Spinal Injections – Re-review

Clinical Expert

Kevin E. Vorenkamp, MD

Department of Anesthesiology & Pain Medicine
Director, Pain Medicine Fellowship
Disclosure

Any unmarked topic will be considered a “Yes”

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

If yes to #7, provide name and funding sources:

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X ___________________________  2/11/16  Kevin E Vorenkamp, MD

Signature  Date  Print Name

So we may contact you regarding this information, please provide the following:

Email Address: ___________________________

Phone Number: ___________________________
Kevin E. Vorenkamp, M.D.
Virginia Mason Medical Center
Department of Anesthesiology & Pain Medicine
1100 Ninth Ave
Mail Stop B2-AN
Seattle, WA 98101
P: 
F:

Experience
2012-current
Virginia Mason Medical Center; Seattle, WA
Member, Department of Anesthesiology & Pain Medicine (07/2012-present)
Director, Pain Medicine Fellowship (07/15-present)

2007-2012
University of Virginia; Charlottesville, VA
Department of Anesthesiology & Pain Medicine
Medical Director, UVA Pain Management Center (2010-2012)
Director, Pain Medicine Fellowship (2009-2012)
Assistant Professor, Anesthesiology & Pain Medicine

2006-2007
Fletcher Allen Healthcare/University of Vermont; Burlington, VT
Fellowship in Pain Medicine

2003-2006
University of Michigan Health System; Ann Arbor, MI
Residency in Anesthesiology

2002-2003
Oakwood Hospital; Dearborn, MI
Transitional Year Residency (Internship)

Education
1998-2002
University of Michigan Medical School; Ann Arbor, MI
MD June, 2002

1994-1998
Ohio Wesleyan University; Delaware, Ohio
B.A May, 1998
Major: Pre-Professional Zoology
Academic All-America (Soccer, 1997)

Certifications
American Board of Anesthesiology (ABA) Certification (Issued 10/5/2007, Certified through 12/31/2017).

License:
Washington Medical License # MD60287283 (Expiration 1/30/2017)
Virginia Medical License # 0101241466 (Lapsed 1/31/2014)
Vermont: Educational Limited #060.0003438 (Lapsed 06/30/2008)
Michigan, #4301080279 (Lapsed 01/31/2007)
DEA BV9512371 (Expiration 05/31/2016)
Memberships
American Medical Association (AMA)
- CPT Editorial Board Panel member (05/2015-present)
  - Advisor (ASA) to CPT: 2012-2015
American Society of Anesthesiologists (ASA)
  - ASA Educational Track Subcommittee on Pain Medicine 2010-Current
    - Chair, Pain Medicine Annual Meeting Workshops 2012-2014
  - Committee on Economics 2011-Current
    - ASA CPT advisor (alternate) 2012-2015
    - ASA Delegate to Multisociety Pain Workgroup 2013-Current
  - Pain Medicine Committee member: 2008-2010, 2015-Current
  - Chronic and Cancer Pain Subcommittee member: 2008-2010
American Society of Regional Anesthesia and Pain Medicine (ASRA)
  - Newsletter committee (2013-2016)
    - Pain Medicine Lead 2014-Current
  - Editorial Board: ASRA-MOCA Pain Medicine CME program; Editorial board
    and question writer 2011-2012
  - Scientific/Education Planning Committee Fall Pain Meeting 2012, 2014-2017
    - Chair, 16th Annual Pain Medicine Meeting (2017)
  - Co-Chair and Founding member: Special Interest Group: Ultrasonography in
    Pain Medicine, Headache: 2014-current
North American Neuromodulation Society (NANS)
  - Annual meeting planning committee 2014-current
American Board of Anesthesiology (ABA): Question writer for pain medicine examination: 2012-2014
Washington State Society of Anesthesiologists (WSSA)
International Spine Intervention Society (ISIS)
American Academy of Pain Medicine (AAPM): 2010-2012

Peer-Reviewed Publications:


**Book Chapters:**


**Additional Publications:**


**Manuscript Review:**

- Regional Anesthesia and Pain Medicine
- Pain Practice
- Pain Medicine
- Neuromodulation
- Journal of Clinical Medicine and Research

**Abstracts/Posters:**

1. May 19-21, 2011: American Pain Society (APS) Annual Scientific Meeting, Austin, TX. **Poster/presentation:**

2. November 19, 2009: **ASRA Fall Pain Meeting. Poster/presentation:**

3. November 20, 2008: **ASRA Fall Pain Meeting. Poster/presentation:**

**National Presentations:**

1. January 30, 2016. **Faculty-ASA Practice Management Conference,** San Diego, CA.
   a. Speaker-Updates in Pain Medicine Coding and Payment 2016.

2. November 19-21, 2015. **Faculty-ASRA Fall Pain Meeting,** Miami, FL.
   d. Speaker, Practice Management and ICD-10: Economic Indicators and Benchmarking Your Pain Practice.
   e. Moderator, Practice Management: Delivering and Demonstrating Value in Pain Medicine.
      i. Speaker, Key Financial Points of a Successful Clinical Care Team: "Incident to" Services in Physician-Directed Clinics and Hospital Services
   f. Speaker, Complex Patients and Basics of Practice Management: Practice Management and Billing in Team-Based Pain Medicine.
   g. Speaker, AHRQ Technology Assessment Report: Update on the Response from the Multi-Society Pain Workgroup.

3. October 26, 2015. **Faculty-ASA Annual Meeting,** San Diego, CA.
   a. Moderator, PAIN WORKSHOP - Pain Medicine Practice Management for 2015 and Beyond, Staying Ahead and Staying Out of Trouble.
   b. Moderator,
      i. Speaker, *Emerging Policies at the Local and Regional Level. LCDs and their Impact on Pain Medicine Practice.*

4. June 1, 2015. **Visiting Professor.** University Hospitals, Cleveland, OH. Pain Medicine Practice Management: Coding, Compliance, Valuation and Reimbursement.
5. **January 23, 2015. Faculty-ASA Practice Management Conference.** Atlanta, GA.
   a. Speaker: Impact of local coverage determinations on pain medicine practice
   b. Speaker: The impact of the affordable care act on pain medicine
   c. Speaker: Pain Medicine Regulatory update 2015

   a. Faculty, Fellows neuromodulation workshop.
   b. Speaker: Interventional Management in Common Craniofacial disorders.

7. **November 13-16, 2014. Faculty-ASRA Fall Pain Meeting.** San Francisco, CA.
      i. Speaker, The Reimbursement Determination Process for New Treatments: CPT Creation
   d. Lead, Advanced practice management special session
      i. CPT Coding – Category 1/2/3 Codes and Unlisted Codes-Reimbursement Challenges and Solutions
      ii. Strategic Planning Advancing Your Mission Statement

8. **October 11-15, 2014. Faculty-ASA Annual Meeting.** New Orleans, LA.
   a. Co-Chair, Pain Medicine Workshops.
   b. Moderator/Speaker, Radiofrequency Ablation for Spinal Pain: Techniques to Optimize Success
      i. Cervical Radiofrequency Ablation: Needle Orientation in Relation to the Medial Branch Anatomy
   c. Moderator/Speaker: Pain Medicine, Practice Management 2014
      i. Billing and compliance-avoiding fraud, maximizing potential
   d. Faculty. Practical pain medicine billing. Practice management: Networking and cultivating relationships.

9. **November 21-24, 2013. Faculty-ASRA Fall Pain Meeting.** Phoenix, AZ.
   b. Speaker, Hands-On Workshop: Cervical MBB and radiofrequency ablation.
   c. Speaker, Special Sessions Radiofrequency Workshop: Technical aspects of SI joint radiofrequency ablation.
   d. Moderator and Speaker: PA/NP Physical exam and diagnosis program: Physical exam for low back pain patients.
   e. Moderator, Moderated e-Poster sessions: Session 1: Chronic and cancer pain.

    a. Chair, Pain Medicine Workshops.
    b. Workshop Faculty. Basic spinal procedures with fluoroscopy.
    c. Workshop Faculty. Practical pain medicine billing. Practice management: Networking and cultivating relationships.

11. **December 1, 2012. Lecturer-American Physician Institute.** Chicago, IL.
    b. Ambulatory Surgery.
    c. Physician Impairment or Disability.

12. **November 15-18, 2012. Faculty-ASRA Fall Pain Meeting.** Miami, FL.
    a. Speaker, Diagnostic block before neurolytic celiac plexus block-what is the utility?
    b. Speaker, Hands-On Workshop: Cervical MBB and radiofrequency ablation.
c. Speaker, Hands-On Workshop: SI Joint, S1 Root injection and piriformis injection.
d. Scientific/Education Planning Committee, 2012 Fall Pain Meeting
a. Chair, Pain Workshops.
b. Moderator and Presenter: Management of Refractory Head Pain./Cervicogenic Headache.
d. Workshop Faculty. Emerging techniques in neuromodulation.
a. Moderator and Presenter, Pro-Con Session: Two Year Pain Medicine Fellowships: A Step in the Right Direction?
b. Speaker: Head and Neck Blocks: Fluoroscopic & Ultrasound Cadaver Workshop
d. Presenter: Cervicogenic Headache.
b. Presenter: Local Medical Review Policies.
   Posters/presentations.
      a. Radiofrequency Lesioning of the SI Joint with the Simplicity III Probe: A case series.
   Poster/presentation: Prolonged improvement from Lumbar Sympathetic Chain Catheter Placement with Home Infusion of Local Anesthetic for Three Patients with Complex Regional Pain Syndrome (CRPS) Type I.

Regional Presentations:


   a. Implantable Technologies: Neurostimulation.
   b. Radiofrequency Procedures and Intradiscal Procedures
Spinal Injections – Re-review

March 18, 2016

Shana Johnson, MD
Physical Medicine & Rehabilitation
WA – Health Care Authority

Background

- Re-review
- 2011 HTCC on spinal injections
- Update on the impact of this intervention on patient oriented outcomes: pain, function, risk of surgery.
- Includes new trials with comparisons to conservative care (medications, therapy)
Geographic Variation in ESI in Medicare Patients


Spine Injection Use in Western WA

2011 HTCC Coverage Determination

- Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are **not a covered benefit**

- Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a **covered benefit** for the treatment of chronic pain

**Limitation 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
  - Maximum of 3 in 6 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
Spinal Injections – Re-review

**UMP PEBB**

Utilization Rates per 1,000 Members >17 years old

<table>
<thead>
<tr>
<th>Year</th>
<th>Foramenal</th>
<th>Epidural</th>
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<td>2014</td>
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**Medicaid Fee-For-Service & Managed Care**

Rate: Utilization per 1,000 Member >17 years Old

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Spinal Injections – Re-review

Labor & Industries Utilization and Costs

Current Agency Coverage Policies

- Follow HTCC 2011 decision
  - Medicaid
  - PEBB
  - Labor & Industries
  - Corrections
Spinal Injections – Re-review

Medical Policies

- **Medicare:** No national coverage decision on spinal injections

- **Noridian LCD:**
  - **Lumbar epidural steroid injection:** Covered after failure of four weeks of non-surgical, non-injection care (with specific exceptions) for patients with pain associated with suspected radicular pain, neurogenic claudication and/or moderate to severe low back pain (NPRS ≥ 3/10) associated with significant impairment of activities of daily living and one of the following: Substantial imaging abnormalities such as a central disc herniation; Severe degenerative disc disease or central spinal stenosis
  - **Facet joint injection or medial branch blocks:** Covered when the following indications are met: at least three months of moderate to severe pain with functional impairment and an inadequate response to conservative care; pain is predominately axial and, with the exception of facet joint cysts, not associated with radiculopathy or neurogenic claudication; and clinical assessment implicates the facet joint as the putative source of pain and there is no non-facet pathology that could explain the source of pain.

Medical Policies

- **Aetna**
  Covers: ESI for radicular pain; Diagnostic facet joint injections; SI joint injections

- **Cigna**
  Covers: ESI for radicular pain; Diagnostic facet joint injections; SI joint injections

- **Humana**
  Covers: ESI for radicular pain; facet injections or medial branch nerve blocks; SI joint injections
Spinal Injections – Re-review

Clinical Guidelines

- **Epidural Steroids**
  - Observational findings on interlaminar and TF ESI report back pain relief from 2 weeks to 3 months and neck pain relief from 1 week to 12 months (Category B2)
  - RCTs comparing interlaminar ESI with saline injection are equivocal regarding pain relief for low back pain with radiculopathy (Category C)
  - Recommendations: ESI may be used to provide pain relief in selected patients with radicular pain or radiculopathy.

- **Facet and SI**
  - Studies with observational findings for facet joint injections indicate pain scores are improved over baselines scores for 1-6 months
  - RCTs report equivocal findings on efficacy of facet joint steroid injections for LBP (Category C)
  - Literature is insufficient to evaluate the efficacy of SI joint injections for pain relief (Category D)
  - Recommendations: Intraarticular facet joint injections may be used for symptomatic relief of facet-mediated pain and Sacroiliac joint injections may be considered for symptomatic relief of SI joint pain.

Agency for Healthcare Research & Quality (AHRQ)

- **ESI for radiculopathy**
  - Immediate improvements in pain and might be associated with immediate improvements in function but benefits were small and not sustained. No effect on long-term risk of surgery.

- **Facet joint injections:**
  - Facet joint corticosteroid injections are not effective for presumed facet joint pain

- **Sacroiliac Injections:**
  - Insufficient evidence to determine efficacy of sacroiliac joint corticosteroid injections.

Spinal Injections – Re-review

New Since 2011

- ESI and radiculopathy due to disc and or foraminal narrowing—current report provides meta-analysis → short-term improvement in pain but not function; no difference in risk of surgery
- ESI vs discectomy—new study available with opposite findings from previous → Insufficient data to draw conclusion
- ESI vs CC—new study available → Insufficient data to draw conclusion
- ESI vs medications—no difference between ESI vs oral gabapentin in pain or function (Cohen 2015)
- ESI and lumbar stenosis—adds 2 studies that reinforced previous report findings of no benefit
- ESI and axial back pain—adds long-term f/u data to previous findings of no benefit

New Since 2011

- Lumbar facet—New study. IASI vs IM steroid. + IASI short term
- Cervical ESI and radiculopathy—New study. ESI vs CC Short-term better pain success with ESI + CC vs CC alone. Worse outcomes in the ESI vs CC in regards to pain and functional measures over intermediate and long terms. (Cohen 2014)
- SI joint pain—New study. Function better in the conservative care group vs injection group. No difference in pain. (Visser 2013)
- Cervical ESI and axial pain—2 new studies; no difference between groups
- Cervical ESI and cervical stenosis—1 new study; no difference between groups
- Cervical facet—both trials in previous report
Evidence Report Summary

- Radicular pain due to disc and/or foraminal narrowing
  - Evidence suggests ESI provide short-term improvement in pain but not function
  - No effect on risk of surgery (cervical or lumbar)

- Spinal stenosis pain
  - Evidence suggests ESI are not effective

Summary

- Axial pain
  - Evidence suggests ESIs are not effective

- Facet joint pain
  - All evidence considered suggests therapeutic injections are not effective

- SI joint pain
  - Evidence insufficient to draw conclusion
Summary

- New studies evaluating injections against conservative care suggest conservative care may be equal to or better than injections in the treatment of radiculopathy or SI joint pain in some clients.
  - ESI vs medications—No difference between ESI vs oral gabapentin in pain or function (Cohen 2015)
  - Cervical ESI and radiculopathy—ESI vs CC. Short-term better pain success with ESI + CC vs CC alone. Worse outcomes in the ESI vs CC in regards to pain and functional measures over intermediate and long terms. (Cohen 2014)
  - SI and injections—Function better in the conservative care group vs injection group. No difference in pain. (Visser 2013)

- Shared decision-making

Agency Recommendation

- Therapeutic Medial Branch Nerve Block injections, Intradiscal injections, Facet injections, Epidural injections for central spinal stenosis and axial pain are not a covered benefit.

- Therapeutic Lumbar Epidural injections, Cervical-thoracic Epidural injections, and Sacroiliac Joint injections are a covered benefit with conditions.
Agency Recommendation

- **Limitation of coverage**
  - Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine are a covered benefit when all of the following conditions are met:
    - History and examination are consistent with radiculopathy
    - With fluoroscopic guidance or CT guidance
    - After failure of conservative therapy
    - No more than two without clinically meaningful improvement in pain and function
    - Maximum of 3 in 6 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
    - No more than one without clinically meaningful improvement in pain and function

More Information
www.hca.wa.gov/hta/Pages/spinal_injections-rr.aspx
**Order of Scheduled Presentations:**

**Spinal Injections – Re-review**

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*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
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<tr>
<td>Ben Snyder, MD</td>
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<td>Brett Stacey, MD</td>
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<td>Alison Stout, DO</td>
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<td>Geoffery E. Sultana, MD</td>
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<td>David J. Tauben, MD, FACP</td>
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<td>Jessi Thao</td>
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<td>Marco Wen, MD</td>
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<tr>
<td>Jiang Wu, MD</td>
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<tr>
<td>Irene Young, MD</td>
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## Disclosure

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1. **myMatrixx** - consultant
2. **American Academy of Pain Medicine** - Board Member, President Elect

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**Representing Providence Health System and Swedish Health System**

Serve as medical director: Swedish Pain Services

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have reviewed and completed this Conflict of Interest form and that the information I have provided herein is true and correct as of this date.

Signed: [Signature]

Date: [Date]

Print Name: [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Email Address]

Phone Number: [Phone Number]
March 2\textsuperscript{nd}, 2016

Dr. Christopher Standaert, Chair  
Health Technology Clinical Committee  
Health Technology Assessment Program  
Washington State Health Care Authority  
P.O. Box 42712  
Olympia, WA 98504-2712

Dear Chair Standaert:

Re: “Spinal Injections – Re-Review” by Dettori JR, et al., dated December 4\textsuperscript{th}, 2015

On behalf of Providence Health & Services, we want to thank you for the opportunity to provide comments on the recent re-review of evidence regarding spinal injections. Providence appreciates the time and effort your agency has contributed to further understanding of evidence in this area, and we look forward to being a partner in this work as the work of the Health Technology Clinical Committee moves forward.

Providence Health & Services is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – especially for those who are poor and vulnerable. In Washington state, Providence and its secular affiliates – including Swedish Health Services, Pacific Medical Centers, and Kadlec – comprise 15 hospitals, 268 physician clinics, senior services, supportive housing, hospice and home health programs, care centers and diverse community services. The combined health system is the largest health care provider in Washington and employs more than 32,000 people statewide. In 2013, Providence and Swedish provided $413 million in community benefit, including $118 million in free and discounted care\textsuperscript{1} for Washingtonians who could not afford to pay. Together, we are working to improve quality, increase access and reduce the cost of care in all of the communities we serve.

Since 2013, Swedish and Providence have cared for more than 130,000 patients with back pain complaints alone, performing 4,000 spinal injection procedures a year in our outpatient facilities. As a system, Swedish and Providence performs 14,000 spine surgeries per year across all 5 states.

We strongly support the use of appropriate interventional procedures for our patients in the treatment of acute and chronic neck and low back pain. Although outcome studies for interventional procedures are challenging, we support the use of evidence-based medicine, including appropriate use of systematic reviews in determining guidelines that can be practical tools for clinicians as they care for the complex population of patients presenting with spine-related pain conditions. It is in this spirit that we

\textsuperscript{1} Community benefit and charity care data is consolidated based on financial reporting.
provide the comments below, which we hope are helpful as you consider the re-review of evidence and determine whether changes in policy are needed.

Our system is concerned that for a variety of reasons, the 2015 scientific review did not represent an appropriate systematic review of efficacy studies. Specific reasons include:

- The review was limited the review to randomized controlled trials, ignoring best available evidence. Many high-quality prospective studies were not included.
- The “Strength of Evidence” approach appears to not weigh high-quality randomized control trials fairly as opposed to low quality ones.
- The extensive review limited subgroup analysis.
- There is a disconnect between the scope and aim of the re-review (examining new evidence for lumbar epidurals and safety concerns with epidurals)
- The HCA also reviewed additional procedures (i.e. facet injections, sacroiliac joint injections, intradiscal procedures) despite the paucity of new literature since the 2011 exercise.

We endorse not reversing the prior decision in 2011 to cover epidural steroid injections and sacroiliac joint injections as there is only new affirmative literature for the efficacy of epidural steroid injections for the treatment of radicular pain from all causes and new and uncited affirmative evidence for sacroiliac joint injections. Additional recommendations and considerations include:

- Consider covering lumbar facet injections for appropriate cases with restrictions per Medicare coverage decisions (LCDs) and MPW recommendation in addition to the fact there is only new evidence in support of the benefit of lumbar facet injections.
- In response to the FDA published statement regarding risks associated with epidural steroid injections, the MPW proactively worked with the safe use initiative (SUI) division of the FDA to produce consensus clinical considerations to enhance the safety of epidural injections. Following these best practice recommendations epidural steroid injections have very acceptable risks, this is contrary to the review’s findings.

Most importantly, Swedish and Providence are concerned the formal review process is tainted in that it lacked appropriate peer to peer review and ignored or underutilized content “experts” to better review studies and formulate accurate recommendations from a very complex review of the expansive scientific literature.

Our system supports the Multi-Society Pain Workgroup (MPW) organized by the Spine Intervention Society (SIS) and their work in presenting critical points to the recent review of interventional procedures for pain. Many of our clinicians are active members of the fifteen professional societies and associations that supported their letter of concern. We urge the Committee to consider the comments that were supported by the Multi-Society Pain Workgroup and we are hopeful that many of their recommendations help to better shape a more rigorous and appropriate review by the Committee.

Again, we thank you for the opportunity to provide our comments on this report. We believe that a more appropriate review will support better patient care by limiting overutilization of services and preventing appropriate patients from being denied access to treatment, ultimately leading to better health outcomes for the many patients in Washington struggling with back pain. We look forward to being a partner in the work ahead as we all strive to implement the latest evidence in to practice for the
health and safety of our patients. For more information, please contact Lauren Platt, State Advocacy Program Manager, at lauren.platt@providence.org or (425) 525-5734.

Sincerely,

Andrew J. Cole, MD
Executive Director
Rehabilitation & Performance Medicine
Swedish Medical Group
Swedish Health System

Steven Stanos, DO
Medical Director, Swedish Pain Services
Medical Director, Occupational Medicine Services
Swedish Medical Group
Swedish Health System

Bonnie Smith
Vice President
Clinical Portfolio, Neurosciences
Clinical Program Services
Providence Health & Services
Disclosure

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I have research funding through NIH, AHRQ and PEOH for research related to back pain treatments and use of epidural steroid injections.

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If yes to #7, provide name and funding Sources: I am representing myself and no institution or funding agency. I am employed by the University of Washington.

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

[Signature] [Date] [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
Washington State Health Technology Assessment
Hearing on Spinal Injections
March 18, 2016

Janna Friedly M.D.
Associate Professor, University of Washington
Department of Rehabilitation Medicine
Co-Director, Comparative Effectiveness, Cost and
Outcomes Research Center (CECORC)

DISCLOSURES

Financial Disclosures:

Research funded by AHRQ, PCORI and NIH

I am salaried by the University of Washington and do not perform spine procedures as part of my clinical practice.
DR. MANCHIKANTI PUBLICATIONS

Funding: All studies self-funded and conducted in a sole private practice with procedures performed by a single provider without external oversight (e.g. DSMB)

IRB approvals: All manuscripts identify “The IRB” without a clearly identifiable, duly registered IRB

Protocol registration: Multiple studies published under one clinicaltrials.gov entry with discrepancies in methods

EXAMPLE OF DISCREPANCIES IN CLINICAL TRIAL REGISTRATION

CLINICALTRIALS.GOV NCT00681447 ENTITLED “A RANDOMIZED, PROSPECTIVE, DOUBLE-BLIND CONTROLLED EVALUATION OF THE EFFECTIVENESS OF LUMBAR INTERLAMINAR EPIDURAL INJECTIONS IN LUMBAR DISC HERNIATION, AND DISCOGENIC PAIN”


Issue: The clinicaltrials.gov study description, inclusion/exclusion criteria, primary and secondary outcomes do not match what is published above.

Also registered under same entry:
1 Manchikanti L, MD, Singh V, MD, Falco F, Cash KA, Pampati V. Evaluation Of The Effectiveness Of Lumbar Interlaminar Epidural Injections In Managing Chronic Pain Of Lumbar Disc Herniation Or Radiculitis: A Randomized, Double-blind, Controlled Trial. Pain Physician. 2010;13;55-65
4 Manchikanti, L, Singh V, Cash KA, Pampati, V, Falco F. A Randomized, Double-blind, Active-control Trial Of The Effectiveness Of Lumbar Interlaminar Epidural Injections In Disc Herniation Randomized Trial Pain Physician 2014;17:860-874
DR. MANCHIKANTI PUBLICATIONS

- **Journal:** The vast majority of his publications appear in Pain Physician which he founded. He is the CEO of ASIPP which owns Pain Physician.

- **Peer review process:** At least 4 RCTs accepted within 8 days of submission (range 4-8 days); another 4 RCTs accepted within 14 days.

---

**Pain Physician 2010; 13:525-510**

**Comparative Effectiveness of a One-Year Follow-Up of Thoracic Medial Branch Blocks in Management of Chronic Thoracic Pain: A Randomized, Double-Blind Active Controlled Trial**

**Background:** Thoracic back pain has been implicated as one of the most common problems seen in Pain Clinics. In 1999, a 26-year-old male with thoracic and lumbar radicular pain after a car accident was treated with a thoracic medial branch block which provided pain relief and improved his functional status. The goal of this study was to evaluate the effectiveness of thoracic medial branch blocks in the management of chronic thoracic pain.

**Objective:** To determine the effectiveness of thoracic medial branch blocks in the management of chronic thoracic pain.

**Methods:** A randomized, double-blind, active controlled trial was performed to evaluate the effectiveness of thoracic medial branch blocks in the management of chronic thoracic pain.

**Outcome Measures:** In the study, outcome measures included the numerical rating scale (NRS) and the visual analog scale (VAS).

**Results:** The results of the study showed that thoracic medial branch blocks were effective in the management of chronic thoracic pain.

**Conclusions:** Thoracic medial branch blocks are an effective treatment option for chronic thoracic pain.

**Clinical Trial:** NCT02255706
### A Randomized, Double-Blind Controlled Trial of Lumbar Interlaminar Epidural Injections in Central Spinal Stenosis: 2-Year Follow-Up

Laxmaiah Manchikanti, MD1, Kimberly A. Cash, RT2, Carla D. McManus, RN, BSN2, Kim S. Damron, RN1, Vidyaasagar Pampati, MSc1, and Frank J.E. Falco, MD1

**Background:** While low back pain is the number one cause of disability in the United States, lumbar spinal stenosis along with intervertebral disc herniation and degenerative spondylolisthesis is one of the 3 most common diagnoses of low back and leg pain for which surgery is performed. Numerous modalities of treatments including drug therapy and complex surgical fusions have been recommended for treatment of central spinal stenosis. Epidural injections are one of the commonly performed nonsurgical interventions in managing central spinal stenosis; however, there has been paucity of literature in reference to efficacy of epidural injections in managing central spinal stenosis with lumbar interlaminar epidural injections.

**Study Design:** A randomized, double-blind, active controlled trial.

**Setting:** Private interventional pain management practice and specialty referral center in the United States.

**Objective:** To assess the effectiveness of lumbar interlaminar epidural injections with or without steroids in providing effective and long-lasting pain relief with improvement in functional status for the management of chronic low back and lower extremity pain related to lumbar central spinal stenosis.

### DR. MANCHIKANTI PUBLICATIONS

At least 12 RCTs conducted simultaneously (particularly 2008-2009) by lead author Manchikanti in one private practice

A single provider performed all procedures with >1300 patients enrolled (if unique patients)

<table>
<thead>
<tr>
<th>Trial Reference</th>
<th>Procedure</th>
<th>Indication</th>
<th>n</th>
<th>Recruitment period</th>
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<tr>
<td>Pain Physician. 2012 Jan-Feb;15(1):S1-63.</td>
<td>lumbar IL ESI</td>
<td>central stenosis</td>
<td>120</td>
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<tr>
<td>Pain Physician. 2013 Sep-Oct;16(5):E491-504.</td>
<td>cervical IL ESI</td>
<td>disc herniation</td>
<td>120</td>
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<tr>
<td>Pain Physician. 2014 Jan-Feb;17(1):E61-74.</td>
<td>lumbar IL ESI</td>
<td>lumbar disc herniation</td>
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Total number of patients recruited: 1324
Disclosure

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided as of this date.

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<tr>
<th>Date</th>
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<tr>
<td>2/18/16</td>
<td>Paul Drugless</td>
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So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
Disclosure

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X [Signature] 2/12/11 [Date] Brandon Messerli [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: __________________________________________________________

Phone Number: __________________________________________________________
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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I am a physician who perform spinal injections.

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Signature: X  Date: 2/13/2016  Print Name: William Anderson

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
Disclosure

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NA

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Jason Gene Attaman DO

Print Name

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[Signature]

[Date]

[Print Name]

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Signature: [Signature]

Date: 2/17/16

Print Name: [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Email Address]

Phone Number: [Phone Number]
Disclosure

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I am a partner and part owner of an orthopedic practice that has a spine division. This division treats patients in part with interventional spine injections that are the topic of discussion. I am trained and perform these injections.

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X  
Signature

2/16/16

Date

ALAN CHEN, MD

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address:  

Phone Number:  

conflict_of_interest_121814-FINAL.docx
Disclosure

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Michele Curatolo

Signature 2-22-2016

Email Address: curatolo@uw.edu

Phone Number:

__________________________

Page 2 of 2
Disclosure

Any unmarked topic will be considered a "Yes"

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I am an physician at the University of Washington and perform these procedures

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If yes to #7, provide name and funding Sources: I am paid my salary by the University of Washington

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Signature: 2/25/16  Rebecca Dale, DO

So we may contact you regarding your presentation, please provide the following:

Email Address: 

Phone Number: 

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Disclosure
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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Signature: X
Date: 2/19/16
Print Name: Natalya Eykhvald

So we may contact you regarding your presentation, please provide the following:

Email Address: 

Phone Number: 

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X  [Signature]  2-15-16  [Print Name]

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Email Address: [Redacted]

Phone Number: [Redacted]
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Signature: [Redacted] Date: 2/18/16

Print Name: [Redacted]

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Email Address: [Redacted]

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X 2/16/17 Jon Geffen, DO
______________________________
Date
______________________________
Print Name

So we may contact you regarding your presentation, please provide the following:

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Phone Number: __________________________________________________________________________
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X  
Signature  
2/19/16  
Date  
Christopher Galt, M.D.  
Print Name  

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X ___________ 03/07/2016  William B. Gra

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Phone Number: ___________________________
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[Signature] 2/19/16 Brandy Gump

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\[\text{X} \hspace{1cm} 2/19/16 \hspace{1cm} \text{Xiang Jiao, ARNP} \]

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If yes to #7, provide name and funding Sources:

________________________________________________________________________________________
________________________________________________________________________________________

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [Signature] 2/18/14 [Date] Stephen Johnson [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
Disclosure
Any unanswered box will be considered a "Yes"

<table>
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<td>1. Royalty or dividends such as consulting fees or honoraria in excess of $5,000</td>
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<td>3. Status of position, for example, board member, trustee, officer</td>
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<td>6. Any other relationship, including lease arrangements</td>
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If yes, list name of organizations that contributed, we will seek to disclose other relationships:

Working as a pain physician called by Yakima Valley Memorial Hospital

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If yes to No., provide name and funding sources:


If you indicate that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets containing any information that you should not be included:

I certify that I have read and understand the Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date:

[Signature] 4/19/2016 Henry Kim, MD

If we have contact you regarding your appointment, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]

Page 2 of 2
Disclosure

Any unmarked topic will be considered a 'Yes'

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Part owner of Via Radiology – Mission Pavilion

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If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, and correct as of this date.

X [Signature] 2/18/2016 [Date]

Hisashi Kobayashi

[Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Blacked Out]

Phone Number: [Blacked Out]
Disclosure

Any unmarked topic will be considered a “Yes”

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Potential conflict as I am a pain specialist employed by Yakima Valley Memorial Hospital.

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [Signature] 2/18/16 [Print Name] Daniel Kwon

So we may contact you regarding your presentation, please provide the following:

Email Address: __________________________

Phone Number: __________________________
Disclosure

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If yes to #7, provide name and funding Sources: Evergreen Health

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If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

[Signature] 2/18/16

Yung J. Lee

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
 Disclosure

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [Signature] 2/15/2016 [Date] [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
WA - Health Technology Assessment

Disclosure

Any unmarked topic will be considered a "Yes"

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*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information provided is true, complete, and correct as of this date.

[Signature] 2-17-16 [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X ___________________________  03/17/2014  Christopher Merfield, MD

Signature  Date  Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: ___________________________  Phone Number: ___________________________
Disclosure
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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Carlos E. Moravek, M.D.

Signature: [REDACTED]
Date: 2/17/16
Print Name: Carlos E. Moravek, M.D.

So we may contact you regarding your presentation, please provide the following:

Email Address: [REDACTED]

Phone Number: [REDACTED]
WA - Health Technology Assessment

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

[Signature]

2-17-16

Linda E Nixon, PA-C

So we may contact you regarding your presentation, please provide the following:

Email Address: [email protected]

Phone Number: [contact information]
Disclosure
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X

So we may contact you regarding your presentation, please provide the following:

Email Address:  

Phone Number:  

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Disclosure
Any unmarked topic will be considered a "Yes"

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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I am a member of the Health Policy Division of the Spine Intervention Society.

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Confidential Declaration of Conflict of Interest Form, I certify that I have read and understand the Conflict of Interest Form and that the information I have provided in this report is accurate and complete.

[X] ______________________________________________________________________________________________

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X

2/17/2016

Brett R Stacey

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: ____________________________________________

Phone Number: ________________________
Disclosure
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I am employed by Evergreen Healthcare as a physician that treats spine conditions and performs epidural steroid injections.

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [Signed]

Date: 1-26-16

Print Name: [Redacted]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
Disclosure

Any unmarked topic will be considered a "Yes"

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Signature: ___________________________ Date: 2/16

Geoffrey E. Sultana MD

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: ___________________________

Phone Number: ___________________________
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If yes, list name of organizations that relationship(s) are with and for #8, describe other relationship:

4. FDA
   ERLA REUS training

7. NIH Center of Excellence in Pain Education
   AHEQ Team Based Opioid Intervention

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[Signature]  [Date]  [Print Name]

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Email Address: [Redacted]

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Signature that I have read and understand the section of interest form and that the information above is both complete and correct as of this date.

[Signature]

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Email Address: [Redacted]

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X Signature 2/8/16 MASCOWEN

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X [Signature] 2/16/16 [Date]

Jiang Wu [Print Name]

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
WA - Health Technology Assessment

Disclosure
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[Signature] [Date]

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: [Redacted]

Phone Number: [Redacted]
HTA
Spinal Injections

Re-review

3.18.16

Disclosures

• Brandon Messerli DO and Paul Dreyfuss MD
• EvergreenHealth Sport & Spine Care
• No financial conflict

• The views expressed here are those of the physicians and do not constitute the opinions of EvergreenHealth
• The Spine Intervention Society (SIS) supports this presentation.
Summary

- Spine injections, when done for appropriate indications and with contemporary techniques, can provide significant benefit for pain relief, disability, and quality of life, and have a very low risk profile as compared to alternative treatments.

- As part of a tiered, multi-modal treatment plan (e.g. therapy, exercise, activity modifications, counseling), this maximizes the effect of the injection, promotes natural recovery, and helps prevent recurrences.

- Alternative treatment options (e.g. surgery, medications) are not always indicated, effective, or desired by the patient and doctor due to risks.

Policy Recommendation

Rather than eliminating spinal injection access for 2.2 million Medicaid, PEBB and L&I enrollees, we recommend coverage policies consistent with the Multi-society Pain Workgroup (MPW) consensus guidelines, which were adopted by Medicare and Noridian, and are appropriately restrictive while allowing physicians to care for our patients using an evidence-based ‘best practice’ approach.
State Law RCW 70.14.110

• “(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.”

Medicare & MPW

• Dr Jacques (CAG Director) and Dr. Tavenner (CMS administrator) endorsed a plan in 2012 to move towards standardizing pain LCDs for national implementation

• All CMS Contractor Medical Directors participated, led by Dr Hecker of Noridian

• Consensus recommendations were sought from stakeholder societies, via the MPW, utilizing a scientific and democratic process with attention to best practices. Led by Drs Baker and Dreyfuss.

• See appendix for the guidelines
MPW

- American Association of Neurological Surgeons
- American Academy of Pain Medicine
- American Academy of Physical Medicine and Rehabilitation
- American College of Radiology
- American Society of Anesthesiologists
- American Society of Regional Anesthesia and Pain Medicine
- North American Neuromodulation Society
- American Society of Neuroradiology
- American Society of Spine Radiology
- Congress of Neurological Surgeons
- International Spine Intervention Society (SIS)
- North American Spine Society
- Society of Interventional Radiology
- American Pain Society

- Represents >100k physicians, including many non-interventionalists from 14 societies

Medicare LCDs

- Noridian, Novitas, Palmetto, WPS, NGS (45/50 states) have fully implemented the MPW recommendations into their LCDs for epidural and facet procedures

- All carriers (50 states) cover ESIs for radicular pain of any cause, and for spinal stenosis with neurogenic claudication

- All carriers (50 states) cover sacroiliac intra-articular steroid injections

- All carriers except Cahaba (47/50 states) cover therapeutic facet intra-articular steroid injections
State Law RCW 70.14.110

• Is there ‘substantial evidence for a contrary determination’?

• Unless there is high quality evidence showing a lack of efficacy, there should not be coverage determinations that oppose Medicare and society guidelines

State Law RCW 70.14.110

• “(i) Give the greatest weight to the evidence determined, based on objective indicators, to be the most valid and reliable”
Validity

• Spectrum’s definition of “validity” appears to only consider the presence of randomization and double blinding (RCTs), and their Key Questions were formulated in order to exclude non-RCTs

• The Law does not state that only RCTs can be included in evidence vendor reviews

• In our opinion, a well designed non-RCT is more valuable than a RCT with antiquated diagnostic and injection techniques

Contemporary ‘Best Practice’

• Recommendations of the MPW and all Medicare carriers

• Advanced Diagnostic Imaging

  • Without advanced imaging, the etiology of the condition is unknown, and the best injection approach to optimally concentrate the injectate at the pathology is unknown

  • Image-guided injections using contrast

  • 7-30% of blind interlaminars ESIs and 9-52% of blind caudal ESIs are injected outside the epidural space and cannot be considered ESIs (Levin. J Spine 2012)
Validity of Trial Methods

- A majority of the RCTs Spectrum included for ESIs did not utilize imaging-confirmed diagnoses or image-guided injections and, at times, were given higher relative weighting than trials with contemporary methods
- It is unknown if enrolled subjects actually had the index condition or if they actually received the index treatment (up to 30-52% likely did not receive an ESI)
- Are these results a valid indicator of the efficacy of modern practice?

HTA Clinical Experts

- The HTA Clinical Experts questioned Spectrum regarding the exclusion of non-RCTs
- Spectrum stated “Comparative observational studies with concurrent controls can be helpful in certain situations when the outcome is “hard” and quantitative (e.g. evaluating death). However, they…have been shown to overestimate the effectiveness of a treatment, especially one based on subjective outcomes.”
- In our opinion, although it may be more challenging to quantitate and collect measures of pain, function, disability, missed work, and surgical rates, these end points remain of great value to the patient
Evidence Based Medicine

- Well respected authors of EBM have studied and challenged the misconception that only RCTs should be evaluated in EBM
- Anglemyer et al assessed 1583 meta-analyses involving 228 different medical conditions: “On average, there is little difference between the results obtained from RCTs and observational studies” (Cochrane Syst Rev 2014)
- “Because it is unusual to find sufficient evidence from RCTs to answer all the key questions of benefit, reviewers should routinely assess the appropriateness of inclusion of observational studies” (Norris. AHRQ and the Effective Health Care Program. J Clin Epid 2011)

State Law RCW 70.14.110

- Other evidence vendors have not excluded non-RCTs in other HTA reviews:
  - e.g. non-pharmacologic treatment of depression, proton beam therapy for cancer radiation, cochlear implants, viscosupplementation
Validity of Trial Outcome Measures

- The NIH taskforce recommended trials in pain medicine utilize categorical data (Deyo. Spine 2014)
- Continuous/group means are a crude assessment of effect and can conceal good responses in a subgroup of patients
- Categorical data allows the subgroup of responders to be revealed (e.g. Ghahreman 2010)
  - e.g. NRS ≥ 50%, RMD ≥ 40%, ODI ≥ 50% improvement
- Spectrum did not fully acknowledge all categorical data available in cited trials, nor assign relatively higher weighting to these trials

Validity of Meta-analysis

- Bias can occur with how trials are weighted and collated
- If weighting does not account for quality of study design, large RCTs with poor methodology can “dilute” the positive outcomes of smaller, well-designed trials
- The methodology for weighting trials in Spectrum’s meta-analyses is not clearly delineated
Spectrum Bias?

- Spectrum is a for-profit company that has an inherent bias to produce a work product that attracts further business by HTAs and other organizations.
- Spectrum earned $79,533 for this re-review and a total of $1,006,427 for the last 11 evidence reviews for WA state.
- It is unclear whether Spectrum has disclosed actual or potential conflicts of interests as required by the state for all public presenters.

Spectrum Bias?

- Spectrum may have a bias to produce results and conclusions that are consistent with prior publications by its authors, which also excluded non-RCTs and largely stated a lack of benefit of spinal injections.
  - HTA 2011 review of spinal injections; Drs Dettori, Hashimoto, and Chou.
  - HTA 2014 review of facet RF neurotomy; Dr Hashimoto.
- Spectrum is one of 3 partners in the Pacific Northwest Evidence-based Practice Center (EPC), and these spinal injection publications also excluded non-RCTs.
  - “Pain Management Injection Therapies for Low Back Pain” in March 2015, commissioned by the Agency for Healthcare Research and Quality (AHRQ); Drs Chou and Hashimoto.
  - “Guidelines for the Evaluation and Management of Low Back Pain: Evidence Review”, commissioned by the American Pain Society; Dr Chou.
Are ESIs safe?

- The FDA in April 2014 released a warning regarding the off-label use of steroids in the epidural space, stating serious complications of “stroke, loss of vision, paralysis and death.”

- The MPW clarified the risks at the FDA Advisory Meeting:
  - No published case reports of serious neurological injury from the use of non-particulate ESIs
  - Rare cases of neurological injury have occurred when particulate steroids have been injected:
    - via a transforminal route in the cervical spine, or in the lumbar spine when standard precautions were not followed
    - via an interlaminar route without image guidance

Non-particulate Steroids

- In animal studies, non-particulate steroids are safe even when injected directly into the vertebral artery

- Non-particulate steroids have been shown to be equally effective to particulate steroids in recent studies
MPW Safety Recommendations

- The MPW worked with the FDA to publish consensus considerations on how to perform ESIs to optimally reduce risk.
- These considerations were endorsed by the regulatory branch of the FDA.
  - Interlaminar ESI - only perform with multi-planar imaging and contrast enhancement
  - Cervical transforaminal ESI - only inject non-particulate steroids
  - Lumbar transforaminal ESI - use non-particulate steroids first line. Particulate steroids can be used second line if DSA or live fluoroscopy are employed

FDA Determination

- No new warnings were published
- FDA publication: Racoosi J et al. NEJM Dec 2015, 373:24 2299-2301
  - "A contraindication ESI label is not necessary as the incidence of serious neurologic injury is very rare"
  - "All catastrophic events reported to FAERS (FDA Adverse Event Reporting System) were only associated with injection of a suspension" (i.e. particulate steroids)
Safety Trial


• 16,638 procedures: 14,956 transforaminal ESIs, 1,682 interlaminar ESIs. Mayo, Penn, and Northwestern.

• When ESIs were performed with best practice methods, no major adverse events occurred

• This trial was not reviewed by Spectrum

Opioids and NSAIDs Risks & Efficacy

• If access to spine injections is eliminated then patients will turn to more aggressive medication use to treat their pain

• Increased opioid use can lead to mis-use/abuse, dependence (gateway drug), tolerance, and complications including death

• SE: opioid-induced hyperalgesia, cognitive impairment, constipation, hypogonadism

• No RCTs show efficacy for use >4 months for LBP. For short-term relief, effect sizes (ES) were moderate for pain, and small for functional, outcomes (Cochrane)

• Increased NSAID use, leading to more GI ulcers, bleeds, renal insufficiency, etc

• >103,000 hospitalizations/year

• 16,500 deaths in those with RA and OA

• NSAIDs only effective (small ES) for short-term relief of LBP (Cochrane)
Deaths from Prescription Opioids
(2001-2014: Increased 3.4 fold)

Surgery Risks

- If spine injections are eliminated, more patients will undergo spine surgery.

- For herniated discs:
  - 3% combined infection and medical complication rate (Stadler. Neurosurg Clin N Am 2014)
  - 10-19% re-operation rate at 4-5 years (Weinstein. Spine 2008; Atlas, Spine 2001)

- For spinal stenosis:
  - 0.2% death rate
  - 13% post-op complication and re-operation rate at 4 years (Weinstein. NEJM 2008; Weinstein. Spine 2010)

- **Spinal injections are far safer than surgery.**
Surgery Efficacy

- For herniated discs:

- For spinal stenosis:
  - At 4 yrs, only 63-70% rate their improvement in leg pain as “major” and are “satisfied” (Weinstein. Spine 2010; Atlas. Spine 2000)

HTCC
Broader Considerations

- If spine injections are eliminated, other potential downstream impact must be considered:
  - unnecessary pain and emotional distress
  - disability, including of daily, family and recreational activities
  - lost wages and labor
  - L&I: delayed return to work, employer hardship, prolonged claims and time-loss payment, more seeking permanent impairment
The Evidence

- Dr Paul Dreyfuss
- We only have time to:
  - highlight pertinent RCTs which used a ‘best practice’ approach
  - review new trials since the 2010 Spectrum report
  - present several trials excluded by Spectrum

Neurogenic Claudication:
Friedly 2014

- RCT, 400 subjects, neurogenic claudication with imaging confirmation of central lumbar stenosis
- Image guided injections (70% via interlaminar (IL) route)
- Randomized to epidural steroid (ESI) / lidocaine vs. epidural lidocaine
- At 3 weeks: ESI group had less intensity of leg pain and a lower Roland-Morris than epidural lidocaine group. Although significant (p=0.01) the differences were relatively small.
Neurogenic Claudication: Friedly 2014

- At 6 weeks both groups showed improvement:
  - Leg pain mean reduction: 42% IL ESI vs. 38% epidural lidocaine
  - Roland-Morris mean reduction: 29% IL ESI vs. 21% epidural lidocaine
  - There was no significant difference between groups for 50% improvement in pain (38% each group) or Roland-Morris (24% steroid and 20% lidocaine)
  - 67% of IL ESI group vs. 54% of epidural lidocaine group reported being “very or somewhat satisfied” with their treatment (p=0.01)

Friedly - Submitted Public Comment

- “This study design does not address the question of which patients benefit from epidural injection of lidocaine plus corticosteroid versus placebo injections or another active treatment.”
- This was a comparative effectiveness not an efficacy trial
Valid Placebo?

• It has *not* been established via randomized trials that epidural anesthetic administered via an interlaminar approach is a valid placebo

• Epidural anesthetic may have unique treatment effects via a different mechanism than epidural steroids
  
  • e.g. washout or dilution of inflammatory mediators, suppression of ectopic nerve discharges, lysis of adhesions

Valid Placebo?

• Bicket 2013

• 3,641 subjects (43 studies) were included in this meta-analysis of ESI vs. epidural non-steroid injection (ENSI) or non-epidural steroid injection (NEI)
**Efficacy Trials: ESI vs NEI**

6/7 (86%) trials used interlaminar or caudal epidural injections

**Valid Placebo?**

- There is a significant benefit of ESI vs non-epidural injection \( p<0.001 \)

- Indirect comparisons also suggested ENSI were two-fold more likely than *non-epidural* injections to achieve positive outcomes \( RR 2.17; 95\% CI, 1.87–2.53 \)

- “The evidence is limited but suggests that epidural *non-steroid* injections (ENSI) may not constitute a true placebo”
Neurogenic Claudication vs Radicular Pain

- Lumbar stenosis causing neurogenic claudication is a condition that is distinct from lumbar radicular pain, in regards to clinical features, pathogenesis, and natural history.

- The Friedly study can *not* be used to judge comparative effectiveness or efficacy of ESI for radicular pain (including that due to spinal stenosis (central, lateral recess, foraminal)).

Lumbar Radicular Pain

- Spectrum concluded that “a greater proportion of patients receiving epidural steroid injections compared with epidural non steroid injections (ENSI) achieved short-term successful pain relief”

- Spectrum defined *short term as <3 months*

- 11 trials, N=1229, RR 1.30 (95% CI: 1.06, 1.58)

- Short term relief in severe radicular pain is of great clinical benefit, and facilitates natural recovery.
Lumbar Radicular Pain: Transforaminal ESI

- The TF ESI studies for treatment of radicular pain due to a disc herniation given the highest rating of “low risk” by Spectrum are the Ghahreman and the Karppinen trials
  - These used a best practice approach
  - Low risk defined as: “study adheres to commonly held tenets of high quality design, execution and avoidance of bias”

Lumbar Radicular Pain: Ghahreman 2010

- RCT of 150 subjects with lumbar radicular pain and image-confirmed disc herniations
- Randomized to 5 groups: transforaminal (TF) ESI, TF anesthetic, TF saline, IM steroid, IM saline
- Primary outcome “success” defined as: >50% reduction of VAS pain, functional improvement, reduction in use of other health care and restoration of patient-specified activities
Lumbar Radicular Pain:
Ghahreman

• 1 month group mean data: TF ESI significantly more effective than the other arms except for TF saline (P= 0.07)
• The results were bimodal: subjects either responded to TF ESIs or not; i.e. a non-parametric distribution

Ghahreman:
Categorical Data

• Successful outcome at 1 month (95% CI)
• TF ESI: 54% (36-72)
• TF anesthetic: 7% (0-17)
• TF saline: 19% (6-32)
• IM steroid: 21% (6-36)
• IM saline: 13% (1-25)
• *Statistically significant benefit of TF ESIs
Lumbar Radicular Pain: Ghahreman

- NNT of TF ESI is 3
  - NNT for CABG to prevent a MI is 10
  - NNT for anti-depressants is 5-6
- Success, however, degrades with time:
  - 25% of the TF ESI retained a successful outcome at 1 year

Lumbar Radicular Pain: Karppinen 2001

- RCT of 160 subjects with lumbar radicular pain and image-confirmed disc herniation
- Randomized to a TF ESI vs saline injections
- Primary outcomes: Mean change in leg pain and ODI
Karpinnen: Sub-group Analysis of Contained Disc Herniations

- At 2 and 4 weeks there was a significant benefit of ESIs vs. epidural saline in leg pain (p<0.02) and ODI (p<0.002)
- At 4 weeks the ESI group had fewer sick days, less surgery, and nearly twice as many with >75% reduction in leg pain
- There was significant cost effectiveness in the ESI group at 1 year (cost reduction of $12,666 per responder)

Lumbar Radicular Pain: Nam 2011

- RCT of 36 subjects with lumbar radicular pain, imaging-confirmed spinal stenosis
- Randomized to TF ESI vs epidural anesthetic
- Primary outcomes: VAS and ODI
Lumbar Radicular Pain: Nam

- At 2, 4, 12 weeks the steroid group showed significant benefit compared to the anesthetic group for both VAS and ODI (p<0.05)

- At 12 weeks “success” (>50% pain relief) was achieved in 76% of the ESI group vs. 42% of the anesthetic group (p<0.05)

- Image-guided TF ESI are effective for lumbar radicular pain due to spinal stenosis

Bhatia included all randomized trials (Vad and Ng trials were excluded by Spectrum) in their meta-analysis of lumbar TF ESIs

There is a significant benefit of ESI vs control injections at 1 and 3 months for radicular pain (even using mean data)
Lumbar Radicular Pain: Kennedy 2014

- Comparative effectiveness randomized double-blinded trial using best practices
- 78 subjects with lumbar radicular pain and image-confirmed lumbar disc herniation
  - TF ESI of 60 mg triamcinolone vs 15 mg dexamethasone
  - Categorical Success at 3 and 6 months: 73% in each group
- Excluded by Spectrum as not a randomized trial with a placebo arm

Lumbar Radicular Pain: Cohen 2012

- Comparative effectiveness trial using best practice injection techniques
- 84 pts with imaging-confirmed lumbar disc herniation causing radicular pain.
  - Randomized to 3 TF injection groups:
    - ESI, epidural anesthetic, epidural etanercept/anesthetic
Lumbar Radicular Pain: Cohen 2012

- Categorical success (>50% leg pain improvement) at 1 month:
  - ESI: 75%
  - Epidural anesthetic: 50%
  - Epidural etanercept/anesthetic: 42% (P=0.09)
- “These results can neither exclude nor prove a modest benefit for steroids.”

Lumbar Radicular Pain: Interlaminar ESI

- The vast majority of the IL ESI trials cited by Spectrum did not use contemporary ‘best practice’ diagnostic (advanced imaging) and/or injection (image-guided) techniques
- There are no new IL ESI efficacy trials with since the 2011 review
Lumbar Radicular Pain: TF vs IL

- *Fluoroscopic-guided* IL ESIs are equally effective to TF ESIs in the short-term treatment of radicular pain due to a disc herniation

- Prospective comparative effectiveness trials:

Lumbar Radicular Pain: Interlaminar ESI

- One new comparative effectiveness trial for which injections were minimized on average to <2 ESIs per year

Lumbar Radicular Pain: Ghai

- RCT of 69 pts with radicular pain due to an image-confirmed disc herniation
- Randomized, double-blinded: *Fluoroscopic-guided* parasagittal IL ESI vs epidural anesthetic
- Primary outcome: >50% NPS improvement

Lumbar Radicular Pain: Ghai

- Categorical success at 3 months (>50% pain relief):
  - ESI: 86%
  - Epidural anesthetic: 50% (p= 0.02)
- Benefit maintained at 6, 9 and 12 months (p<0.05)
- The ESI group also showed a significant improvement in modified ODI at all time-points (2 weeks-12 months) (p=0.001)
Lumbar Radicular Pain: ESI Surgery Sparing Effect

• Riew JBJS 2006: the only RCT evaluating surgery sparing effects of ESI as the primary outcome measure

• 55 patients awaiting surgery with radicular pain due to compressive etiologies

• Randomized, double-blinded: TF ESIs vs epidural anesthetic

• 71% of ESI group vs 33% of the anesthetic group cancelled surgery at 13-38 months (p<0.004)

• 80% of those who cancelled surgery still did not have surgery in the next 5 years

Lumbar Radicular Pain: ESI Surgery Sparing Effect

• Meta-analysis of 4 RCTs: Bicket et al. Spine J 2015;5:348-62

• 33-50% of those considering surgery who had ESI (vs conservative care alone) avoided surgery

• Radcliff 2012, Radcliff 2013, Butterman 2004, Gerszten 2010

• Not cited by Spectrum
Lumbar Radicular Pain: Cost Effectiveness

- Non-operative care revealed only a modest benefit in quality adjusted life years (QALYs) in favor of surgery over 2 years (mean 1.64 vs 1.44) (Tosteson. Spine 2008)
  - …but at a much higher cost
  - the mean total surgical costs (direct and indirect) were $27,273 vs. non-operative costs of $13,135

Lumbar Radicular Pain: Cost Effectiveness

- Pragmatic RCT in 50 patients of ESI+usual care vs usual care alone
- Small but significant difference in favor of the ESI+usual care group for pain, disability and satisfaction
- Adding ESIs to usual care alone was more cost effective, mainly due to increased work productivity
  - Spijker-Huiges. Archives PMR 2015;96:381-7
  - Not cited by Spectrum
Cervical Radicular Pain: ESI

- There are no new efficacy trials but there is one new comparative effectiveness trial
- Cohen et al. Anesthesiology 2014; 121:1045-55
  - Showed benefit of ESI+conservative care over either treatment in isolation
  - Methods represent contemporary 'best practice' as ESIs are only one aspect of a comprehensive, multi-modal treatment plan for our patients

Cervical Facet Pain: Intra-articular (IA) steroid injections

- Prior HTCC non-coverage determination largely based on a negative efficacy trial in whiplash patients (Barnsley 1994)
- Spectrum cited a new trial evaluating facet injections performed as part of a multimodal treatment program (Park J Anesth 2012)
  - Diagnosis established by controlled medial branch blocks (contemporary best practice)
  - This study had serious methodological flaws, but suggested an added benefit of facet injections to multimodal care at 1 year
Cervical Facet Pain:
IA steroid injections

- There is one new prospective trial in those with atraumatic facet pain
  - *Not cited by Spectrum*

Cervical Facet Pain:
Folman

- 30 pts with cervical facet joint arthritis
- If an IA anesthetic injections provided “excellent pain relief”, an IA steroid injection was separately performed in the same joint(s)
  - 73% had >90% relief at 3 weeks
  - 40% had >90% relief at 3 months
  - Average time to 50% return of pre-treatment level of pain was 13 weeks
Lumbar Facet Pain: IA steroid injections

- Prior HTCC non-coverage determination largely based on the negative RCTs of Lilius and Carrette
- These studies do not represent best practice methods
- e.g. diagnosis not confirmed with diagnostic blocks, large volume injectates which do not remain IA, suboptimal outcome measures
- See appendix for details

Lumbar Facet Pain: IA steroid injections

- Two new trials exist. Both studies rated by Spectrum as having a “moderate quality of evidence” with a “low risk of bias”
  - “Significantly greater improvement in pain and function following IA facet injections vs IM steroid injections in the short-term” (Ribeiro. Spine 2013)
  - “No difference in pain or function in those receiving IA facet injections vs. radiofrequency neurotomy (HCA covered procedure) in the intermediate term” (Lakemeier. Anesth Analg 2013)
Lumbar Facet Pain:
IA steroid injections

- Three prospective trials (2 randomized) evaluated IA facet injections in subjects with physiological evidence of facet joint inflammation (+ SPECT)
  - Excluded by Spectrum. See appendix for details.
- Collectively, these trials showed benefit for IA facet injections in 151 pts, with benefit maintained at 3 months

Sacroiliac Joint Pain:
IA steroid injections

- The HTCC in 2011 allowed coverage for SI joint injections
- There is only one new Spectrum cited study (Visser. Eur Spine J 2013)
  - This was not an efficacy trial but a comparative effectiveness trial of PT, manual therapy, or SI joint injection in those with a presumptive diagnosis of SIJ pain (not confirmed with diagnostic blocks)
Sacroiliac Joint Pain:
IA steroid injections

- Prospective trial of 39 pts with SI joint pain, established by >75% relief from dual IA blocks, received an IA steroid injection
- 67% experienced >50% pain relief for a mean duration of 37 weeks
  - Not cited by Spectrum

Sacroiliac Joint Pain:
Spondyloarthropathy

- 10 prospective observational studies show benefit of IA steroid injections.
- Success rate range: 60% at 1 month to 92% success at 10 months
  - Spectrum exclude trials due to spondyloarthropathy despite the key questions not asking for such an exclusion
Sacroiliac Joint Pain:
Spondyloarthropathy

- One small RCT (n=13) demonstrated a statistically significant reduction in pain with IA steroid injection vs IA saline injection

- At 1 month, 5 of the 6 injections with corticosteroid provided greater than 70% relief of pain compared with none of the 7 placebo injections. (P< 0.05)


- Spectrum exclude trials due to spondyloarthropathy despite the key questions not asking for such an exclusion

Coverage
Recommendations
Maintain Non-Coverage

• We are not advocating for:
  • "therapeutic" medial branch blocks
  • ESI for axial low back or neck pain
  • ESIs for failed back surgery syndrome
  • Intra-discal steroid injections
  • There is no new evidence with a low risk of bias in support of these procedures

ESI for Neurogenic Claudication

• Consider these facts:
  • All 8 Medicare carriers (50 states) cover ESI for neurogenic claudication
  • The HTCC needs to decide if there is ‘substantial evidence to a contrary determination’, as opposed to Medicare (Noridian LCD) and the MPW Consensus Guidelines (State Law RCW 70.14.110)
  • The Friedly study was not an efficacy study, but a comparative effectiveness study
  • At 3 weeks, the ESI group showed significant benefit over the epidural anesthetic group
  • At 6 weeks, both groups showed improvement
ESI for Radicular Pain

- There is no reason to alter prior coverage determinations for the use of ESI in the treatment of *radicular pain* from any etiology (including central spinal stenosis), as there are no new methodologically sound trials without a high risk of bias that demonstrate lack of ESI efficacy vs control injections

- All 8 Medicare carriers (50 states) cover ESI for radicular pain from any etiology

- Recommend following the MPW guidelines for coverage and safety precautions (see appendix)

Facet IA Steroid Injections

- Consider a coverage determination of facet injections

- We endorse the MPW Guidelines, which were utilized by Medicare LCDs in 47 of 50 states.
  - See Appendix for guidelines

- New moderate quality trials show benefit of IA steroid injections vs. IM injections, and equal benefit to RF neurotomy

- Spectrum excluded evidence that shows patients with SPECT+ joints can benefit from IA facet steroid injections for 3 months

- Although there are no new efficacy trials in cervical facet injections there is one small prospective trial showing effectiveness of IA facet steroid injections in those with facet arthritis
Sacroiliac IA Steroid Injections

• There is no reason to alter prior coverage determinations for the use of IA steroid injections, as there is no new evidence showing lack of efficacy

• There is evidence that was excluded by Spectrum showing both efficacy and effectiveness of IA steroid injections

• IA steroid injections are covered by all Medicare carriers (all 50 states)

• We endorse clear restrictions to performance of initial and subsequent sacroiliac joint injections
  • See appendix

Thank You

We are pleased that we were able to both express our concerns with the committee on the limitations of Spectrum’s report and share all clinically relevant and credible evidence so the committee can make informed coverage determinations
Appendix

MPW Guidelines: ESI for Radicular Pain

• Radicular pain or neurogenic claudication.

• Xrays +/- MRI or CT

• ≥ 3/10 pain with ADL impairments, unresponsive to conservative care

• Failure of ≥ 4 wks of conservative care unless:
  • severe pain unresponsive to medical management
  • moderate pain with significant functional loss at work or home
  • cannot tolerate conservative care due to pain flares or co-morbidites
  • prior successful ESI for same condition
MPW Guidelines:  
ESI for Radicular Pain

- Must use imaging-guidance and contrast media. Films saved of needle position and contrast flow.
- No >2 injections (1-level bilateral, or 2-level unilateral).
- No >3 ESI in 6 months or >6 ESI in 12 months. Includes multi-level and diagnostic.
- If prior injection provided no benefit, must have clear clinical rationale to try another level. No "series of 3".
- Not combined with facet or sacroiliac joint injections unless there is a facet synovial cyst contributing to nerve root impingement.

MPW Guidelines:  
Facet injections

- For predominately axial pain, but a lesser degree of somatic referred pain into the lower extremity is not an exclusion.
- Pain has been present for at least 3 months.
- 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 co-morbidities limit such a trial.
- Must use fluoroscopy or CT guidance and contrast media.
- Repeat injections of same joint(s) only allowed if ≥ 50% relief and improved ADLs for a minimum of 3 months.
Sacroiliac Joint Injections:
Coverage Considerations

- Current Restrictions:
  - With Fluoroscopic guidance or CT guidance
  - After failure of conservative therapy
  - No more than one without clinically meaningful improvement in pain and function, subject to agency review"

- Recommend amend restrictions to:
  - With fluoroscopic or CT guidance with contrast (unless contraindicated)
  - After failure of conservative care in those with pain for at least 3 months
  - Repeat injections are not covered unless there was >50% relief of pain with improvement in ADLs for a minimum of 3 months from the prior injection.

MPW: ESI Safety Guidelines

- Key recommendations to maximally reduce risk included:
  - Only perform interlaminar ESIs with multiplanar imaging and contrast enhancement, either with particulate or non-particulate steroid
  - Only inject non-particulate steroids when performing cervical TF ESI
  - Use non-particulate steroids first line when performing lumbar TF ESI
  - Particulate steroids can be used second line in the lumbar spine only if additional methods (DSA or live fluoroscopy) are employed to assure lack of injection into a reinforcing artery to the spinal cord
Lilius and Carrette: Facet trials

- Z-jt pain not established with adequate diagnostic blocks using a best practice method prior to randomization (Lilius, Carrette)

- Mixed population likely (not pure z-jt) making response difference detection more difficult (Lilius, Carrette)

- Excessive volumes (8 cc) injected “into” the z-jts which rendered them completely non-specific injections (Lilius)

- No control of co-interventions (Lilius, Carrette)

- Sub-optimal outcome measures (Lilius)

Dolan: Facet SPECT trial

- Prospective trial-58 patients with presumed facet pain

- 22 positive SPECT pts, 36 negative SPECT pts

- Those with positive SPECT scans had a 79% response rate to IA corticosteroid at 3 months vs. 42% with negative SPECT (p<0.01), but this difference was lost at 6 months (Dolan. Br J Rheum 1996:35:1269)
Ackerman:
Facet SPECT trial

- 46 SPECT positive pts, mean age 39
- Axial pain, + extension-rotation pain
- Prospective, double-blinded
- Randomized 1:1 to IA injection vs MBB with steroid (active comparison group/control)
- At 12 wks, 61% (IA) vs. 26% (MBB) had >50% relief and improved Oswestry (p < 0.05) (Ackerman 2008)

Pneumaticos:
Facet SPECT trial

- 47 pts clinically chosen for facet injections, Randomized 2:1 (SPECT performed, not performed)
- IA injections compared in SPECT positive vs. SPECT negative vs. injection based on clinical data only (SPECT not performed)
- 13/15 (86%) in SPECT positive group had a positive response ("better vs same or worse") at 1 month compared with 2/16 (13%) and 5/16 (31%) in the other groups  (p=.008)
- This significant difference was maintained at 3 months
- Difference not present at 6 months.
- 50% less joints treated in SPECT positive group  (Pneumaticos 2006)
Spinal Injections

March 18, 2016

Health Technology Assessment

Prepared by:

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Robin Hashimoto, PhD
Erika Brodt, BS
Krystle Pagarigan, BS
Eric Schnell, BS

Background

Spinal injections

- Typically considered only after failure of conservative treatment
- Injection of anti-inflammatory agent (steroid) and local anesthetic into spine or surrounding nerves and joints
- Injection often monitored with fluoroscopic guidance
- Deliver treatment directly to pain source (theoretical advantage)
Conditions Receiving Spinal Injections

- Lumbar or cervical radiculopathy due to disc pathology and/or foraminal narrowing
- Lumbar or cervical spinal (central) stenosis
- Lumbar or cervical pain without radiculopathy
- Failed surgery
- Lumbar or cervical facet joint pain
- Sacroiliac joint pain

Epidural Steroid Injection (ESI)

- One of the most common injections
- FDA has approved several injectable corticosteroids for a variety of conditions
- Corticosteroids not approved for epidural administration
Key Questions

When used in adult patients with subacute or chronic back or neck pain:

1. What is the evidence of efficacy and effectiveness of spinal injections?
2. What is the evidence of safety of spinal injections?
3. What is the evidence that spinal injections have differential efficacy or safety issues in subpopulations?
4. What is the evidence of cost implications and cost effectiveness of spinal injections?
Inclusion Criteria

Participants

- Adults with subacute (4-12 weeks) or chronic (>12 weeks) pain in the lumbar or cervical spine with or without radiculopathy or radiculitis

Intervention

- Spinal injections (epidural, facet, sacroiliac)

Comparators

- Control Injections
  - Anesthetic +/- saline, saline alone, dry needle
  - Epidural, non-epidural, intraarticular, extra-articular
- Control injections plus other medication
  - e.g., Clonidine, Etanercept
- Disc or decompression procedure
- Conservative care (e.g., physical therapy)
- Medial branch radiofrequency denervation
# Inclusion Criteria

## Outcomes (primary)

- **Pain relief**
  - Proportion of patients achieving ≥50% improvement
  - Mean improvement (MCID: 1.5 on 0-10 scale)

- **Physical function**
  - Proportion of patients achieving ≥50% improvement
  - Mean improvement
    - (MCID: ODI: 10 pts, RMDQ: 5 pts, NDI: 8.5 pts)

- **Composite Outcome**
  - Proportion of patients achieving ≥50% improvement in pain and function

- **Risk of surgery**
- **Adverse events**

## Study Design

- **KQs 1 and 3 (efficacy, differential efficacy):**
  - Randomized controlled trials

- **KQ 2 (safety):**
  - Randomized controlled trials
  - Observational studies of at least 100 patients where harm detection was primary objectives
  - FDA reports and reviews of case reports of serious harms

- **KQ 4 (cost-effectiveness):**
  - Economic analyses
**Literature Search**

1. Total Citations (n=3864)

2. Title/Abstract exclusion (n=3702)

3. Retrieved for full-text evaluation (n=162)

4. Excluded at full-text review (n=38)

5. Publications included (n = 124)
   - 72 RCTs (in 95 publications)
   - 3 nonrandomized comparative studies
   - 22 case series
   - 1 FDA summary report of adverse events
   - 3 economic evaluations

---

**Overall strength of evidence (GRADE)**

<table>
<thead>
<tr>
<th>Quality rating</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High confidence that the evidence reflects the true effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate confidence in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.</td>
</tr>
<tr>
<td>Low</td>
<td>Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.</td>
</tr>
</tbody>
</table>
### Results Efficacy (Lumbar)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Comparison</th>
<th>RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiculopathy due to disc pathology and/or foraminal narrowing</td>
<td>ESI vs. Control injection</td>
<td>23 RCTs</td>
</tr>
<tr>
<td></td>
<td>ESI vs. Control injection with other medication</td>
<td>3 RCTs</td>
</tr>
<tr>
<td></td>
<td>ESI vs. Disc or decompression procedure</td>
<td>4 RCTs</td>
</tr>
<tr>
<td></td>
<td>ESI vs. Conservative care</td>
<td>2 RCTs</td>
</tr>
<tr>
<td>Radiculopathy attributed to multiple causes</td>
<td>ESI vs. Control Injection</td>
<td>3 RCTs</td>
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<td>Stenosis</td>
<td>ESI vs. Control Injection</td>
<td>7 RCTs</td>
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<td>ESI vs. Control injection with other medication</td>
<td>1 RCT</td>
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<tr>
<td></td>
<td>ESI vs. Decompression procedure</td>
<td>1 RCT</td>
</tr>
<tr>
<td></td>
<td>ESI vs. Conservative care</td>
<td>1 RCT</td>
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<tr>
<td>Low back pain without radiculopathy</td>
<td>ESI vs. Control Injection</td>
<td>2 RCTs</td>
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<tr>
<td></td>
<td>Intraludic steroid injection vs. Intraludic control injection</td>
<td>3 RCTs</td>
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<td>Intraludic non-steroid injection vs. Intraludic control injection</td>
<td>1 RCT</td>
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<tr>
<td></td>
<td>Intraludic steroid injection plus Discography vs. Discography alone</td>
<td>1 RCT</td>
</tr>
<tr>
<td>Failed Back Syndrome</td>
<td>ESI vs. Control Injection</td>
<td>1 RCT</td>
</tr>
<tr>
<td></td>
<td>ESI vs. Control injection with other medication</td>
<td>3 RCTs</td>
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<tr>
<td>Facet joint pain</td>
<td>IASI vs Intra-articular control injection</td>
<td>3 RCTs</td>
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<tr>
<td></td>
<td>IASI vs Intramuscular steroid injection</td>
<td>1 RCTs</td>
</tr>
<tr>
<td></td>
<td>IASI vs Medial branch radiofrequency denervation</td>
<td>1 RCT</td>
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<tr>
<td></td>
<td>EASI vs Extra-articular control injection</td>
<td>2 RCTs</td>
</tr>
<tr>
<td></td>
<td>EASI vs Medial branch radiofrequency denervation</td>
<td>1 RCT</td>
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<td>Sacroiliac pain</td>
<td>IASI vs Conservative care</td>
<td>1 RCT</td>
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<td></td>
<td>EASI vs Extra-articular control injection</td>
<td>1 RCT</td>
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### Results Efficacy (Cervical)

<table>
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<tr>
<th>Condition</th>
<th>Comparison</th>
<th>RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiculopathy attributed to disc pathology</td>
<td>ESI vs. Conservative care</td>
<td>1 RCT</td>
</tr>
<tr>
<td>Cervicobrachialgia (pain with or without radiculopathy or stenosis)</td>
<td>ESI vs. Control Injection</td>
<td>1 RCT</td>
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<tr>
<td>Disc herniation with or without radiculopathy</td>
<td>ESI vs. Control Injection</td>
<td>1 RCT</td>
</tr>
<tr>
<td>Nonradicular neck pain</td>
<td>ESI vs. Control Injection</td>
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</tr>
<tr>
<td>Spinal stenosis</td>
<td>ESI vs. Control Injection</td>
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</tr>
<tr>
<td>Failed Surgery Syndrome</td>
<td>ESI vs. Control Injection</td>
<td>1 RCT</td>
</tr>
<tr>
<td>Facet joint pain</td>
<td>IASI vs. Intra-articular control injection</td>
<td>2 RCTs</td>
</tr>
<tr>
<td></td>
<td>IASI vs. Conservative care</td>
<td>1 RCT</td>
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</table>
Lumbar Radiculopathy due to disc or foraminal narrowing

Lumbar Radiculopathy: ESI vs. Control Injections (Short-term pain success)

<table>
<thead>
<tr>
<th>Study</th>
<th>Control</th>
<th>ESII</th>
<th>Randomization</th>
<th>Event Rate</th>
<th>Total Event Rate</th>
<th>Risk Ratio</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Chintan 2017</td>
<td>No</td>
<td>Yes</td>
<td>50</td>
<td>112</td>
<td>162</td>
<td>1.00</td>
<td>(1.00, 1.00)</td>
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<tr>
<td>Maitland 2012</td>
<td>No</td>
<td>Yes</td>
<td>48</td>
<td>96</td>
<td>144</td>
<td>1.00</td>
<td>(1.00, 1.00)</td>
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<td>James 2016</td>
<td>No</td>
<td>Yes</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>1.00</td>
<td>(1.00, 1.00)</td>
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</table>

Quality of evidence: LOW
## Lumbar Radiculopathy: ESI vs. Control Injections
### (Intermediate-term pain success)

<table>
<thead>
<tr>
<th>Study</th>
<th>ESIs</th>
<th>Fluoroscopy Guidance</th>
<th>Randomised</th>
<th>Jadad Score</th>
<th>Total Events</th>
<th>Control</th>
<th>Subtotal (95% CI)</th>
<th>Risk Ratio</th>
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<tbody>
<tr>
<td>Manchester 2011</td>
<td>EN0/0</td>
<td>Yes</td>
<td>Yes</td>
<td>5</td>
<td>60</td>
<td>50</td>
<td>82 (63, 102)</td>
<td>1.07 (0.88, 1.30)</td>
</tr>
<tr>
<td></td>
<td>EN24</td>
<td>Yes</td>
<td>Yes</td>
<td>5</td>
<td>60</td>
<td>60</td>
<td>82 (63, 102)</td>
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<td></td>
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<td>60</td>
<td>60</td>
<td>82 (63, 102)</td>
<td>1.07 (0.88, 1.30)</td>
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</tbody>
</table>

**Quality of evidence: LOW**

### Lumbar Radiculopathy: ESI vs. Control Injections
### (Long-term pain success)

<table>
<thead>
<tr>
<th>Study</th>
<th>ESIs</th>
<th>Fluoroscopy Guidance</th>
<th>Randomised</th>
<th>Jadad Score</th>
<th>Total Events</th>
<th>Control</th>
<th>Subtotal (95% CI)</th>
<th>Risk Ratio</th>
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</thead>
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<td>60</td>
<td>60</td>
<td>82 (63, 102)</td>
<td>1.07 (0.88, 1.30)</td>
</tr>
</tbody>
</table>

**Quality of evidence: LOW**
Lumbar Radiculopathy: ESI vs. Control Injections

Mean Pain Improvement

**Short-** (15 RCTs, N = 1748)
**Intermediate-** (5 RCTs, N = 587)
**and Long-term** (8 RCTs, N = 905)

No difference between groups

Quality of evidence: LOW

---

<table>
<thead>
<tr>
<th>Study</th>
<th>Control</th>
<th>ESI</th>
<th>Pain/Outcome</th>
<th>Randomized</th>
<th>Attrition</th>
<th>Total Events</th>
<th>Events</th>
<th>Control</th>
<th>ESI</th>
<th>Risk Ratio</th>
<th>Quality of evidence</th>
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</thead>
<tbody>
<tr>
<td>Cabin</td>
<td>ENKI 3 3 No</td>
<td>52</td>
<td>121</td>
<td>19</td>
<td>43</td>
<td>180</td>
<td>181</td>
<td>12</td>
<td>23</td>
<td>1.00</td>
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<tr>
<td>March</td>
<td>ENKI 3 Yes</td>
<td>46</td>
<td>86</td>
<td>37</td>
<td>60</td>
<td>180</td>
<td>180</td>
<td>12</td>
<td>23</td>
<td>1.00</td>
<td>LOW</td>
</tr>
<tr>
<td>Total</td>
<td>189</td>
<td>367</td>
<td>219</td>
<td>272</td>
<td>362</td>
<td>362</td>
<td>242</td>
<td>182</td>
<td>182</td>
<td>1.00</td>
<td>LOW</td>
</tr>
<tr>
<td>Lumbar</td>
<td>ENKI 3 Yes</td>
<td>49</td>
<td>60</td>
<td>46</td>
<td>60</td>
<td>180</td>
<td>180</td>
<td>12</td>
<td>23</td>
<td>1.00</td>
<td>LOW</td>
</tr>
<tr>
<td>Total</td>
<td>188</td>
<td>360</td>
<td>214</td>
<td>246</td>
<td>360</td>
<td>360</td>
<td>242</td>
<td>182</td>
<td>182</td>
<td>1.00</td>
<td>LOW</td>
</tr>
</tbody>
</table>

Quality of evidence: LOW
Lumbar Radiculopathy: ESI vs. Control Injections

(Intermediate-term functional success)

| Study                  | PDD Initial | Planar Imaging | Randomized | Parallel | Treatment | Sublumbar | Total | Weight | Risk Ratio
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchon /2012 /112/50</td>
<td>ENSI 12</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>1.02 [0.82, 1.26]</td>
<td>1.02 [0.82, 1.26]</td>
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<tr>
<td>Labeled ESI</td>
<td>10</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>1.02 [0.82, 1.26]</td>
<td>1.02 [0.82, 1.26]</td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>1.02 [0.82, 1.26]</td>
<td>1.02 [0.82, 1.26]</td>
<td></td>
</tr>
</tbody>
</table>

Quality of evidence: INSUFFICIENT

Lumbar Radiculopathy: ESI vs. Control Injections

(Long-term functional success)

| Study                  | PDD Initial | Planar Imaging | Randomized | Parallel | Treatment | Sublumbar | Total | Weight | Risk Ratio
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>Manchon /2012 /112/50</td>
<td>ENSI 12</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>1.02 [0.82, 1.26]</td>
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<td>Labeled ESI</td>
<td>10</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>1.02 [0.82, 1.26]</td>
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<td>Total events</td>
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<td>1.02 [0.82, 1.26]</td>
<td>1.02 [0.82, 1.26]</td>
<td></td>
</tr>
</tbody>
</table>

Quality of evidence: MODERATE
Lumbar Radiculopathy: ESI vs. Control Injections

Mean Function Improvement

Short- (11 RCTs, N = 1396)
intermediate- (6 RCTs, N = 740)
and long-term (8 RCTs, N = 1033)
No difference between groups
Quality of evidence: LOW

Composite Score Success (%)

Intermediate- or long-term (3 RCTs, N = 360)
No differences between groups
Quality of evidence: INSUFFICIENT Intermediate-term, LOW long-term

Lumbar Radiculopathy: ESI vs. Control Injections

Cumulative Risk of Surgery

Quality of evidence: LOW
Lumbar Radiculopathy: ESI vs. Other Controls

Discectomy:
Prior report: 1 RCT (N = 100), ESI with poorer outcomes vs. discectomy in the short- and intermediate term
✓ Newly added: 1 RCT (N = 50), no difference between groups in the short-term
Quality of evidence: INSUFFICIENT

Radiofrequency nucleoplasty:
✓ Newly added: 2 RCTs (N = 169)
ESI performed poorer than nucleoplasty in pain and ODI improvement in the short- (2 RCTs), intermediate- (1 RCT), and long-term (1 RCT)
No difference in risk of undergoing surgery (2 RCTs)
Quality of evidence: LOW

Conservative care:
Prior report: 1 RCT (N = 36), no difference between groups in the short- and intermediate-term
✓ Newly added: 1 study (N = 102), ESI with better outcomes in the intermediate-term
Quality of evidence: INSUFFICIENT

Lumbar Stenosis (central)
Lumbar Stenosis: ESI vs. Control Injections
Short-term Pain Success

<table>
<thead>
<tr>
<th>Study</th>
<th>RM</th>
<th>No ESI</th>
<th>ESI</th>
<th>ENSO</th>
<th>Total</th>
<th>Weight</th>
<th>Risk Ratio</th>
<th>Quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchado 01.12</td>
<td>Yes</td>
<td>31 50 50 44 19.0% 0.04 (0.01, 0.12)</td>
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<td></td>
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<td>HIGH</td>
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<td>Subtotal 0% CI</td>
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<td></td>
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<tr>
<td>Total events</td>
<td>51</td>
<td>50</td>
<td>50</td>
<td>44</td>
<td>19.0%</td>
<td>0.04 (0.01, 0.12)</td>
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<tr>
<td>Heterogeneity: Not applicable</td>
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<tr>
<td>Test for overall effect: Z = 3.94 (P = 0.00)</td>
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</table>

Lumbar Stenosis: ESI vs. Control Injections
Long-term Pain Success

<table>
<thead>
<tr>
<th>Study</th>
<th>RM</th>
<th>No ESI</th>
<th>ESI</th>
<th>ENSO</th>
<th>Total</th>
<th>Weight</th>
<th>Risk Ratio</th>
<th>Quality of evidence</th>
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</thead>
<tbody>
<tr>
<td>Fayers 2014</td>
<td>Yes</td>
<td>74 193 193 92 29.3% 0.06 (0.01, 0.29)</td>
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<td>LOW</td>
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<tr>
<td>Subtotal 0% CI</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Total events</td>
<td>193</td>
<td>193</td>
<td>193</td>
<td>92</td>
<td>29.3%</td>
<td>0.06 (0.01, 0.29)</td>
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<td>Heterogeneity: Not applicable</td>
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<tr>
<td>Test for overall effect: Z = 2.38 (P = 0.01)</td>
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<tr>
<td>Test for subgroup differences: OR = 0.71, df = 2 (P = 0.05), P = 0.1</td>
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Quality of evidence:

HIGH

LOW
Lumbar Stenosis: ESI vs. Control Injections

Mean Pain Improvement

Short-term (4 RCTs, N = 642)
No difference between groups

Quality of evidence: LOW

Lumbar Stenosis: ESI vs. Control Injections

Short-term Functional Success

Quality of evidence: HIGH
Lumbar Stenosis: ESI vs. Control Injections

Mean Function Improvement

Short-term (4 RCTs, N = 642)
No difference between groups
Quality of evidence: LOW

Composite Score Success (%)

Short-term (3 RCTs, N = 256)
No differences between groups
Quality of evidence: INSUFFICIENT

Lumbar Stenosis: ESI vs. Control Injections

Cumulative Risk of Surgery

<table>
<thead>
<tr>
<th>Study</th>
<th>ESI</th>
<th>N</th>
<th>ESI/Control</th>
<th>OR</th>
<th>Weight</th>
<th>Risk Ratio</th>
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<tr>
<td>Cumulative</td>
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<tr>
<td>Lumbar (95% CI)</td>
<td>26.8</td>
<td>8</td>
<td>18</td>
<td>7</td>
<td>12</td>
<td>0.79 (0.39, 1.56)</td>
</tr>
<tr>
<td>Total events</td>
<td></td>
<td>8</td>
<td></td>
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<tr>
<td>Heterogeneity:</td>
<td>not applicable</td>
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<tr>
<td>Test for overall effect: Z = -0.78 (P = 0.44)</td>
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</table>

| Transforaminal |     |    |             |     |        |            |
| Cumulative     |     |    |             |     |        |            |
| Lumbar (95% CI)| 20.5| 6  | 23          | 4   | 14     | 0.91 (0.31, 2.08) |
| Total events   |     | 6  |             |     |        |            |
| Heterogeneity: | not applicable |     |             |     |        |            |
| Test for overall effect: Z = -0.71 (P = 0.48) |

| Total 95% CI   | 256 | 256| 314.44%     | 17  | 19     | 2.24 (0.92, 5.51) |

Quality of evidence: LOW
**Lumbar Stenosis: ESI vs. Other Controls**

**Decompression:**
- Newly added: 1 RCT (N=38)
  - ESI was associated with a lower likelihood of pain success (≥2-pt. improvement) compared with MILD procedure: 35% vs. 76%, RR 0.5 (0.2 to 0.9);
  - No difference in VAS pain scores or ODI improvement. (1 RCT, N = 38)

  Quality of evidence: LOW

**Conservative Care:**
- Prior report: 1 RCT (N = 29)
  - No difference in pain or function in the short- or intermediate-term

  Quality of evidence: LOW

---

**Axial Low Back Pain without Radiculopathy**
Axial Low Back Pain:
Epidural Steroid vs. Control Injections

Pain, Function, and Composite Success (%);
Mean Pain and Function Improvement

Newly added: 2 RCTs (N = 240)
Short-, intermediate- or long-term
No differences between groups
Quality of evidence: INSUFFICIENT Short-term, LOW Intermediate- and long-term

Failed Lumbar Surgery
Failed Lumbar Surgery: ESI vs. Control Injections

Function and Composite Success (%);
Mean Pain and Function Improvement

- Newly added: 1 RCT (N = 140)
- Short-, intermediate- or long-term:
  No differences between groups
  Quality of evidence: LOW

Lumbar Facet Pain
Lumbar Facet

Mean Pain and Function Improvement

**Intra-articular Steroid versus Intra-articular Control Injections**
Prior report: Short- and intermediate-term pain (3 RCTs, N = 227) or function (1 RCT, N = 60):
No differences between groups
*Quality of evidence: LOW*

**Intra-articular Steroid versus Intramuscular Steroid Injection**
*Newly added: 1 RCT (N = 60)*

- **Short-term**
  - Greater improvement in intra-articular vs. intramuscular steroid
  - MD for pain, -1.6; 95% CI: -2.62, -0.58; and MD for RMDQ, -2.7; (-4.7, -0.7)

- **Intermediate-term**
  - No difference between groups in the intermediate-term for pain or function
  - *Quality of evidence: MODERATE*

Lumbar Facet Pain

Pain and Function Success (%)

**Extra-articular Steroid versus Extra-articular Control Injection**
Short-, intermediate- and long-term pain (2 RCTs, N = 204) and function success (1 RCT, N = 120): No difference between groups
*Quality of evidence: LOW*
Sacroiliac Pain

Intra-articular steroid vs conservative care
- Newly added: 1 RCT (N = 51)
  - Short-term pain or composite score success or mean improvement in pain:
    No difference between groups
  - Short-term mean improvement in function:
    Less improvement in the steroid injection group vs. physical or manual therapy
    Quality of evidence: LOW

Extra-articular steroid vs extra-articular control injection
- Prior report: Short-term mean improvement in pain (1 RCT, N = 24)
  - Greater improvement in pain in the extra-articular steroid group vs. control injection
    Quality of evidence: LOW
Cervical Radiculopathy due to disc or foraminal narrowing

Cervical Radiculopathy: ESI vs. conservative care (CC)

- Newly added: 1 RCT (N = 105)

  **Mean Improvement in Pain**
  - Short-term mean: No difference between groups
  - Intermediate-term mean: Less improvement in pain with ESI vs. CC
  - mean difference: **1.1 (0.5, 1.7)**
  - Quality of evidence: **LOW**

  **Mean Improvement in Function**
  - Short- and intermediate-term mean: Worse function (NDI) with ESI vs. CC
  - mean difference: **1.7 (0.6, 2.8)** in short-term; **5.6 (4.7, 6.5)** in intermediate-term
  - Quality of evidence: **LOW**

  **Risk of Surgery**
  - No difference between groups
  - Quality of evidence: **LOW**
Cervical Radiculopathy: ESI + CC vs. CC alone

Newly added: 1 RCT (N = 107)

Mean Pain Improvement
Short-term: Greater in the ESI + CC group vs. CC alone
MD: -1.3 (-1.9, -0.7)
Intermediate-term: No difference between groups
Quality of evidence: LOW

Mean Function Improvement
Short- and intermediate-term mean: Worse function (NDI) with ESI + CC vs. CC
MD: 4.0 (95% CI: 2.9, 5.1) short-term
MD: 9.6 (95% CI: 8.7, 10.5) intermediate-term
Quality of evidence: LOW

Risk of Surgery:
No difference between groups
Quality of evidence: LOW

Nonradicular neck pain

ESI vs. control injection

Newly added: 1 RCT (N = 120)

Pain and function success and improvement
Short, intermediate-, long-term: No difference between groups
Quality of evidence: LOW
Cervical Spinal Stenosis

ESI vs. control injection

✓ Newly added: 1 RCT (N = 60)

Pain and function success and improvement

Short, intermediate-, long-term: No difference between groups

Quality of evidence: LOW

Failed cervical surgery

ESI vs. control injection

✓ Newly added: 1 RCT (N = 56)

Pain and function success and improvement

Short, intermediate-, long-term: No difference between groups

Quality of evidence: LOW
Cervical facet joint

Intra-articular Steroid Injection vs. intra-articular control injection

Pain and function success and improvement

Short-term
Prior report: 1 RCT (N = 41)
No difference between groups

Short-, intermediate-, long-term
/ Newly added: 1 RCT (N = 120)
No difference between groups
Quality of evidence: LOW

Safety of Spinal Injections

Catastrophic adverse events: permanent tetra or paraplegia, blindness, death, arachnoiditis, stroke, cardiac arrest, spinal cord infarction or injury, meningitis

Serious adverse events: epidural or retroperitoneal hematoma, deep infection, respiratory failure, spinal nerve injury, hematoma, intravascular injection of steroid with neurologic sequelae, nerve root injury, subarachnoid injection, seroma, neurovascular complications, surgery or hospitalization necessary due to adverse events, and angina attributed to the procedure.

Non-serious adverse events: all other adverse events such as cerebrospinal fluid tap, dural puncture or tears, new neurological symptoms, sensory deficits, paresthesia and numbness in lower extremity, excessive pain, procedural bleeding, and procedural hypotension
Safety of Spinal Injections

Catastrophic adverse events
- No incidence of any catastrophic events across 60 RCTs for all injection types (N = 6290 patients)
- No such events were reported across 25 observational studies

Quality of evidence: LOW

FDA Adverse Events Reporting Database
- Catastrophic AEs can occur following ESIs, but such events are very rare
- 131 major neurological AEs, including five deaths and 41 cases of arachnoiditis
- Other events: brainstem stroke, motor-incomplete tetraplegia, paraplegia, paralysis, spinal cord infarction, cardiac arrest, blindness, and meningitis
- This report was unable to make a causal connection between AEs and injection location, injection approach, use of imaging, or type of steroid injected

Safety of Spinal Injections

Serious AEs
Across all included RCTs (regardless of injection location, type, or approach) (60 RCTs, N = 6290, 1 FDA report) serious AEs are rare, risk ranging from 0-4%

Quality of evidence: MODERATE

Non-serious AEs
Across all included RCTs and observational studies (regardless of injection location, type, or approach), non-serious AEs can occur but are relatively infrequent. However, methods for evaluating such events were not well reported.

Quality of evidence: MODERATE
Differential Efficacy or Safety Spinal Injections

Lumbar radiculopathy: ESI vs. control injections
- Disc prolapse vs. foraminal narrowing (1 RCT, N=124)
- Disc herniation vs. extrusion (1 RCT, N=128)
- Disc herniation vs. disc degeneration (1 RCT, N=183)
- Symptom duration (<3 or 4 vs ≥3 or 4 months) (2 RCT, N=378)
- Baseline scores for anxiety or depression, SF-36, ODI, neurological abnormalities, prior episodes of sciatica, coexistent back pain, work status, or sex (1 RCT, N=228)
  Quality of evidence: INSUFFICIENT

Lumbar radiculopathy: ESI vs. disc decompression
- Symptom duration (<1 vs 1-3 vs >3 years) (1 RCT, N=90)
  Quality of evidence: INSUFFICIENT

Lumbar stenosis: ESI vs. control injections (1 RCT, N=400)
- EQ-5D index score
- Employment status
- Treatment expectation
- Sex
- Race
- Ethnicity
- Education
- Smoking history
- Diabetes status
- Pain duration
- Stenosis severity
- Age
- Body mass index
- EQ-5D pain scores
- Patient Health Questionnaire-8 scores
- Generalized Anxiety Disorder-7 scores
- Pain Catastrophizing Scale
- Fear-Avoidance Beliefs Questionnaire physical activities subscale scores
- Injection approach

Quality of evidence: INSUFFICIENT
**Cost Effectiveness**

**Lumbar radiculopathy: ESI vs. control injections**

One poorly conducted (QHES 49/100) cost-effectiveness study conducted alongside an RCT of fluoroscopically-guided ESI versus saline injection reported the cost per positive response (≥75% improvement in leg pain and absence of surgery).

**Results:** Mixed in short-term dependent on MRI classification of disc herniation, extrusion or bulge. No difference after 3 months.

One reasonably well conducted (QHES 78/100) cost utility analysis. Utilities based on SF-36 through 3 months. The incremental cost per QALY of a single ESI (over non-epidural saline injection) was somewhat lower but remained high, ranging from £25,746 to £167,145 for the provider and purchaser perspectives, respectively. The authors concluded that the cost-effectiveness ratios are higher than the NICE thresholds and did not support NHS coverage.

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**Cost Effectiveness**

**Lumbar spinal stenosis**

A relatively well-conducted cost-utility study (QHES 73/100) compared serial ESI (i.e., 6 injections) to two different procedures (minimally invasive decompression and surgical decompression). Utility values were derived from EQ-5D, SF-6D, or ODI data.

**Results:**

ESI was dominated by minimally invasive decompression, with cost per QALYs of $81,518 and $43,760, respectively.

ESI dominated surgical decompression, which had a cost per QALY of $125,985.

The authors concluded that minimally invasive decompression was the most cost-effective treatment option in this patient population. However, the study made a number of assumptions that increase the risk of bias of their conclusions, including the assumption that patients had already failed ESI, which impacted the QALY values for this group.
Summary

Radiculopathy due to disc and or foraminal narrowing
• Epidural steroid injections for radiculopathy are associated with short-term mild improvement in lumbar pain but not function. Benefits are small and not sustained. (Similar to previous report, added meta-analysis and long-term f/u)
• No evidence of improved cervical pain or function by adding epidural steroid injection compared to conservative care. (New comparison to this report)
• There is no effect on the risk of surgery. (New outcome to this report)
• Evidence does not suggest that effectiveness varies based on any particular characteristic. (Similar to previous report)

Spinal stenosis
• Evidence suggests that epidural steroid injections are not effective in treating patients with spinal stenosis. (Similar to previous report)

Nonradicular axial pain
• Evidence suggests that epidural steroid injections are not effective for nonradicular back pain. (Similar to previous report, added long-term F/U)

Failed Prior Surgery
• Epidural steroid injections are not effective in reducing pain or improving function at any time frame in patients who fail prior surgery. (Similar to previous report, added cervical and long-term f/u)

Sacroiliac joint pain
• Intra-articular sacroiliac joint steroid injections are not effective in the short-term for presumed SI joint pain compared with physical or manual therapy. (New comparison to this report)
Summary

Facet joint pain
• Facet joint steroid injections are not effective for presumed facet joint pain. (Similar to previous report)

Safety
• Catastrophic events are very rare but can occur following epidural steroid injections (Added to this report)
• Serious (or major) adverse events are rare. (Similar to previous report)
• Non-serious (or minor) adverse events occur relatively infrequently (Similar to previous report)

Thank you
Health Technology Clinical Committee
Findings and Coverage Decision
Topic: Spinal Injections
Meeting Date: March 18th, 2011
Final Adoption: June 17th, 2011

Number and Coverage Topic
20110318B – Spinal Injections

HTCC Coverage Determination

Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are not a covered benefit

Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a covered benefit for the treatment of chronic pain

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 3 in 6 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

❖ Non-Covered Indicators
  - Therapeutic Medial Branch Nerve Block injections; Intradiscal injections and Facet injections are not a covered benefit.

❖ Agency Contact Information

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<thead>
<tr>
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<th>Contact Phone Number</th>
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<tbody>
<tr>
<td>Labor and Industries</td>
<td>1-800-547-8367</td>
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<tr>
<td>Public Employees Health Plan</td>
<td>1-800-762-6004</td>
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<tr>
<td>Health and Recovery Services Administration</td>
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Health Technology Background

The Spinal Injections topic was selected and published in December 2009 to undergo an evidence review process. The evidence based technology assessment report indicates that an estimated 75% of the population has had an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, a percentage which implicates significant social and economic impacts. The risk of spinal pain increases with age as a result of disc disease and spinal degeneration. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. Chronic spinal pain can be attributed to a number of pathologies, including (but not limited to) degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, and whiplash.

Treatment for chronic back pain typically begins with the identification of the underlying cause of pain and follows with conventional medical management (CMM), which varies with the diagnosis. CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.

Patients who don’t respond to non-invasive treatment are typically referred for more invasive and non-surgical therapies such as spinal injections in an attempt to provide pain relief. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver the treatment medication directly to the site involved in the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes.

In November 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Spinal Injections report is 299 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on March 18th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov under the committee section.
Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. **Evidence availability and technology features**
   
The committee concludes that the best available evidence on Spinal Injections has been collected and summarized. The evidence is presented below:

   - The evidence based technology assessment report estimates 75% of the population has an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, with significant social and economic impacts. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. The source and pathology of chronic spinal pain is not well understood but has been attributed degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, among other causes.

   - The evidence based technology assessment report indicates treatment for chronic back pain typically begins with the identification (or ruling out) of underlying cause of pain and beginning conventional medical management (CMM). CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.

   - The evidence based technology assessment report indicates that a small percentage of non-responsive patients may proceed to invasive therapies, including spinal injections. Spinal injections are not curative but are intended to provide pain relief and functional improvement for up to several months. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver medication directly to the site thought to be the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes. According to one study examining Medicare claims of lumbosacral injections, the number of epidural steroidal injections increased 271% and the number of facet injections increased 231% from 1994 to 2001. A similar study found that lumbar facet joint injections/diagnostic blocks increased 161% from 2002 to 2006.

   - Despite dramatic growth in procedures, evidence about the impact of spinal injections on important patient oriented outcomes related to impact on pain, physical function, opioid use; return to work; quality of life; patient satisfaction; avoidance of more invasive surgery; expected duration of impact; need for repeat procedures; frequency and type of harms; as well as clinical impacts of multilevel or procedure differences and any evidence about differential effect based on different patient, social or provider characteristics; different injection types; and impact of cost is needed.

   - The evidence based technology assessment report indicates that the Spinal injection evidence base is extensive: initial search resulted in over 2,700 potential citations; and based on evaluation against inclusion criteria, 1 Systematic review; 22 RCTs, 24 Observational Studies and two economic studies were included.
     - Evidence was identified on five injection types: epidural (lumbar and cervical); facet joint; sacroiliac; intradiscal injections and medial branch blocks.
     - Key strengths of the overall body of evidence are a large evidence base including randomized clinical trials.
Limitations in the overall body of evidence: despite well validated measures to evaluate treatment outcomes, evidence is limited by the variety of different measures or non-validated measures used; most studies were limited by a focus on one outcome - impact on short term pain; studies not including a placebo arm are limited when measuring subjective improvement in pain; many studies were limited by short duration (3 month or less) for treatment of a chronic condition; there remains uncertainty over clinically meaningful improvement for pain and function; and the variety of injection methods and types.

2. **Is the technology safe?**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- **Major Complications:** the evidence based technology assessment report indicated that major reported complications of spinal injection include dural puncture; subarachnoid puncture and angina pectoris, though rates are rare.
  - There were no cases of death or paralysis related to the procedure in the included studies, though death unrelated to the procedure was reported in 10 of 1146 patients in the RCTs, and there have been case reports of death and paralysis in the published literature.
  - For dural or subarachnoid punctures, or other life threatening complications, the reported rates ranged from 3 in 710 injections to 5 in 7240 (cervical) and 1 in 1556 injections to 1 in 10,416 injections for lumbar.

- **Minor Complications:** the evidence based technology assessment report indicated that minor complications are more common but are generally transient in nature. The overall minor complication rate ranged from 0.06% to 16.3% of injections or patients in 19 RCTs and 14 case series, and complications included: pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritis, irregular periods, and insomnia.

- **Radiation Exposure to the Physician:** the evidence based technology assessment report indicated that approximately 50% of four million interventional medical procedures per year are performed under fluoroscopic guidance. Fluoroscopy for spinal injections is routinely used to ensure correct needle placement, accurate delivery of the injectate, and avoidance of complications. Incorrect needle placement during spinal injections without the use of fluoroscopy has been reported by various studies in 12.5% to 38.3% of patients. A C-arm fluoroscope allows the X-ray tube to be moved around the prone patient and an image intensifier enhances the image, making it easier to interpret. Although studies have shown that radiation exposure to physicians using fluoroscopy for spinal injections is within safety limits, other methods, including ultrasound and CT, are being investigated as non-radioactive or lower radioactive methods of needle guidance.
3. **Is the technology effective?**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- Discussion focused on the following categories of injections: lumbar epidural; cervical/thoracic epidural; facet joint injection; sacroiliac joint injection; medial branch block; and intradiscal injection. Further differentiation was not focused on as the evidence based technology report indicated low to very low overall strength of evidence of different impact. The low level of evidence reported no consistent differential impact based on the approach to administering the injection; the diagnosis, pre-injection pain intensity; type of steroid, gender, age or other patient characteristics.

- **Epidural Steroid Injections for lumbar or low back pain with sciatica or radiculopathy** was highly studied and reported on; however, the overall strength of evidence is low based on the individual trial limitations and the inconsistency in results. Low back pain with sciatica or radiculopathy *the evidence is mixed* about the impact of spinal injection on pain (and in some studies function); with some studies showing a inferior results compared to placebo or other interventions and some studies showing a positive result.
  - When compared to placebo for caudal or interlaminar: *In the short-term* (≤3 months) there was mixed evidence based on data from twenty RCTs, seventeen of which were included in the Chou/APS SR (seven were considered to be higher-quality trials). Seven of seventeen studies included in the SR reported no benefit or inferior results while another seven reported positive results and three reported unclear results. Three LoE IIb RCTs published after the SR were added here, two reported on pain (both negative) and three on function (two negative and one positive) at three months. *In the long-term* (>3 months) there was mixed evidence based on data from twelve RCTs, nine of which were included in the Chou/APS SR. Seven of nine studies included in the SR reported no benefit or inferior results while positive results were reported by one study and another reported mixed results. Regarding the more recent RCTs included here, two reported on pain (both negative at twelve months, although one was positive at six months) and three on function (mixed results, one positive, one mixed, and one negative). (SoE = Low)
  - When compared to placebo for transforaminal: mixed evidence based on data from four RCTs, two of which were included in the Chou/APS SR and considered to be higher-quality and two of which were more recent LoE IIb studies. In terms of pain relief, the data suggest a benefit at two weeks (one study), mixed results at one month (two studies- one positive and one negative), and no benefit by 3 months. No benefit in function was reported at three months by two studies. Long-term data were mixed as reported by two higher-quality RCTs, both of which were reported in the Chou/APS SR, with one study reported positive results while the other showed no benefit. When compared to intramuscular injections, transforaminal steroid injections were superior to intramuscular injections in terms of pain relief at one month based on data from one LoE IIb RCT. (SoE = Low)

- **Epidural Steroid Injections for lumbar or low back pain without sciatica or radiculopathy** was also studied and reported on, and the overall strength of evidence is low to moderate based on the individual trial limitations and indication studied. The evidence indicates *no benefit of* spinal injections compared either to placebo, physical therapy, trigger point injection, discectomy or dry needling.
  - Low back pain (without sciatica or radiculopathy) compared to placebo showed no benefit based on data from three RCTs, one of which was included in the Chou/APS SR
and considered to be a lower-quality trial. The two more recent RCTs rated IIb also reported no benefit in pain, function, or opioid use at three months or in employment at twelve months. (SoE = Moderate)

- Spinal Stenosis compared to placebo: In the short-term (24 hours – 3 months), there was no benefit based on data from four RCTs, three of which was included in the Chou/APS SR; one was considered to be a higher-quality trial. Three of four studies reported no benefit; one study reported improved walking distance at one week. In a recent RCT, LoE IIb there was no benefit in pain, function, or opioid use at three months. (SoE = moderate). In the long-term (13 – 30 months), there was no benefit based on data from two RCTs as reported in the Chou/APS SR. (SoE = Low)

- Failed back surgery syndrome compared to placebo: no benefit based on data from three RCTs, two of which were included in the Chou/APS SR and considered to be lower-quality trials. In the one recent LoE IIb RCT, there was no benefit in pain, function, or opioid use at three months. (SoE = Moderate)

- Spinal Stenosis compared to physical therapy or control: no benefit in terms of pain, function, or quality of life at three and six months based on data from one LoE IIb RCT. (SoE = Very Low)

**Epidural Steroid Injections for cervical pain** reported overall strength of evidence of very low based on small number of trials, trial limitation and inconsistent results. The evidence indicates mixed benefit of epidural cervical spinal injections.

- For neck pain with disc herniation and radiculitis (comparator = placebo): no benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

- Neck pain without disc herniation and radiculitis (comparator = placebo): no benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

- Neck pain with disc compression and radiculitis (comparator = intramuscular injection): epidural injections were superior to intramuscular injections in the posterior neck in terms of pain, analgesic use, and employment at one week and twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

**Facet Joint Steroid Injections** overall had low strength of evidence of no benefit based on four RCTs.

- Confirmed or presumed lumbar facet joint pain compared to placebo: no benefit in the first three months based on data from two RCTs included in the Chou/APS SR, one of which was considered to be lower-quality. Although one of the studies reported a statistically meaningful benefit at six months in patient improvement following steroid injection, the rationale for this late response is not clear. (SoE = Low)

- Non-radicular back pain and facet joint osteoarthritis compared to hyaluronic acid: no benefit in the injection of steroids versus hyaluronic acid into the facet joint at six months based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)

- Confirmed cervical facet joint pain compared to placebo: no benefit in terms of the length of pain relief based on data from one LoE IIb RCT. No long-term data was reported. (SoE = Very Low)

**Sacroiliac Joint Steroid Injections** had low overall strength of evidence of benefit based on one RCT.

- For sacroiliac Joint Pain, compared to placebo: sacroiliac joint injections were superior to placebo injections based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)
Intradiscal Injections overall had moderate strength of evidence of no benefit based on seven RCTs.

- For discogenic back pain, steroid injection compared to placebo: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
- For sciatica compared to chemotherapy: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
- For low back pain without radiculopathy using neurolytic agent compared to placebo: intradiscal injections with methylene blue were superior to placebo injections in terms of pain, function, patient satisfaction, and analgesic use in the long-term (6-24 months) based on data from one LoE IIa RCT. (SoE = Low)

Medial Branch Blocks overall had low to very low strength of evidence of no benefit based on four RCTs.

- For confirmed lumbar facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
- For presumed lumbar facet joint pain compared to Sarapin: no benefit in injections with Sarapin with or without steroid based on data from one higher-quality and one lower-quality RCT included in the Chou/APS SR. (SoE = Low)

For confirmed cervical facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use or employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

4. Special Populations?

- Approach of the Epidural Steroid Injection: the evidence based technology assessment report indicated no consistent evidence from a systematic review of six RCTs and two additional RCTs published since the systematic review that one approach is more efficacious in administering lumbar epidural steroid. The results of one lower quality RCT suggest that interlaminar injections may not be as efficacious as transforminal in patients with axial only pain from spinal stenosis. However, more study is needed to verify these findings.

- Diagnosis: the evidence based technology assessment report indicated no consistent evidence that epidural steroid injections have differential efficacy or effectiveness among various diagnoses of the lumbar or cervical spine.

- Pre-injection pain intensity or duration, type of steroid, sex, age, or MRI findings: the evidence based technology assessment report indicated no consistent evidence that pre-injection pain intensity or duration, type of steroid used as injectate, sex, age or pre-injection MRI findings are associated with outcome in patients receiving epidural steroid injections of the lumbar or cervical spine.

5. Is the technology cost-effective?

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- The evidence based technology assessment report reported no evidence that epidural steroid injections are cost effective based on data from two economic analyses. One moderately well conducted cost utility analysis (QHES 78/100) suggested that one epidural steroid injection is a more cost effective patient management strategy than up to three injections and that cost effectiveness ratios for epidural steroid injections are too high to be considered cost effective by
UK conventions. Further, the budget impact of epidural spinal injections is likely large because of high use. Poor economic data (QHES 49/100) from a second trial (Karppinen) suggested that over one year epidural steroid injections do not show cost or outcome advantages compared to saline injections, and that contained herniations may be more responsive to steroid injection than bulges or extrusions.

- The evidence based technology assessment report reported no economic data were available for facet injections, medial branch blocks, sacroiliac joint injections, or intradiscal injections or for any type of cervical injection.
  - Washington state agency utilization and cost information indicated costs for Spinal Injections of $55M for the past four years with a rising trend.

6. Medicare Decision and Expert Treatment Guidelines
Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

- The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for any spinal injections.
- Guidelines – a search of the core sources and relevant specialty groups identified fourteen guidelines.
  - American Pain Society (APS), 2009: For patients with nonradicular low back pain, the APS is unable to assess the benefit of epidural steroid injection, facet joint steroid injection, medial branch block, or sacroiliac joint injection based on insufficient or poor evidence. Corticosteroid facet joint injection is not recommended based on moderate evidence. Intradiscal steroid injection is not recommended for treatment of nonradicular low back pain based on good evidence. For patients with radicular low back pain, the APS found moderate evidence for short-term (through three months) benefit from epidural steroid injections based on fair evidence. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis is not offered based on insufficient or poor evidence.
  - American Society of Interventional Pain Physicians, 2009: The recommendation for caudal epidural steroid injection in managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc herniation or radiculitis is 1A or 1B, indicating a strong recommendation where the benefits outweigh the risks of treatment. In addition, the recommendation for caudal epidural steroid injection for patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C, also indicating a strong recommendation. The recommendation for use of cervical interlaminar epidural injection for disc herniation and radiculitis to achieve short-term relief is 1C. For patients seeking long-term relief, the recommendation is 2B (weak recommendation), indicating benefits are balanced with risks and burdens of treatment. In patients with spinal stenosis and discogenic pain without disc herniation and radiculitis the recommendation is 2C (very weak, with uncertainty in estimates of benefits, risk, and burden of treatment). The recommendation for lumbar transforaminal epidural injections is 1C. Intraarticular facet joint injections are not recommended. Cervical, thoracic, and lumbar facet joint nerve blocks are recommended to provide both short-term and long-term relief in the treatment of chronic facet joint pain (recommendation 1B or 1C).
  - Institute for Clinical Systems Improvement (ICSI), 2009: Epidural steroid injections and facet joint injections are classified as level I (standard, first-line) therapeutic procedures, and are recommended as part of a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions. Evidence is limited when such procedures are used alone.
American College of Occupational and Environmental Medicine (ACOEM), 2008: Epidural glucocorticosteroid injection is recommended as a treatment option for subacute radicular pain syndromes, and as an option for second-line treatment of acute flare-ups of spinal stenosis associated with true radicular or radiculomyelopathic symptoms based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence).

Institute for Clinical Systems Improvement (ICSI), 2008: ICSI recommends epidural steroid injection only after conservative treatment has failed and to avoid surgical intervention. ICSI finds limited evidence for the efficacy of epidural steroid injection, but indicates it may allow patients to progress with conservative treatments. Epidural steroid injection should be performed under fluoroscopy with contrast in order to prevent treatment failure.

Work Loss Data Institute, Low back – lumbar & thoracic (acute & chronic), 2008: Epidural steroid injection and sacroiliac joint injections are recommended as part of a comprehensive treatment plan for low back pain. Specifically, epidural steroid injection is recommended to avoid surgery for severe cases with radiculopathy, but does not offer long-term functional benefit. “Series of three” epidural steroid injections, facet joint injection (multiple series, thoracic, and medical branch blocks), and intradiscal steroid injection were considered but are not recommended.

Work Loss Data, Neck and upper back (acute & chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan for radicular pain. Specifically, epidural steroid injection is recommended to avoid surgery in severe cases with neurologic findings. Facet joint injection was considered but is not recommended.

American Academy of Neurology, 2007: The American Academy of Neurology indicates the use of epidural steroid injections may result in a small magnitude of improvement in radicular lumbosacral pain when evaluated 2-6 weeks post-injection, but the recommendation is classified as a level C (possibly effective) due to the small number of relevant studies, highly select patient population, and variation in comparison treatments in the evidence base. Epidural steroid injections are not recommended for radicular lumbosacral pain due to a lack of evidence for improvement of function, need for surgery or long-term pain relief beyond 3 months. This recommendation is classified as level B (probably ineffective based on Class I-III evidence). There was insufficient evidence to make a recommendation regarding the use of epidural steroid injections to treat cervical radicular pain.

American College of Occupational and Environmental Medicine, 2007: The use of epidural glucocorticoid injection is recommended as a second-line treatment of acute spinal stenosis flare-ups, and as a treatment option for acute or subacute radicular pain based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence). The ACOEM makes no recommendation regarding the use of facet joint injection for flare-ups of neuropathic pain or chronic low back pain (Evidence Rating I: insufficient evidence). Facet joint injection is not recommended for any radicular pain syndrome, chronic non-specific axial pain, and repeat injections are not recommended for patients who failed to achieve lasting functional improvements after a prior injection for neuropathic or chronic low back pain based on evidence that treatment is ineffective or that costs or harms outweigh benefits to the patient (Evidence Rating B: moderate evidence).
pain syndromes lasting at least 3 weeks after treatment with NSAIDs and when pain is not trending towards spontaneous resolution. Both treatments are recommended based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). The use of facet joint injections is not recommended for acute, subacute, chronic low back pain, and radicular pain syndrome based on evidence that the treatment is ineffective or that harms and cost exceed benefits to the patient (Evidence Rating B: moderate evidence). Sacroiliac joint corticosteroid injection is recommended as an option for patients with specified known cause of sacroiliitis (Evidence Rating C: limited evidence). The use of epidural glucocorticosteroid injection is not recommended for acute, subacute, or chronic low back pain in the absence of radicular signs and symptoms (Evidence Rating C: limited evidence).

- American College of Physicians and the American Pain Society, 2007: Epidural steroid injection is an option for patients with prolapsed lumbar disc with persistent radicular symptoms who have not responded to noninvasive therapy. No specific recommendation is given for this or any other injection therapy of interest.

- North American Spine Society (NASS), 2007: The NASS recommends nonfluoroscopically-guided interlaminar epidural steroid injection as a treatment option for short-term symptom relief in patients with neurogenic claudication or radiculopathy. A single radiographically-guided transforaminal injection may also provide short-term symptom relief for patients with radiculopathy (Grade B: fair evidence). A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections may provide long-term symptom relief in patients with radiculopathy or neurogenic intermittent claudication, but evidence supporting this recommendation is of poor quality.

- EuroCOST: European evidence-based guideline COST B13 Working Group on Guidelines for Chronic Low Back Pain, 2006: Epidural steroid injection, facet joint injection, and facet nerve blocks are not recommended based on a lack of evidence or conflicting evidence. Intradiscal injections are not recommended for the treatment chronic nonspecific low back pain based on evidence they are not effective (level B: moderate evidence).

- American Association of Neurological Surgeons; Congress of Neurological Surgeons, 2005: Lumbar epidural injections and facet injections are recommended as treatment options for temporary, symptomatic relief in some patients with chronic low back pain, but epidural injections are not recommended for long-term relief of pain, based on Class III evidence (unclear clinical certainty). Facet injections are not recommended as long-term treatment for low back pain based on Class I evidence (high clinical certainty).

**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 Spinal Injections demonstrates that there is sufficient evidence to cover with conditions the use of therapeutic Epidural injections in the lumbar or cervical-thoracic spine for chronic pain.
- The committee concluded that the current evidence on Spinal Injections demonstrates that there is sufficient evidence to cover with conditions therapeutic Sacroiliac joint injections for chronic pain.
The committee concluded that the current evidence on Spinal Injections demonstrates that there is insufficient evidence to cover the other therapeutic spinal injections: Facet joint injections; medial branch block injections; and Intradiscal injections.

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 lumbar epidural injections. Based on these findings, the committee voted to cover with conditions cervical-thoracic epidural injections. Based on these findings, the committee voted to not cover medial branch blocks. Based on these findings, the committee voted to not cover Intradiscal injections. Based on these findings, the committee voted to cover with conditions Sacroiliac joint injections.

Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, therapeutic Epidural Injections in the lumbar or cervical-thoracic spine is 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
- Maximum of 3 in 6 months

Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, 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
- No more than one without clinically meaningful improvement in pain and function, under agency review

**Health Technology Clinical Committee Authority**

Washington State’s legislature believes it is important to use a scientific 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, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and 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 Health Technology Clinical Committee (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 their 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.
**Key Questions and Background**

Spinal Injections – Re-review

**Background**

*Disease*

Back and neck pain are common conditions, with sixty to eighty percent of U.S. adults afflicted at some time during their life. Back pain, and then neck pain, are the most common causes of disability and loss of productivity. In most patients reporting low back pain (>85%), symptoms cannot reliably be attributed to a specific spinal disease or pathology (Chou R, Qaseem A, Owens DK, et al. Diagnostic imaging for low back pain: advice for high-value health care from the American College of Physicians. Ann Intern Med. 2011;154(3):181-9.) Some believe that a similar majority of neck pain is non-specific. Most patients’ symptoms resolve satisfactorily within a relatively short time span (six weeks). In 5 – 10% of patients, pain does not satisfactorily resolve and the symptoms can be disabling and the social and economic impact of chronic pain is enormous. Discovering the cause for nonspecific low back and neck pain symptoms remains challenging. Some psychosocial risk factors for the progression to chronicity have been identified, but the origin and neurophysiologic pain sensations are poorly understood.

*Treatments*

Chronic pain treatment may include pharmacological treatment, physical therapy, psychological care and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulations, electrical stimulation, injections, implanted devices, and other surgical treatment. Treatment strategies generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment often involves a combination of interventions.

*Technology*

Spinal injections are not usually performed until non-surgical treatments have been given a fair trial and have not provided adequate relief. Intraspinal injections are intended to provide relief by injection of an anti-inflammatory agent (e.g. steroid); and/or anesthetic into the spine or space around the spinal nerves and joints. Intraspinal injections include epidural steroid injections, facet joint injections, medial branch block, sacroiliac joint injections and intradiscal steroid injections.
Prior Washington Health Care Authority Coverage Determination

Given that there were significant questions about the safety, efficacy and effectiveness (particularly long term), and the cost effectiveness of spinal injections, the Washington State HCA commissioned a Health Technology Assessment (HTA) on Spinal Injections and in 2011, the Health Technology Clinical Committee (HTCC) issued the following coverage determination:

Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are not a covered benefit

Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a covered benefit for the treatment of chronic pain following certain specific conditions.

Current Situation

Since the last HTCC meeting, new literature has been identified addressing the topic. In addition, new safety concerns have emerged for epidural injections from the FDA. Therefore, the HCA selected this topic for re-review.

Objectives

The primary aim of this assessment is to update the previous review on spinal injections.

Key Questions

When used in adult patients with subacute or chronic back or neck pain:

1. What is the evidence of efficacy and effectiveness of spinal injections? Including consideration of:
   a. Short-term and long-term measures, including measures related to:
   b. repeated spinal injections multilevel spinal injections bilateral versus unilateral spinal injections
   c. Impact on clinically meaningful physical function and pain  Impact on quality of life, patient satisfaction
   d. Opioid use, return to work, and any other reported surrogate measures

2. What is the evidence of the safety of spinal injections? Including:
   a. Adverse event type and frequency (mortality, major morbidity, other)
   e. Dural or arachnoid puncture
   f. Infection
   g. Epidural or intradural hematoma
   h. Allergic reaction
   i. Nerve or spinal cord injury
   j. Artery/vein damage/puncture
   k. Arachnoiditis
3. What is the evidence that spinal injections have differential efficacy or safety issues in sub populations? Including consideration of:
   a. Patient characteristics (gender, age, psychological or psychosocial co-morbidities, diagnosis, duration of pain)
   b. Injection characteristics (type of steroid [particulate, non-particulate], use of guidance, route of administration, provider type, setting, or other provider characteristics)
   c. Provider type, setting, or other provider characteristics
   d. Payer/beneficiary type: including worker’s compensation, Medicaid, state employees

4. What is the evidence of cost implications and cost-effectiveness of spinal injections? Including:
   a. Direct costs over short term and over expected duration of effect
   b. Comparative costs

### Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Study Component</th>
<th>Inclusion</th>
<th>Exclusion</th>
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<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>Adults with:</td>
<td>• Children&lt;br&gt;• Acute major trauma&lt;br&gt;• Cancer&lt;br&gt;• Infection&lt;br&gt;• Cauda equina syndrome&lt;br&gt;• Fibromyalgia&lt;br&gt;• Spondyloarthropathy&lt;br&gt;• Osteoporosis&lt;br&gt;• Vertebral compression fracture</td>
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<td>• Cervical or lumbar sub-acute or chronic pain with or without radiculopathy or radiculitis</td>
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<td><strong>Intervention</strong></td>
<td>Lumbar, sacral or cervical therapeutic spinal injections to include:</td>
<td>• Extraspinal injections (Botulinum toxin injections, local injections, paraspinal muscle injections, prolotherapy)&lt;br&gt;• Chemonucleolysis&lt;br&gt;• Radiofrequency denervation, intradiscal electrothermal therapy, coblation nucleoplasty and related procedures&lt;br&gt;• Drugs added to corticosteroids such as hyaluronidase and clonidine</td>
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<td></td>
<td>• Epidural injections&lt;br&gt;• Facet joint injections&lt;br&gt;• Medial branch block&lt;br&gt;• Sacroiliac joint injections&lt;br&gt;• Intradiscal injections</td>
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<td><strong>Comparators</strong></td>
<td>• Placebo or active control</td>
<td>• Spinal steroid injections</td>
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<td><strong>Outcomes</strong></td>
<td>• Pain&lt;br&gt;• Physical function&lt;br&gt;• Health-related quality of life&lt;br&gt;• Patient satisfaction&lt;br&gt;• Opioid use&lt;br&gt;• Prevention of surgery&lt;br&gt;• Complications and adverse effects (e.g. procedural complications and technical failures).</td>
<td>• Non-clinical outcomes</td>
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<td>Study Design</td>
<td>• KQs 1 &amp; 3: RCTs</td>
<td>• Case series other than those with N ≥ 100 for key question 2</td>
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<td>• KQ 2: RCTs, observational studies with harm detection as primary purpose, and reviews of case reports of serious harms</td>
<td>• Case reports other than for context</td>
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<td>• KQ 4: Formal economic studies</td>
<td>• Non-clinical studies (e.g., technical reports)</td>
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<td>• Studies in which &lt; 75% (or an unreported percentage) of patients have any of the excluded diagnoses (see above)</td>
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<tr>
<td>Publication</td>
<td>• Studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports</td>
<td>• Abstracts, editorials, letters</td>
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<td>• Full formal economic analyses (e.g. cost-utility studies) published in English in an HTA, or in a peer-reviewed journal published after those represented in previous HTAs.</td>
<td>• Duplicate publications of the same study which do not report on different outcomes</td>
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<td>• Single reports from multicenter trials</td>
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<td>• Studies reporting on the technical aspects spinal injections</td>
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<td>• Narrative reviews</td>
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<td>• Articles identified as preliminary reports when results are published in later versions</td>
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<td>• Incomplete economic evaluations such as costing studies</td>
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**Public Comment & Response**

See Draft Key Questions: Public Comment and Response document published separately.
HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA’s goal is to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

**Principle One: Determinations are evidence-based**

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective\(^1\) as expressed by the following standards\(^2\):

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

**Principle Two: Determinations result in health benefit**

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms\(^3\):

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

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1. Based on Legislative mandate: See RCW 70.14.100(2).
The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.

In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.

The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

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**Using evidence as the basis for a coverage decision**

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. **Availability of Evidence:**
   Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. ** Sufficiency of the Evidence:**
   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence using characteristics such as:
   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - The amount of evidence (sparse to many number of evidence or events or individuals studied);
   - Consistency of evidence (results vary or largely similar);
   - Recency (timeliness of information);
   - Directness of evidence (link between technology and outcome);
   - Relevance of evidence (applicability to agency program and clients);
   - Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

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4 Based on GRADE recommendation: [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
3. **Factors for Consideration - Importance**

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

### HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

**Discussion Document:**

What are the key factors and health outcomes and what evidence is there?

<table>
<thead>
<tr>
<th>Safety Outcomes</th>
<th>Safety Evidence</th>
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<td>Injection related adverse events</td>
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<th>Efficacy – Effectiveness Outcomes</th>
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<td>Pain relief short term</td>
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<td>Pain relief intermediate-term</td>
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<td>Pain relief long-term</td>
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<td>Physical function</td>
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<td>Composite of pain and function</td>
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<td>Risk of surgery</td>
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<td><strong>Special Population / Considerations Outcomes</strong></td>
<td><strong>Special Populations / Considerations Evidence</strong></td>
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<td><strong>Cost Outcomes</strong></td>
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<td>Costs</td>
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<td>Cost-effectiveness</td>
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## Medicare Coverage and Guidelines

**Centers for Medicare and Medicaid Services:**
There are currently no National Coverage Decisions published from the Centers for Medicare and Medicaid services.

**Clinical Guidelines**

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<tr>
<th>Organization(s)</th>
<th>Title (year)</th>
<th>Search Dates</th>
<th>Population Investigated</th>
<th>Intervention</th>
<th>Evidence Base Available</th>
<th>Recommendations</th>
<th>Level of Evidence</th>
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</thead>
</table>
• Cervical interlaminar epidural injections  
• Cervical facet joint nerve blocks  
• Lumbar facet joint nerve blocks  
• Sacroiliac joint injections  
Sacroiliac joint blocks | NR | • Caudal, interlaminar, and transforaminal steroid injections may be used for lumbar radiculitis  
• Caudal, interlaminar, and transforaminal steroid injections may be used for lumbar spine stenosis | Good* |
• Sacroiliac joint injections  
• Epidural steroid injections (both transforaminal and interlaminar) | RCTs & Observational studies (study number NR) NR | • Intraarticular facet joint injections may be used for symptomatic relief of facet-mediated pain  
• Sacroiliac joint injections may be considered for symptomatic pain relief of sacroiliac joint pain  
• Epidural steroid injections may be used as part of a | C2/ B2† |

Caudal & interlaminar injections: Fair*  
Transforaminal injections: limited*
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<th>Organization(s)</th>
<th>Search Dates</th>
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<tbody>
<tr>
<td>updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. (2010)</td>
<td></td>
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<td>studies (study number NR)</td>
<td>multimodal treatment regimen in select patients with radicular pain or radiculopathy</td>
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</table>
| Colorado Division of Workers’ Compensation 60                                 | 2001 – 2010  | Individuals qualifying under Colorado’s Workers’ Compensation Act as injured workers with chronic pain | • Epidural steroid injections  
• Facet injections  
• Sacroiliac joint injections  
Intradiscal steroid injections | NR          | • Intradiscal steroid injections are not recommended for discogenic back pain  
• Epidural injections should be limited to acute exacerbations of radicular pain  
• Facet joint injections are not recommended in subacute low back pain, and are only permitted in chronic low back pain  
• Sacroiliac joint injections are not recommended in subacute low back pain, and are only permitted in chronic low back pain. | NR               |
| Chronic pain disorder medical treatment guidelines (2012)                     |              |                                                                                        |                                                                              | NR                      |                                                                                  |                   |
| Colorado Division of Workers’ Compensation 62                                 | 2006 – 2012  | Individuals who qualify as injured workers with low back pain under Colorado Workers’ Compensation Act | • Epidural injections  
• Intradiscal injections  
• Sacroiliac joint injections  
• Transforaminal injections with Etanercept  
Facet injections | NR          | • There is no proven benefit from adding steroids to local anesthetic spinal injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement.  
• Intradiscal steroid injections are not recommended for patients with non-radicular pain. | NR               |
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<th>Organization(s) Title (year)</th>
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| Colorado Division of Workers’ Compensation<sup>61</sup>  
*Cervical spine injury medical treatments.* (2014) | 2006 – 2012 | Those who qualify as injured workers with cervical spine injuries under the Colorado Workers’ Compensation act. | • Epidural steroid injections (including transforaminal and interlaminar)  
• Intradiscal steroid injections  
• Transforaminal injections with Etanercept  
Facet injections | NR | • Epidural injections are not recommended for non-radicular cervical pain  
• Intradiscal injections in patients with non-radicular back pain are not recommended  
• Transforaminal injections with Etanercept is not recommended  
• Facet injections may be recommended | NR |
| Goertz/ Institute for Clinical Systems Improvement<sup>89</sup>  
*Adult acute and subacute low back pain.* (2012) | May 2011 – June 2012 | ≥18 years old in primary care who have symptoms of acute or subacute low back pain or radiculopathy | Epidural steroid injections | 5 sources (study type NR) | • Epidural steroid injections may be used for LBP, with a radicular component to assist with short-term pain relief | Weak‡ |
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<tr>
<th>Organization(s) Title (year)</th>
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</table>
| Hooten/Institute for Clinical Systems Improvement<sup>103</sup>  
*Assessment and management of chronic pain. (2013)** | August 2011 – August 2013 | ≥18 years old with chronic pain | • Facet joint injections  
• Epidural corticosteroid injections  
• Transforaminal epidural injections  
Sacroiliac joint injections | 1 SR  
3 studies (type NR)  
3 case reports, 2 studies (type NR)  
NR | • Facet joint injections have not been found to provide sustained therapeutic benefits  
• There is limited evidence to support the efficacy of epidural corticosteroid injections  
• Transforaminal epidural injections may be used for cervical procedures, when used as part of a longitudinal care plan  
• More studies are needed before a recommendation can be made for sacroiliac joint injections | Low§  
High§  
Low§  
NR |
| Toward Optimized Practice<sup>203</sup>  
*Guideline for the evidence-informed primary care management of low back pain. (2011)* | January 2002 – December 2010 | ≥18 years old in primary care setting with nonspecific low back pain. Excluding: pregnant women; diagnosis or treatment of specific causes of low back pain such as: inpatient treatments; referred pain (from abdomen, kidney, ovary, pelvis, bladder); inflammatory conditions; infections; degenerative and structural changes; fracture; neoplasm; metabolic bone disease | • Epidural steroid injections  
• Medial branch blocks  
Intraarticular facet joint blocks | SRs (study number NR) & 8 Guidelines  
SR & IHE database | • Epidural steroid injections are recommended for those with chronic low back pain  
• Do not use epidural steroid injections in patients with acute or subacute low back pain without radiculopathy  
• Epidural steroid injections may be helpful in patients with acute or subacute low back pain in the presence of radiculopathy  
• Medial branch blocks and intraarticular facet joint blocks may be beneficial for patients with pain originating from lumbar facet joints | NR |
<p>| U.S. Food and Drug Administration Safe Use Initiative, an expert | NR | NR | Epidural steroid injections | Best available scientific evidence or | • All cervical interlaminar ESI should be performed using image guidance, with | NR |</p>
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<thead>
<tr>
<th>Organization(s)</th>
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<tr>
<td>multidisciplinary working group, and 13 specialty stakeholder societies††</td>
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<td>expert opinion‡‡</td>
<td>appropriate anteroposterior, lateral, or contralateral oblique views and a test dose of contrast medium.</td>
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<td>Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections (2015)</td>
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<td>• Cervical transforaminal ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction imaging, using an anteroposterior view, before injecting any substance that may be hazardous to the patient.</td>
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<td>• Cervical interlaminar ESIs are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level.</td>
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<td>• Particulate steroids should not be used in therapeutic cervical transforaminal injections.</td>
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<td>• All lumbar interlaminar ESIs should be performed using image guidance, with appropriate anteroposterior, lateral, or contralateral oblique views and a test dose of contrast medium.</td>
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<td>• Lumbar transforaminal ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction imaging, using an anteroposterior view, before</td>
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<td>Organization(s) Title (year)</td>
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<td>injecting any substance that may be hazardous to the patient.</td>
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<td>A nonparticulate steroid (e.g., dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.</td>
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<td>There are situations where particulate steroids could be used in the performance of lumbar transforaminal ESIs.</td>
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**ESI: Epidural Steroid Injection**

* United States Preventative Task Force criteria:
  - **Good**: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).
  - **Fair**: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
  - **Poor or Limited**: Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

† Guideline definitions for Scientific Evidence:
  - **Category A**: supportive literature; RCTs that report statistically significant (p<0.01) differences between clinical interventions for a specified clinical outcome.
    - **Level 1**: the literature contains multiple RCTs, and the aggregated findings are supported by meta-analyses
    - **Level 2**: the literature contains multiple RCTs but there in an insufficient number of studies to conduct a viable meta-analysis
    - **Level 3**: the literature contains a single RCT
  - relationships among clinical interventions and clinical outcomes.
    - **Level 1**: the literature contains observational comparisons of clinical interventions or conditions and indicates statistically significant differences between clinical interventions for a specified clinical outcome
    - **Level 2**: the literature contains non-comparative observational studies with associative or descriptive statistics
    - **Level 3**: the literature contains case reports
  - **Category C**: equivocal literature; literature cannot determine whether there are beneficial or harmful relationships among clinical interventions and clinical outcomes.
    - **Level 1**: meta-analysis did not find significant differences among groups or conditions
    - **Level 2**: there is an insufficient number of studies to conduct meta-analysis and (1) RCTs have not found significant differences among groups or conditions or (2) RCTs report inconsistent findings
    - **Level 3**: observational studies report inconsistent findings or do not permit interference of beneficial or harmful relationships
  - **Category D**: insufficient evidence from literature; the lack of scientific evidence in the literature. (1) No identified studies address the specified relationships among interventions and outcomes. (2) The available literature cannot be used to assess relationships among clinical interventions and clinical outcomes. The literature either does not meet the criteria for content as defined in the “focus” of the guidelines or does not permit a clear interpretation of findings due to methodological concerns.

‡ Institute for Clinical Systems Improvement evidence grading:
  - **High**: further research is very unlikely to change our confidence in the estimate of effect.
Weak: The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.

Strong: The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.

Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Weak: The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.

Strong: The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.

Category B: suggestive literature; information from observational studies permits inference of beneficial or harmful

Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.

Weak: The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

Strong: The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.

§ Crosswalk between Institute for Clinical Systems Improvement evidence grading system and GRADE:

High: further research is very unlikely to change our confidence in the estimate of effect

Moderate: further research is likely to have an impact on our confidence in the estimate of effect and may change the estimate

Low: further research is very likely to have an impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain

** Guideline is an updated version of one included in previous report.

†† The U.S. FDA Safe Use Initiative group convened and facilitated teleconferences conducted by the working group (details not provided), which drafted, discussed, and formulated a set of clinical considerations. Once clinical considerations were drafted, representatives from a number of national pain organizations were invited to review and vote on them. New studies published after the initial vote were summarized by the working group and presented to the national organizations, who then revoted on clinical considerations given the new data.

‡‡ When evidence was lacking, expert opinion was sought both within the working group and from leading scientific societies or associations with interest or expertise in the subject of epidural injections.
Clinical Committee Findings and Decisions

Efficacy Considerations
- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
  - Does the use of the technology result in better sensitivity and better specificity?
  - Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety
- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact
- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?
Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.
Is there sufficient evidence under some or all situations that the technology is:

<table>
<thead>
<tr>
<th></th>
<th>Unproven (no)</th>
<th>Equivalent (yes)</th>
<th>Less (yes)</th>
<th>More (yes)</th>
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<tbody>
<tr>
<td>Effective</td>
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<td>Safe</td>
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<tr>
<td>Cost-effective</td>
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Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations.

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

_____ Not Covered  _____ Covered Unconditionally  _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?
**Next Step: Final Determination**

Following review of the proposed findings and decision document and public comments:

**Final Vote**

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.