

Washington State
Health Care Authority
Health Technology Assessment

Program Updates

Josh Morse, MPH
HTA Program Director

May 20, 2016

Today's Agenda

1. Bronchial Thermoplasty for Asthma
2. Autologous Blood/ Platelet-rich Plasma Injections

Other Topics Scheduled for 2016-17

July 8

- Meeting by phone
- Final action on today's draft decisions

November 18

- Fecal Microbiota Transplantation
- Negative-Pressure Wound Therapy

January 20

- Pharmacogenetics

3

2016 Final Technology Selections

- Extracorporeal Shock Wave Therapy for Musculoskeletal Conditions
- Interventions for Treatment of Migraines/ Headaches
- Varicose Veins
- Skin Substitutes
- Mammogram: Computer-Aided Detection Mammograph
- Artificial Disc Replacement (Re-review)

4

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.

5

Washington State
Health Care Authority

Health Technology Clinical Committee

Date: March 18, 2016

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

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

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

HTCC MINUTES

Members Present: Gregory Brown, MD, PhD; Joann Elmore, MD MPH; Louise Kaplan, PhD, ARNP; David K. McCulloch, MD, FRCP; Carson Odegard DC, MPH; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh, MD; Tony Yen, MD

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Standaert, chair called the meeting to order. Sufficient members were present to constitute a quorum.

2. **January 15, 2016 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve was seconded. Minutes adopted by the committee with corrections noted.

Action: Eleven committee members approved the January 15, 2016 meeting minutes.

3. **Novocure 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. The committee reviewed and discussed the comment. No changes were made to the draft based on the comment.

Action: Eleven committee members voted to approve the Novocure findings and decision document

4. **Cardiac Stents - Re-review 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 after the comment period. Committee members reviewed the comment and modified the draft to correct a typographical error and reformat language for clarity based on staff suggestion. Staff was directed to modify the final determination per the committee's changes.

Action: Eleven members voted to approve the Cardiac Stents - Re-review findings and decision document.

Draft

5. Extracorporeal Membrane Oxygenation Therapy (ECMO):

Agency Utilization and Outcomes:

G. Steve Hammond, PhD, MD, MHA, Chief Medical Officer, Washington Department of Corrections presented the state agency perspective for ECMO to the committee. The full presentation is published with [March 18, meeting materials](#).

Scheduled and Open Public Comments:

The chair called for public comments.

No scheduled or open public comments received.

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for ECMO, Eileen Bulger, MD, FACS, Chief of Trauma, Harborview Medical Center, Seattle, WA.

Elizabeth Russo, MD, Institute for Clinical and Economic Review presented the evidence review of extracorporeal membrane oxygenation therapy. The full presentation is published with [March 18, meeting materials](#).

HTCC Coverage Vote and Formal Action

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on ECMO is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of ECMO compared to conventional intensive care management. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions extracorporeal membrane oxygenation therapy.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Extracorporeal Membrane Oxygenation Therapy	0	11	0

Discussion

The committee reviewed and discussed the evidence, and the quality and limitations of the evidence. Based on the available information and including contextual input from the clinical expert the committee developed conditions for coverage for ECMO to address use for patients with severe life threatening respiratory or cardiac dysfunction that is not responding to conventional management but is potentially reversible; as a bridging therapy for patients in pulmonary failure and

who are on a pulmonary transplant list; and as a bridging therapy for patient in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation. All procedures should only be provided at a facility participating in the Extracorporeal Life Support Organization (ELSO) registry to continue to collect valuable registry data for future use. With the above noted condition the committee voted to cover ECMO with conditions.

Limitations

In patients with severe life threatening, but potentially reversible, acute respiratory or cardiac dysfunction unresponsive to conventional management.

As a bridging therapy for patients in pulmonary failure who are on a pulmonary transplant list.

As a bridging therapy for patients in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation.

All procedures only at a facility participating in the ELSO case registry.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for ECMO.

The committee discussed clinical guidelines identified for treatment addressing use of ECMO from the following organizations:

Extracorporeal Life Support Organization (ELSO)(2010)

American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (AHA)(2010)

International Society of Heart and Lung Transplantation (ISHLT)(2010)

American Thoracic Society (1997)

National Institute for Health and Care Excellence (NICE)(2014)

The chair noted consistency with existing guidelines and the fact that some of the guidelines preceded some of the available literature.

The committee chair directed HTA staff to prepare a findings and decision document on ECMO reflective of the vote for final approval at the next public meeting.

6. Shana Johnson, MD presented the state agency perspective and utilization rates for the spinal injections re-review topic to the committee. The full presentation is published with [March 18, meeting materials](#).

Scheduled and Open Public Comments:

The chair called for public comments. Comments were provided by:

- Steven Stanos, DO
- Janna Friedly, MD
- Paul Dreyfuss, MD & Brandon Messerli, DO (*Representing the following*)
 - William A. Anderson, MD
 - Jason G. Attaman, DO
 - Kevin Berry
 - Doug Burns, MD
 - Alan Chen, MD
 - Michele Curatolo, MD, PhD
 - Rebecca C. Dale, DO
 - Natalya Eykhvald
 - Kelvin Franke, DO
 - Zing Fu, MD
 - Jon Geffen, DO
 - Christopher Godbout, MD
 - William B. Gray, DO
 - Brandy Gump
 - Michael Hatzakis, MD
 - Xiang Jing, ARNP
 - Stephen Johnson, MD
 - Henry Kim, MD
 - Eric Kinder, MD
 - Hisashi Kobayashi, MD
 - Daniel Kwon, MD
 - Yung Lee, DO
 - Katrina Lewis, MD
 - Carolyn Marquardt, MD
 - Christopher Merifield, MD, MHA
 - Carlos E. Moravek, MD
 - Linda Nixon, PAC
 - Chan Saetern
 - Richard Seroussi, MD
 - Virtaj Singh, MD
 - Ben Snyder, MD
 - Brett Stacey, MD
 - Alison Stout, DO
 - Geoffery E. Sultana, MD
 - David J. Tauben, MD, FACP
 - Jessi Thao
 - Marco Wen, MD
 - Jiang Wu, MD
 - Irene Young, MD
 - Ryan Zhender, MD
- Kathy Kroening
- Diana Kusulos
- Carol Glenn
- Carol O'Connell
- Henry Sherwood
- Brett Stacey, MD
- Richard Seroussi, MD

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for spinal injections re-review, Kevin Vorenkamp, MD.

Joseph Dettori, PhD, Spectrum Research Incorporated, presented the evidence review addressing spinal injections re-review. The full presentation is published with [March 18, meeting materials](#).

HTCC Coverage Vote and Formal Action:

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence for spinal injections is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of spinal injections compared to alternatives. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions spinal injections with no change to the conditions from the original determination. The committee did add a clarifying statement to make clear that the determination does not apply to injections for “inflammatory arthropathy”.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Spinal Injections	0	11	0

Discussion

The committee reviewed and discussed the evidence for use of spinal injections. The committee determined that new evidence did not support a change in the original determination of coverage with conditions and the original conditions were not changed.

Limitations*

- Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain;
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy;
 - No more than two without clinically meaningful improvement in pain and function; and
 - Maximum of three in six months.
- Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy; and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review.

*Limitations do not apply to injections for inflammatory arthropathy

Non-Covered Indicators:

- Therapeutic medial branch nerve block injections; intradiscal injections and facet injections are not a covered benefit.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no NCD for spinal injections.

The committee discussed and reviewed treatment criteria from clinical guidelines identified for spinal injections from the following organizations:

- American Society for Interventional Pain Management (2013)
- American Society of Anesthesiologists Task Force/American Society of Regional Anesthesia and Pain Management (2010)
- Colorado Division of Workers' Compensation (2012), (2014)
- Institute for Clinical Systems Improvement (2012)
- Toward Optimized Practice (2011)
- U.S. Food and Drug Administration Safe Use Initiative (2015)

The chair noted consistency with existing guidelines with some differences based on evidence analysis and interpretation.

The committee chair directed HTA staff to prepare a findings and decision document on spinal injections reflective of the majority vote for final approval at the next public meeting.

7. Josh Morse, HTA program director presented a status update on HTA technology assessments now in process and those scheduled for 2016.
8. **Meeting adjourned.**

Extracorporeal Membrane Oxygenation (ECMO)

DRAFT Findings and Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received two comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on extracorporeal membrane oxygenation (ECMO).

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	January 5, to January 20, 2015	16
Public comments	0	
Selected technologies published	February 4, to March 6, 2015	31
Public comments	1	
Draft key questions published	September 24, to October 8, 2015	15
Public comments	0	
Final key questions published	October 20, 2015	
Draft report published	December 16, to January 14, 2016	30
Public comments	0	
Final report published	February 12, 2016	
Public meeting	March 18, 2016	
Draft findings & decision published	March 8, to March 22, 2016	15
Public comments	0	

Overview

Category	Comment Period	
	March 8, to March 22, 2016	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

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

Topic: Extracorporeal Membrane Oxygenation Therapy
Meeting Date: March 18, 2016
Final Adoption:

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

Number and Coverage Topic:

20160318A – Extracorporeal Membrane Oxygenation Therapy (ECMO)

HTCC Coverage Determination:

Extracorporeal membrane oxygenation therapy is a **covered benefit with conditions**.

HTCC Reimbursement Determination:

Limitations of Coverage:

In patients with severe life-threatening, but potentially reversible, acute respiratory or cardiac dysfunction unresponsive to conventional management.

As a bridging therapy for patients in pulmonary failure who are on a pulmonary transplant list.

As a bridging therapy for patients in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation.

All procedures only at a facility participating in the ELSO case registry.

Non-Covered Indicators:

N/A

Agency Contact Information:

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

Draft

HTCC Coverage Vote and Formal Action

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on ECMO is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of ECMO compared to conventional intensive care management. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions extracorporeal membrane oxygenation therapy.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Extracorporeal Membrane Oxygenation Therapy	0	11	0

Discussion

The committee reviewed and discussed the evidence, and the quality and limitations of the evidence. Based on the available information and including contextual input from the clinical expert, the committee developed conditions for coverage for ECMO to address use for patients with severe life-threatening respiratory or cardiac dysfunction that is not responding to conventional management but is potentially reversible; as a bridging therapy for patients in pulmonary failure and who are on a pulmonary transplant list; and as a bridging therapy for patient in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation. All procedures should only be provided at a facility participating in the Extracorporeal Life Support Organization (ELSO) registry to continue to collect valuable registry data for future use. With the above noted condition the committee voted to cover ECMO with conditions.

Limitations

In patients with severe life-threatening, but potentially reversible, acute respiratory or cardiac dysfunction unresponsive to conventional management.

As a bridging therapy for patients in pulmonary failure who are on a pulmonary transplant list.

As a bridging therapy for patients in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation

All procedures only at a facility participating in the ELSO case registry.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for ECMO.

The committee discussed clinical guidelines addressing use of ECMO from the following organizations:

- Extracorporeal Life Support Organization (ELSO)(2010)
- American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (AHA)(2010)
- International Society of Heart and Lung Transplantation (ISHLT)(2010)
- American Thoracic Society (1997)
- National Institute for Health and Care Excellence (NICE)(2014)

The chair noted consistency with existing guidelines and the fact that some of the guidelines preceded some of the available literature.

The committee chair directed HTA staff to prepare a findings and decision document on ECMO reflective of the 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.

DRAFT Spinal Injections

Findings & Decision
 Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received two comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on spinal injections.

Timeline

Phase	Date	Public Comment Days
Technology Recommendations published	January 5, to January 20, 2015	16
Public comments	1	
Selected Technologies published	February 4, to March 6, 2015	31
Public comments	0	
Draft Key Questions published	September 1, to 15, 2015	15
Public comments	3	
Final Key Questions published	October 13, 2015	
Draft Report published	December 16, to January 14, 2016	30
Public comments	3	
Final Report published	February 12, 2016	
Public Meeting	March 18, 2016	
Draft Findings & Decision published	March 8, to March 22, 2016	15
Public comments	2	

Overview

Category	Comment Period	
	March 8, to March 22, 2016	Cited Evidence
Patient, relative and citizen	0	0
Legislator and public official	1	0
Health care professional	1	1
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	2	1

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Brandon Messerli, DO	EvergreenHealth	yes
<input type="checkbox"/>	2. Shana Johnson, MD, HCA	Agency Medical Director's Group	no

April 21, 2016

Washington State Health Care Authority
626 8th Avenue SE
P.O. Box 45502
Olympia, WA 98504-5502

Submitted via e-mail: shtap@hca.wa.gov

Dear Health Technology Coverage Committee:

We commend the committee for its thorough consideration of the evidence and public comments regarding the spine injection re-review of March 18th. This letter is in regards to the Draft Findings & Decisions.

A topic for consideration is the proposed coverage of facet joint injections for “inflammatory arthropathy”. As facet joint injections for non-inflammatory conditions are excluded from coverage, the interpretation of what constitutes inflammatory arthropathy is paramount. At the HTCC meeting there was consensus agreement to cover facet joint injections for spondyloarthropathy, which is a distinct systemic clinical condition that is diagnosed with a combination of clinical, imaging, and laboratory findings. There remains debate, however, regarding coverage of steroid injections for inflamed facet joints without a diagnosis of spondyloarthropathy.

An inflamed facet joint is often diagnosed by advanced imaging, with findings of a joint effusion, synovial cyst, peri-articular edema, and/or peri-articular cystic change. SPECT scans can isolate specific facet joints with increased bone metabolism and hyperemia, which will occur in progressive arthritis (1,2) more than joints with a stable degree of arthropathy. A study of 621 MR images by Lakadamyali (3) found that facet joint effusions were found in 86% of those with LBP versus 46% of asymptomatic controls, and, similarly, synovial cysts were found in 62% versus 15%. Earlier studies (4,5,6) found that those subjects with SPECT-positive facet joints responded better to intra-articular steroid injections (IASI) than those SPECT-negative joints. In a randomized, double-blind trial by Ackerman (7), there was a 61% responder rate to IASI in subjects with SPECT-positive joints, as compared to a 26% responder rate with SPECT-negative joints at 3 months follow-up.

It is notable that Spectrum’s 2016 final evidence report found there is moderate quality of evidence with low risk of bias showing benefit of intra-articular lumbar facet steroid injections as compared to intra-muscular steroid injection at 3 months, based on the randomized controlled trial (RCT) of Ribeiro (8). Spectrum also found moderate quality of evidence with low risk of bias that IASI is as effective as radiofrequency neurotomy for treatment of facet joint pain at 6 months, based on the RCT of Lakemeier (9). We agree with these conclusions and, in fact, one of the HTCC members commented on these same findings at the March 18th meeting. Neurotomy has clearly demonstrated effectiveness, and thus was approved by the HTCC for coverage in 2014.

There are a number of clinical factors to be considered when deciding to pursue IASI versus neurotomy. IASI is a relatively brief procedure that can provide immediate pain relief, which is beneficial for patients with severe pain or an acute flare-up. Conversely, neurotomy requires dual

positive medial branch nerve blocks in order to determine if the patient is a candidate for neurotomy. Practically, it can take 2-4 weeks to perform these 3 procedures, followed by up to a 4 week period of time before the patient actually achieves pain relief after the neurotomy. The cost of 1 procedure (for IASI) versus 3 procedures (for neurotomy) is another consideration. Additionally, not all patients desire thermal neurotomy and would favor a non-destructive intervention such as IASI when all other conservative options have otherwise failed to provide relief. In some patients with posterior spinal fusion, the proximity of the hardware to the medial branch nerves precludes use of thermal neurotomy; whereas IASI can be readily performed.

Although there are no RCTs demonstrating the value of cervical facet IASI, there are no clear physiological or anatomical reasons why cervical facet joints would respond differently than the lumbar spine. There is one prospective trial by Folman (10) that showed in 30 subjects with cervical facet arthritis, diagnosed by a single intra-articular injection with excellent pain relief, that a single corticosteroid injection could provide >90% relief at 3 weeks in 73% of subjects, and in 40% of subjects at 3 months.

Washington State Law RCW 70.14.110 states that “(HTCC) determinations shall be consistent with decisions made under the federal Medicare program and in expert treatment guidelines, including those from specialty physician organizations, unless the committee concludes that substantial evidence regarding the safety, efficacy, and cost-effectiveness of the technology supports a contrary determination.” As we demonstrated in our March 18th presentation, the federal Medicare program has implemented coverage for IASI in 47 of 50 states, including Noridian and Washington State. Medicare administrators worked with the Multi-Society Pain Workgroup (MPW) in order to develop coverage guidelines based on the science and best practice. The MPW convened a panel of experts, representing 14 medical societies and >100,000 physicians, and these MPW guidelines were used to formulate these Local Coverage Decisions (LCDs). As Spectrum found a moderate quality of evidence for benefit of IASI, there is clearly *not* substantial evidence for a contrary determination.

These facts being considered, we consider it prudent to provide coverage of IASI for all etiologies of inflammatory arthropathy, including spondyloarthropathy. However, we recommend policy restrictions in order to prevent over-use of these procedures. We believe the MPW guidelines, shown below, are appropriately restrictive, and are a valuable resource for the HTCC in determining its own coverage determinations.

Sincerely,

Brandon Messerli DO
Paul Dreyfuss MD
Kevin Vorenkamp MD

MPW Guidelines for Facet Injections:

- Pain has been present for at least 3 months.
- For predominately axial pain, but a lesser degree of somatic referred pain into the lower extremity is not an exclusion.
- Absence of non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Radicular pain or neurogenic claudication is an exclusion to performing a facet injection unless the radicular pain is caused by a facet synovial cyst.
- Failure of ≥ 4 weeks of a conservative care trial unless patient is unable to tolerate such or comorbidities limit such a trial.
- Must use fluoroscopy or CT guidance and contrast media for performance of the facet joint injection.
- Repeat injections of same joint(s) only allowed if $\geq 50\%$ relief *and* improved ADLs for a minimum of 3 months.

References:

1. Hutton CW. 99mTc HMDP bone scanning in generalized nodal osteoarthritis. II. The four hour bone scan image predicts radiographic change. *Ann Rheum Dis.* 1986 Aug;45(8):622-6.
2. Kim. Magnetic resonance image-based morphological predictors of single photon emission computed tomography-positive facet arthropathy in patients with axial back pain. *Neurosurgery.* 2006 Jul;59(1):147-56.
3. Lakadamyali. STIR Sequence for Depiction of Degenerative Changes in Posterior Stabilizing Elements in Patients with Lower Back Pain. *American J of Roentgenology.* 2008 Oct;191(4):973-9.
4. Holder LE. Planar and high-resolution SPECT bone imaging in the diagnosis of facet syndrome. *J Nucl Med.* 1995 Jan;36(1):37-44.
5. Dolan. The value of SPECT scans in identifying back pain likely to benefit from facet joint injection. *Br J Rheumatol.* 1996 Dec;35(12):1269-73.
6. Pneumaticos SG. Low back pain: prediction of short-term outcome of facet joint injection with bone scintigraphy. *Radiology.* 2006 Feb;238(2):693-8.
7. Ackerman. Pain relief with intraarticular or medial branch nerve blocks in patients with positive lumbar facet joint SPECT imaging: a 12-week outcome study. *South Med J.* 2008 Sep;101(9):931-4.
8. Ribeiro. Effect of facet joint injection versus systemic steroids in low back pain: a randomized controlled trial. *Spine (Phila Pa 1976).* 2013 Nov 1;38(23):1995-2002.
9. Lakemeier. A comparison of intraarticular lumbar facet joint steroid injections and lumbar facet joint radiofrequency denervation in the treatment of low back pain: a randomized, controlled, double-blind trial. *Anesth Analg.* 2013 Jul;117(1):228-35.
10. Folman. Relief of cervical pain after selective blockade of the cervical zygapophyseal joint. *Harefuah.* 2004 143:339-341.



STATE OF WASHINGTON
HEALTH CARE AUTHORITY

626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

April 13, 2016

Health Care Authority
Health Technology Assessment Program
PO Box 42712
Olympia, WA 98504-2712

Dear Members of the Clinical Committee:

The Agency Medical Director's group recommends two edits to improve the clarity of the spinal injection decision.

Suggested edit one: Replace the sentence "Limitations do not apply to injections for inflammatory arthropathy" with "This coverage policy does not apply to those with chronic inflammatory rheumatic disease or spondyloarthropathy including: ankylosing spondylitis, psoriatic arthritis, reactive arthritis, or enteropathic arthritis." This edit provides a more specific definition of the patient population with inflammatory arthropathy.

Suggested edit two: Add therapeutic prior to Facet injections. "Non-covered indicators: Therapeutic Medial Branch Nerve Block injections; Intradiscal injections and Therapeutic Facet injections are not a covered benefit." This edit clarifies that non-coverage applies only to Therapeutic Facet injections and not Diagnostic Facet injections.

Thank you for considering these edits. If you have any questions, please contact me, Shana Johnson, MD at shana.johnson@hca.wa.gov .

Sincerely,

Agency Medical Director's Group

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

Topic: Spinal Injections

Meeting Date: March 18, 2016

Final Adoption:

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

Number and Coverage Topic:

20160318B – Spinal Injections

HTCC Coverage Determination:

Spinal injections are a covered benefit with conditions.

HTCC Reimbursement Determination:

Limitations of Coverage*:

- Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain;
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy;
 - No more than two without clinically meaningful improvement in pain and function; and
 - Maximum of three in six months.
- Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy; and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review.

* Limitations do not apply to injections for inflammatory arthropathy.

Non-Covered Indicators:

Therapeutic medial branch nerve block injections; intradiscal injections and facet injections are not a covered benefit.

Draft

Agency Contact Information:

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

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 for spinal injections is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of spinal injections compared to alternatives. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions spinal injections with no change to the conditions from the original determination. The committee did add a clarifying statement to make clear that the determination does not apply to injections for “inflammatory arthropathy”.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Spinal Injections	0	11	0

Discussion

The committee reviewed and discussed the evidence for use of spinal injections. The committee determined that new evidence did not support a change in the original determination of coverage with conditions and the original conditions were not changed.

Limitations*

- Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain;
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy;
 - No more than two without clinically meaningful improvement in pain and function; and
 - Maximum of three in six months
- Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With fluoroscopic guidance or CT guidance
 - After failure of conservative therapy, and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review

* Limitations do not apply to injections for inflammatory arthropathy.

Non-Covered Indicators

- Therapeutic medial branch nerve block injections; intradiscal injections and facet injections are not a covered benefit.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no NCD for spinal injections.

The committee discussed and reviewed treatment criteria from clinical guidelines identified for spinal injections from the following organizations:

American Society for Interventional Pain Management (2013)

American Society of Anesthesiologists Task Force/American Society of Regional Anesthesia and Pain Management (2010)

Colorado Division of Workers' Compensation (2012), (2014)

Institute for Clinical Systems Improvement (2012)

Toward Optimized Practice (2011)

U.S. Food and Drug Administration Safe Use Initiative (2015)

The chair noted consistency with existing guidelines with some differences based on evidence analysis and interpretation.

The committee chair directed HTA staff to prepare a findings and decision document on spinal injections 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.

Draft