The committee concluded the draft determination is less restrictive than the guidelines from the American Academy of Orthopaedic Surgeons and the National Institute for Health Care Excellence (NICE), and is different from the American College of Rheumatology. The committee cited more recent evidence, the recent meta-analysis included in the review and the underlying trial data in the meta-analysis as reasons for differing from these guidelines.

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

6. Hip Resurfacing (Re-review):

Scheduled and Open Public Comments: The Chair called for public comments. No public comments were presented.

Agency Utilization and Outcomes:

G. Steven Hammond, MD, MPH, Medical Director, WA Department of Corrections, presented the state agency utilization rates for Hip Resurfacing to the committee. The full presentation is published with [November 15, meeting materials](#).

Vendor Report and HTCC Q & A

Clinical expert, previously introduced, for both of the November meeting’s topics, Howard A Chansky, MD, Professor and Vice Chair, Orthopaedics and Sports Medicine, University of Washington.

Joseph R Dettori, PhD, MPH of Spectrum Research, Inc, presented the evidence re-review addressing Hip Resurfacing. The full presentation is published with [November 15, meeting materials](#).

Committee Discussion and Decision

The HTCC reviewed and considered the Hip Resurfacing technology assessment re-review 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
Hip Resurfacing	11	0	0

Covered Conditions

None.

Limitations of Coverage

Not applicable.

The committee checked for availability of a Medicare coverage decision. There is no national coverage determination (NCD) for Hip Resurfacing. The committee reviewed and considered available guidelines including those of the American College of Occupational and Environmental Medicine (ACOEM) and the National Institute for Health and Clinical Excellence (NICE). ACOEM gives a recommendation of grade ‘C’ for certain patients and NICE includes the treatment as an option for some conditions. The HTCC determination differed from these guidelines; the committee specified the reasons for differing include the most recent evidence addressing safety including the registries and cohort studies included in the evidence report with no definable benefit compared to alternatives.

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

The Chair called for further comments. No further comments on re-review of Hip Resurfacing.

- 7. Meeting adjourned.

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

Topic: Hyaluronic Acid/ Viscosupplementation
Meeting Date: November 15, 2013
Final Adoption:

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

<http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx>

Number and Coverage Topic:

20131114A – Hyaluronic Acid/ Viscosupplementation

HTCC Coverage Determination:

Hyaluronic Acid/ Viscosupplementation is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination:

Limitations of Coverage

Hyaluronic Acid/Viscosupplementation is a **covered benefit for the treatment of pain associated with osteoarthritis of the knee (OA), when all of the following conditions are met:**

- Restricted to patients who have a medical contraindication to other forms of non-surgical care;
- Is limited to two courses per year with at least four months between courses; and
- Documented evidence of clinical benefit in terms of pain and function from the prior course of treatment is required for subsequent treatment courses.

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 agency and state utilization information. The committee concluded that the current evidence on Hyaluronic Acid/ Viscosupplementation 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 Hyaluronic Acid/ Viscosupplementation.

Hyaluronic Acid/ Viscosupplementation

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Hyaluronic Acid/ Viscosupplementation	0	0	11

Discussion

The Chair called for discussion of conditions of coverage for Hyaluronic Acid/ Viscosupplementation 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

Hyaluronic Acid/Viscosupplementation is a **covered benefit for the treatment of pain associated with osteoarthritis of the knee (OA), when all of the following conditions are met:**

- Restricted to patients who have a medical contraindication to other forms of non-surgical care;
- Is limited to two courses per year with at least four months between courses; and
- Documented evidence of clinical benefit in terms of pain and function from the prior course of treatment is required for subsequent treatment courses.

Action

The committee checked for availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Hyaluronic Acid/Viscosupplementation. The committee also reviewed practice guidelines from The American Academy of Orthopaedic Surgeons, American College of Rheumatology; National Institute for Health and Care Excellence; and Osteoarthritis Research Society International.

Draft

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.

Hyaluronic Acid/ Viscosupplementation

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 Hyaluronic Acid/ Viscosupplementation.

Overview of Comments		
Category	Comment Period Dec 13 – 27, 2013	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	1	0
Industry & manufacturer	1	0
Professional society & advocacy organization	1	0
Total	3	0

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 19, 2012	
Public comments due	December 3, 2012	15
Selected technologies published	December 6, 2012	
Public comments due	January 7, 2013	32
Draft Key Questions published	March 21, 2013	
Public comments due	April 8, 2013	19
Final Key Questions published	May 14, 2013	
Draft report published	August 5, 2013	
Public comments due	September 4, 2013	31
Final report published	October 14, 2013	
Public meeting date	November 15, 2013	
Findings & decision published	December 13, 2013	
Public comments due	December 27, 2013	15

HA VISCOSUPPLEMENT COALITION

Bioventus LLC, Durham, NC; DePuy Synthes Mitek Sports Medicine, Raynham, MA;
Ferring Pharmaceuticals Inc., Parsippany, NJ; Fidia Pharma USA, Inc., Parsippany, NJ; Zimmer, Inc., Warsaw, IN
4721 Emperor Boulevard Suite 100 Durham, NC 27703

December 19, 2013

To: shtap@hca.wa.gov

On behalf of the HA/Viscosupplement Coalition (HAVC), we thank you for the opportunity to submit comments in response to the Draft Findings and Decision for Hyaluronic Acid/Viscosupplementation, dated November 15, 2013.

We are very pleased that the Health Technology Clinical Committee maintained coverage for hyaluronic acid/viscosupplementation, allowing continued access to this beneficial therapy for Washington State insured beneficiaries.

We appreciate the need to add the coverage conditions, and believe that they are reasonable.

One item of note, in the *Action* Section is it noted that Medicare coverage was reviewed and that there was no national coverage decision (NCD). While that is certainly true, it is important to note that all Medicare Administrative Contractors do independently provide coverage for viscosupplementation.

Thank you again for your consideration.

Sincerely yours,

Peter Heeckt, MD, PhD, Bioventus
Samir Bhattacharyya, Ph.D., *Mitek Sports Medicine*
John Evangelista, MD, Fidia Pharma USA Inc.
Yvonne Bokelman, MBA, FACHE, Zimmer Inc.
Anke Fierlinger, MD, Ferring Pharmaceuticals Inc.

From: Mecklenburg, Robert Robert.Mecklenburg@vmmc.org
To: HCA ST Health Tech Assessment Prog
Cc:
Subject: Hyaluronic acid

Sent: Tue 12/17/2013 8:19 AM

“Restricted to patients who have a medical contraindication to other forms of non-surgical care;”

Does this include a contraindication to physical measures such as strengthening, assistive devices and activity modification?

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From: William Alkire [<mailto:bbcove@comcast.net>]
To: Morse, Josiah (HCA)
Cc:
Subject: Alkire/Visco/information

Sent: Friday, January 24, 2014 8:01 AM

Josh,

I recognize that the public comment period has passed for the Viscosupplementation review. However, my clients thought it would be helpful for the program and the HTCC committee to have the attached information before the March 21st final decision. Your consideration is appreciated.....Bill

Alkire & Associates
Bill Alkire, Principal
Cell-360-480-4906

Hiroshi Ohuchi, M.D., Associate Editor

On January 1, 2014, Hiroshi Ohuchi, M.D., became an Associate Editor, replacing Michael J. Rossi, M.D., who completed his term. Dr. Ohuchi is the Director of Sports Medicine at the Kameda Medical Center in Kamogawa, Japan. He earned his medical degree at Tokyo Medical and Dental University School of Medicine and did his residency in orthopaedic surgery at Saku Central Hospital, continuing at Nissan Tamagawa Hospital in Tokyo. He went on to Sakudaira Sports Medicine and Arthroscopy Center for Fellowship training in sports medicine and arthroscopic surgery, Ohwaki Hospital for sports orthopaedics clinic, and Karuizawa Hospital for joint surgery and sports medicine clinic. He later undertook an international

fellowship in sports medicine and arthroscopic surgery at the Taos Orthopaedic Institute in Taos, New Mexico. Dr. Ohuchi is board certified in orthopaedic surgery and orthopaedic sports medicine and is an active member of numerous Japanese orthopaedic societies as well as ISAKOS, AAOS, AANA, and AOSSM. He became a reviewer for *Arthroscopy* in 2009 and came on the Editorial Board in 2011. He is team doctor for the Tokyo 23 Football Club and serves as a medical support doctor for the Japanese Olympic Committee. He lives with his wife and twin daughters on the sea coast not far from Tokyo. Please join me in welcoming Hiroshi Ohuchi to our editorial team.

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<http://dx.doi.org/10.1016/j.arthro.2013.11.009>

Gary G. Poehling, M.D.
Editor-in-Chief

Congratulations and Condemnations: Level I Evidence Prize for Femoral Tunnel Position in ACL Reconstruction, and AAOS Clinical Practice Guidelines Miss the Mark—Again

We are always excited by a new year,¹⁻⁵ and on behalf of the Associate Editors we are excited to announce the winner of the 2013 Arthroscopy Journal Prize for best Level I Evidence. Table 1 lists the articles published in *Arthroscopy* in 2013 of this highest level of evidence.⁶⁻¹⁷

Seriously?

Only 12 articles in 12 months? Research is challenging, but as editors we relish original scientific articles of the highest levels of evidence, so we strongly urge authors to bring it on.¹⁸ Please send us your reports of studies of the highest levels of evidence and, in the future, please attempt to pursue higher level research. On the other hand, level of evidence is but one measure of the quality of a scientific study, and randomized controlled trials represent Level II evidence if the quality is low or follow-up is less than stellar.^{19,20}

It gives us great pleasure to announce that “Femoral Tunnel Position on Conventional Magnetic Resonance Imaging After Anterior Cruciate Ligament Reconstruc-

tion in Young Men: Transtibial Technique Versus Anteromedial Portal Technique” by Noh, Roh, Yang, Yi, and Lee¹⁴ is our 2013 Level I Evidence prize winner. We congratulate the authors, who will receive a check for \$5,000, certificates suitable for framing, and everlasting glory. We also acknowledge “Comparison of Intra-Articular Injections of Plasma Rich in Growth Factors (PRGF-Endoret) Versus Durolane Hyaluronic Acid in the Treatment of Patients With Symptomatic Osteoarthritis: A Randomized Controlled Trial” by Vaquerizo, Plasencia, Arribas, Padilla, Orive, and Anitua¹⁷ as a particularly well performed study. In fact, one reason it did not achieve first prize in 2013 was that this same group won this prize for related research in 2012.²¹ We also recognize Level I work by editors who, according to the rules, were excluded from the competition.^{13,16}

Editorial controversy...again?^{18,22} In our opinion, Louis McIntyre and his colleagues have a lot of guts for speaking up, yet again, and proclaiming that the American Academy of Orthopaedic Surgeons (AAOS)

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<http://dx.doi.org/10.1016/j.arthro.2013.11.008>

Table 1. Level I Studies Published in *Arthroscopy* in 2013

Title	Authors	Issue	Page
Plasma Rich in Growth Factors in Arthroscopic Rotator Cuff Repair: A Randomized, Double-Blind, Controlled Clinical Trial	Ruiz-Moneo, Molano-Muñoz, Prieto, Algorta	January	2
Arthroscopic Labral Repair Versus Selective Labral Debridement in Female Patients With Femoroacetabular Impingement: A Prospective Randomized Study	Krych, Thompson, Knutson, Scoon, Coleman	January	46
Randomized Controlled Trial of Osteoconductive Fixation Screws for Anterior Cruciate Ligament Reconstruction: A Comparison of the Calaxo and Milagro Screws	Bourke, Salmon, Waller, Winalski, Williams, Linklater, Vasanji, Roe, Pinczewski	January	74
Arthroscopic Single-Row Versus Double-Row Rotator Cuff Repair: A Meta-analysis of the Randomized Clinical Trials	Sheibani-Rad, Giveans, Arnoczky, Bedi	February	343
Does Cast Immobilization Contribute to Posterior Stability After Posterior Cruciate Ligament Reconstruction?	Yoon, Park, Lee, Kim, Park, Oh	March	500
Validity of a Novel Arthroscopic Test to Diagnose Posterolateral Rotational Instability of the Knee Joint: The Lateral Gutter Drive-Through Test	Shen, Zhang, Lv, Hong, Wang, Zhang, Feng	April	695
Ultrasonography- or Electrophysiology-Guided Suprascapular Nerve Block in Arthroscopic Acromioplasty: A Prospective, Double-Blind, Parallel-Group, Randomized Controlled Study of Efficacy	Ko, Kang, Hwang	May	794
Efficacy of Marrow-Stimulating Technique in Arthroscopic Rotator Cuff Repair: A Prospective Randomized Study	Milano Saccomanno, Careri, Taccardo, De Vitis, Fabbriani	May	802
Femoral Tunnel Position on Conventional Magnetic Resonance Imaging After Anterior Cruciate Ligament Reconstruction in Young Men: Transtibial Technique Versus Anteromedial Portal Technique	Noh, Roh, Yang, Yi, Lee	May	882
Postoperative Fentanyl Patch Versus Subacromial Bupivacaine Infusion in Arthroscopic Shoulder Surgery	Merivirta, Äärilä, Aantaa, Koivisto, Leino, Liukas, Kuusniemi	July	1,129
Randomized Controlled Trial Comparing All-Inside Anterior Cruciate Ligament Reconstruction Technique With Anterior Cruciate Ligament Reconstruction With a Full Tibial Tunnel	Lubowitz, Schwartzberg Smith	July	1,195
Comparison of Intra-Articular Injections of Plasma Rich in Growth Factors (PRGF-Endoret) Versus Durolane Hyaluronic Acid in the Treatment of Patients With Symptomatic Osteoarthritis: A Randomized Controlled Trial	Vaquerizo, Plasencia, Arribas, Seijas, Padilla, Orive, Anitua	October	1,635

clinical practice guidelines miss the mark.²³ To be honest, your editors felt uncomfortable when we and Dr. McIntyre first proclaimed that an AAOS CPG missed the mark, way back in 2012.²⁴ (“Does anybody remember 2012?”)

Here is the background: in 2008, AAOS published a “Clinical Practice Guideline on the Treatment of Osteoarthritis of the Knee” by Richmond, Hunter, Irrgang, et al.²⁵ to guide management of patients with knee OA. These CPGs were revised this year.²⁶

Simply put, Bannuru, Vaysbrot, McIntyre state that the 2013 AAOS CPG “recommended against the use of viscosupplementation, for failing to meet the new criterion of Minimum Clinically Important Improvement (MCII). However, the AAOS’s methodology contained numerous flaws...[and] the current state of research on MCII allows it to be used only as a supplementary instrument, not a basis for clinical decision making.”²³

In the opinion of your editors, the use of knee hyaluronate viscosupplementation may be clinically insignificant for some patients, but it can be of significant benefit for others, as Bannuru, Vaysbrot, and McIntyre make clear in this issue. This opinion is based on our own extensive clinical experience, and this opinion is also evidence-based, as it is reported in the same 2013 AAOS CPG,²⁶ that some published literature does show clear and statistically significant improvement of knee OA symptoms after viscosupplementation treatment. The bottom line is that there are many criteria for evaluating the quality and importance and clinical relevance and generalizability of medical research, and no research is perfect. Furthermore, we are shocked that an institution as eminent as the American Academy of Orthopaedic Surgeons, of which we are proud members, would publish guidelines that seem so inconsistent with the mission of the AAOS, which states: “AAOS will champion the interests of all patients, serve our members and the profession, and advance the highest quality musculoskeletal health.”²⁷ In our opinion, it is not in the interests of *all* patients to recommend against a treatment that is of significant benefit for *some* patients, especially when that treatment is for a disease (knee OA) that is not preventable, and for which there is no cure. In our opinion, it does not serve AAOS members and our profession to recommend against a treatment that AAOS members provide their own patients, many of whom demand such treatment because viscosupplementation decreases their knee OA pain and limitations of function with a risk-to-benefit profile they prefer to alternative treatments, including no treatment at all. Again, in our opinion, it does not advance the highest quality of musculoskeletal health to publish CPGs based on methods that are controversial, insofar as there are other ways to assess the medical literature.²³ We believe that the AAOS should seek the counsel of independent experts to review the AAOS CPG methods and alternatives and, in the interim, refrain from CPG activity and publication in accordance with the AAOS Mission that additionally states that AAOS’s “major activities” require “defensible criteria against which all goals are established.”²⁷ It takes guts to say it: “Cease and desist.”

Your editors do not have all the answers to clinical questions,^{28,29} because science and medicine continue to evolve.^{30,31} In the past, we have shared the humble words of Donald H. Johnson, M.D., member emeritus of the *Arthroscopy* Journal Board of Trustees: “Based on past experience, it is likely that half of what we today believe

to be correct arthroscopic knowledge or treatment is wrong. The problem is. . . I don’t know which half.”³²

Future research may find that there are more effective treatments for knee OA than viscosupplementation. On the other hand, in the future, we may find that viscosupplementation is a routinely recommended treatment for knee OA.

It may be for good reason that Dhawan, Mather Karas, Ellman, Young, Bach, and Cole report in this issue of *Arthroscopy* that, “...significant gaps exists between CPGs established by the AAOS in 2008 and current practice patterns in the non-arthroplasty treatment of knee OA in the United States.”³³ Perhaps, for now, it could be better were the AAOS to be less dogmatic.

James H. Lubowitz, M.D.

Assistant Editor-in-Chief

Matthew T. Provencher, M.D.

Deputy Editor

Gary G. Poehling, M.D.

Editor-in-Chief

Replies to www.newmexicokneesurgery.com

References

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Did the American Academy of Orthopaedic Surgeons Osteoarthritis Guidelines Miss the Mark?

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and Louis F. McIntyre, M.D.

Abstract: The American Academy of Orthopaedic Surgeons (AAOS) 2013 guidelines for knee osteoarthritis recommended against the use of viscosupplementation for failing to meet the criterion of minimum clinically important improvement (MCII). However, the AAOS's methodology contained numerous flaws in obtaining, displaying, and interpreting MCII-based results. The current state of research on MCII allows it to be used only as a supplementary instrument, not a basis for clinical decision making. The AAOS guidelines should reflect this consideration in their recommendations to avoid condemning potentially viable treatments in the context of limited available alternatives.

Value, quality, comparative effectiveness: these are terms we see and hear with increasing frequency in relation to the delivery of health care. They are used in connection with the term evidence-based medicine (EBM), which is a concept meant to promote the scientific proof of treatment efficacy throughout medicine and surgery.¹ In the past, physicians were the arbiters of proof of efficacy through their analysis and interpretation of the medical literature. Orthopaedic surgeons reviewed their literature, mostly case series (Level IV) and case-control studies (Level III), and treatment recommendations were made to patients based on the analysis leavened with expert opinion and experience. The increasing reliance on third-party reimbursement of medical services and the resulting cost escalation associated with this payment method have forced the government and insurers to examine exactly what it is they are paying for when services are

performed.² One of the main purposes of EBM when performed by payers, therefore, is economic.

Evidence-based analyses of medical services are now commonplace and becoming widespread. These analyses are used in determining coverage decisions for medical services. The federal government has invested over \$1 billion in the Patient-Centered Outcomes Research Institute, and insurers each perform their own evidence synthesis of the literature. Many states use these methodologies, especially when evaluating high-cost and innovative procedures.³ In addition, international EBM analyses such as those performed by the National Institute for Health and Clinical Excellence in England are cited in the United States when EBM analyses are performed.⁴ There is no standardization throughout these various programs in choosing the methodology used to determine the value of studies in the literature. In addition, expert input from orthopaedic surgeons is also variable. This lack of standardization and expert input has led to confusion about the value of much of the orthopaedic literature in EBM studies.

The American Academy of Orthopaedic Surgeons (AAOS) has developed its own quality initiative and EBM process including clinical practice guidelines (CPG) and appropriate use criteria.⁵ This quality initiative is meant to make sure that the real experts in musculoskeletal care are involved in the EBM process. The CPG process has been controversial because of its evidence-synthesis rules that stress randomized clinical trials (Level I) and do not allow inclusion of much of the Level III and IV evidence available in the literature.⁶⁻⁸ In addition, some statistical metrics such as minimum clinically important improvement (MCII) and minimum clinically important difference (MCID)

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result in significant changes in the way even Level I studies are assessed for value. In the recently published CPG on osteoarthritis (OA) of the knee,⁹ the MCII was used as a metric in the strong recommendation against the use of viscosupplementation in treating knee OA, despite studies that showed statistically significant improvement of symptoms after treatment with certain types of hyaluronic acid.

Because one of the tenets of EBM is the incorporation of expert opinion, it is important for orthopaedic surgeons to understand the various methodologic rules and analytic metrics used in these analyses. Armed with this understanding, physicians can critically evaluate EBM analyses to provide important expert-opinion filters to such programs. Physicians can then advocate for or against EBM studies, providing the expert opinion that is essential to their proper use. In this way, access to safe and effective care will be maintained for patients.

Commentary

The most recent AAOS CPG for knee OA raised controversy by “strongly recommending” against the use of viscosupplementation.⁹ This negative shift from the 2008 “inconclusive” recommendations followed changes in CPG methodology rather than an evidence trend. Furthermore, the significant limitations of the AAOS methodology called into question the guidelines’ verdict and highlighted the profound impact that unfavorable recommendations may have on multiple stakeholders. We aim to discuss the methodologic flaws of the AAOS guidelines that led to recommendations against certain treatments, such as viscosupplementation, potentially depriving some patients of effective remedies for a disease with a very limited range of therapeutic options (Fig 1).

The guidelines included only 14 hyaluronic acid studies, in stark contrast with the 89 articles covered by the latest systematic review on viscosupplementation.¹⁰ To compare treatments, the AAOS 2013 guidelines used a relatively new metric termed the “minimum clinically important improvement”—that is, the “smallest clinical change that is important to patients.”⁹ Although the AAOS’s meta-analyses showed statistically significant treatment effects of viscosupplementation, it was nevertheless deemed ineffective because it did not meet MCII thresholds. In theory, MCII is a helpful tool to show how statistically significant improvements may not always be clinically relevant. However, as intuitive as it appears, this instrument requires proper understanding and grasp of its limitations from those using these guidelines. Several caveats should be considered for the appropriate interpretation of MCII-based conclusions.

First, it is essential to critically appraise how the MCII was derived. The AAOS sourced the MCII/MCID values from Tubach et al.¹¹ (2005) and Angst et al.¹² (2001). Angst et al. used the metric of MCID, which assesses

both improvement and deterioration, whereas Tubach et al. used MCII (which assesses only improvement). The studies evaluated cohorts of knee/hip OA patients undergoing different interventions: nonsteroidal anti-inflammatory drugs¹¹ or inpatient rehabilitation.¹² However, the AAOS did not consider that MCID or MCII values are context specific.¹³ For example, Angst et al. observed that MCID absolute values differed for improvement versus deterioration, whereas Tubach et al., as well as other authors before them,^{11,12,14,15} found that the main confounding factor in the determination of MCII/MCID was the baseline symptom severity. Besides regression-to-the-mean and “floor” and “ceiling” phenomena, this dependence of MCID/MCII on baseline values could be explained by the influence of patients’ expectations on their determination of treatment effect.¹⁶ Thus the MCII could depend on other factors shaping patients’ expectations, such as the types of treatments in a randomized trial. Current literature also associates MCII/MCID levels with time between outcome assessments and age.¹⁷ Consequently, MCII values calculated for specific therapies may not be applicable to other treatments or patients with different baseline characteristics. Furthermore, Tubach et al. anchored MCII to a “good” level of improvement in 75% of patients or more, surpassing a “fair” positive change (defined as “reasonable effect but could be better”). This may have set the criterion for the “smallest” clinically important improvement too high to be used as a standard for determining a treatment’s efficacy.

Second, one should be aware of how MCII values were presented to readers. For forest-plot presentation, the AAOS guidelines “standardized” MCII values by dividing them by the standard deviation of a “mean baseline score” and then displayed them as bold red lines. Because of the dependence of MCID/MCII on a study population’s heterogeneity, previous research has suggested dividing MCID/MCII by an agreed-on population-based standard deviation rather than standard deviations pooled from individual trials and then using the same measure throughout.¹⁷ This should lead to consistent MCII cutoff values for the same condition and outcome across all treatments, which was not the case in the AAOS guidelines. Moreover, no adjustment was made for the fact that effect sizes calculated from each trial (less precision) would be biased toward the null-effect, whereas MCII standardized by the pooled standard deviation (high precision) would be biased away from the null-effect. Hypothetically, featuring clinically and statistically significant cutoffs in the same plot may be helpful. However, presenting MCII as a red line more prominent than the null-effect line could have been misleading to the AAOS voting panel, especially given the lack of transparency in how the standardized MCII cutoffs were different for different treatments.

Finally, it is critical to correctly interpret the results of analyses performed using the MCII. It is debatable

<ul style="list-style-type: none"> • The AAOS 2013 guideline for knee OA issued a strong recommendation against the use of viscosupplementation. • Although hyaluronic acid products showed statistically significant treatment effects, the unfavorable recommendation was based on failure to meet the Minimum Clinically Important Improvement (MCII) thresholds. 	
MCII methodological points	AAOS 2013 guideline
<ul style="list-style-type: none"> • MCII are context-specific and may not be applicable across treatments or patient populations. • Standardized MCII values for the same condition and outcome should be uniform across all treatments. • MCII are derived from within-patient comparisons and may not be applicable for between-group comparisons. • MCII is a distributional characteristic that should be expressed as a range, with proportions of patients in each group that achieved outcomes reaching the lower bound. 	<ul style="list-style-type: none"> • The AAOS evaluated various treatments with MCII obtained from 2 nonrandomized trials of everyday-practice NSAIDs and rehabilitation. • The AAOS standardization procedure lacked transparency, and MCII cut-offs inexplicably differed across treatments. • The AAOS used MCII for between-group comparisons while failing to account for the placebo effect. • MCII were expressed as a single cut-off point, thereby dismissing a share of patients who have achieved clinically significant improvement.
<ul style="list-style-type: none"> • MCII is a difficult concept that is sensitive to improper analysis. It is a supplementary tool for pointing out the difference between statistically and clinically relevant findings, not an ultimate metric for evaluating a treatment's efficacy. The AAOS guideline should re-evaluate its recommendations to reflect these considerations. 	

Fig 1. Summary of key points.

whether MCII should be used at all for between-group comparisons when the cutoff values were derived from within-patient comparisons.¹⁷ Notably, this would disregard the placebo effect and still require the between-group difference to be as large as the within-patient improvement to achieve “clinical significance.” Even if we accept the MCII for between-treatment comparison, the interpretation of results could be overly simplistic. Contrary to statistically significant cutoffs for effect sizes, MCII is a distributional characteristic that carries a degree of uncertainty, and it should be expressed as a range, not a single point.¹⁷ Therefore, for between-group comparison, the results should be expressed as proportions of patients in each group that achieved outcomes reaching or exceeding the lower bound of the MCII range.¹⁸ Accordingly, even when treatment effects did not reach an MCII

“cutoff,” there could still be a significant proportion of patients who crossed that threshold and for whom clinically significant improvement was achieved.¹⁸

In conclusion, the AAOS should be commended for its efforts to highlight the fact that significant effect sizes do not always translate into clinically pertinent findings. However, the question arises as to whether its committee's recommendations were biased by improper use of a single metric in an analysis that used a very small subset of studies based on arbitrary criteria. Applied appropriately, MCII can be a useful tool for comprehensive presentation of study results; however, it should not be a cornerstone of clinical decision making. In addition, multiple variables associated with treatment of a patient with OA, such as arthritis severity, the number of compartments involved, alignment, age,

body weight, activity level, and medical comorbidities, were not addressed in these guidelines. Although guidelines can assist treatment decisions, they are not definitive and must therefore be used with caution and as an ancillary to clinical reasoning on a case-by-case basis. Guideline developers should word recommendations carefully to avoid losing therapeutic options that may benefit a subset of patients in a field in which few safe and effective treatments are available.

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

Topic: Hip Resurfacing
Meeting Date: November 15, 2013
Final Adoption:

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

<http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx>

Number and Coverage Topic:

20131114B – Hip Resurfacing (Re-review)

HTCC Coverage Determination:

Hip Resurfacing is **not a covered benefit**.

HTCC Reimbursement Determination:

Limitations of Coverage

Not applicable.

Non-Covered Indicators

All

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 determined 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 Hip Resurfacing indicates the technology is less safe than alternatives and cost-effectiveness is unproven. 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 not cover Hip Resurfacing.

Hip Resurfacing

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Hip Resurfacing	11	0	0

Discussion

Limitations of Coverage

Not applicable

Non-Covered Indicators

All

Action

The committee checked for availability of a Medicare coverage decision. There is no national coverage determination (NCD) for Hip Resurfacing. The committee reviewed and considered available guidelines including those of the American College of Occupational and Environmental Medicine and the National Institute for Health and Clinical Excellence. The committee chair directed HTA staff to prepare a Findings and Decisions document for Hip Resurfacing.

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.

Draft

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

Hip Resurfacing
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 Hip Resurfacing.

Overview of Comments		
Category	Comment Period Dec 13 – 27, 2013	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

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 19, 2012	
Public comments due	December 3, 2012	15
Selected technologies published	December 6, 2012	
Public comments due	January 7, 2013	32
Draft Key Questions published	May 23, 2013	
Public comments due	June 7, 2013	16
Final Key Questions published	June 25, 2013	
Draft report published	August 27, 2013	
Public comments due	September 26, 2013	31
Final report published	October 1, 2013	
Public meeting date	November 15, 2013	
Findings & decision published	December 13, 2013	
Public comments due	December 27, 2013	15