Washington State Health Care Authority
Health Technology Assessment

Order of Scheduled Presentations

***TOPIC*:** Facet Neurotomy

	Name	Notes
1.	Paul Dreyfuss, MD EvergreenHealth Sport & Spine Care Alison Stout, DO EvergreenHealth Sport & Spine Care Ryan Zehnder, MD EvergreenHealth Sport & Spine Care Brandon Messerli, DO EvergreenHealth Sport & Spine Care Doug Burns, MD EvergreenHealth Sport & Spine Care	No slides.
2.	Kevin VorenKamp, MD EvergreenHealth Sport & Spine Care	

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

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

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

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 [redacted] 2.23.14 Paul Dreyfuss

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Washington State Health Care Authority

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Any unmarked topic will be considered a "Yes"

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X [redacted] 2/25/14

Signature *Date*

Ryan Zehnder

Print Name

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

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5.	Research funding.		X
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X [redacted] 2/25/14 Brandon Messerli

Signature Date Print Name

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126
360-586-8827 (fax)

Washington State Health Care Authority

Health Technology Assessment

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Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

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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 [redacted] 2/26/14

Signature *Date*

Print Name

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Health Technology Assessment
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Washington State Health Care Authority — Health Technology Assessment

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4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.	X	

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

American Academy of Pain Medicine, Ultrasonologists North American Spine Society, ISIS, McKenzie Institute USA - all travel for teaching or lectures

	Potential Conflict Type	Yes	No
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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 [redacted] 2/27/14 Alison Stout D.O.

Signature Date Print Name

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Health Technology Assessment
PO Box 42712
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360-725-5126

Disclosure

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X [redacted] 3/16/14 Kevin E. Vorenkamp

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Medial Branch (Facet) Radiofrequency Ablation (Neurotomy)

Kevin E. Vorenkamp, M.D
Virginia Mason Medical Center
Seattle, Washington

Spectrum Report

Multiple Flaws:

- No physicians involved with the report
- Methodological flaws
  - Placebo controlled trials for an invasive procedure for patients with chronic pain may not be considered ethical
- In the introduction, incorrectly states the technique variations
  - "Cooled RF" is not synonymous with pulsed RF and is in fact a thermal lesion
    - "There are two types of radiofrequency neurotomy: thermal (or non-pulsed), and cooled (or pulsed)"

Alternative Guidance

Multisociety Pain Workgroup (MPW)

- 14 Societies, Chaired by Ray Baker, M.D.
- "The CMDs have asked the MPW to review all of the pain management LCDs, and to make provisions which should be kept and which should be altered or eliminated."
- Facet interventions were the 2nd of several topics reviewed

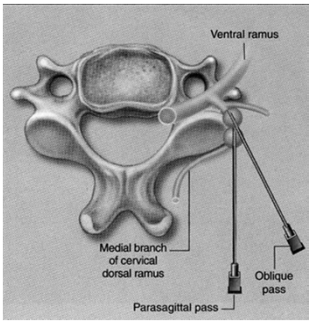
Facet RFA Recommendations from MPW

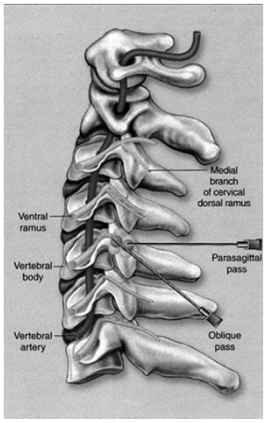
- Dual-diagnostic blocks
- >80% Relief
- Contrast verified
- Under multiplanar fluoroscopic imaging, RF cannulae should be placed adjacent and maximally parallel to each of the two medial branch nerves innervating the target joint. This best assures an optimal lesion and subsequent prolonged duration of relief.
- Physician qualifications (edited/added by CMDs)

Lord et al, NEJM '96

- Randomized, double-blind, controlled trial in 24 patients with chronic pain following flexion-extension injury
- One of several studies demonstrating good benefit when proper patient selection and procedural technique are used
- Similar results reported in cervical spine (including C2-3/TON) and lumbar spine

Cervical radiofrequency facet denervation





Lord SB, Barnsley L, Wallis BJ, McDonald GJ, Bogduk N. Percutaneous radiofrequency neurotomy for chronic cervical zygapophyseal joint pain. N Engl J Med 335:1721-6, 1996.

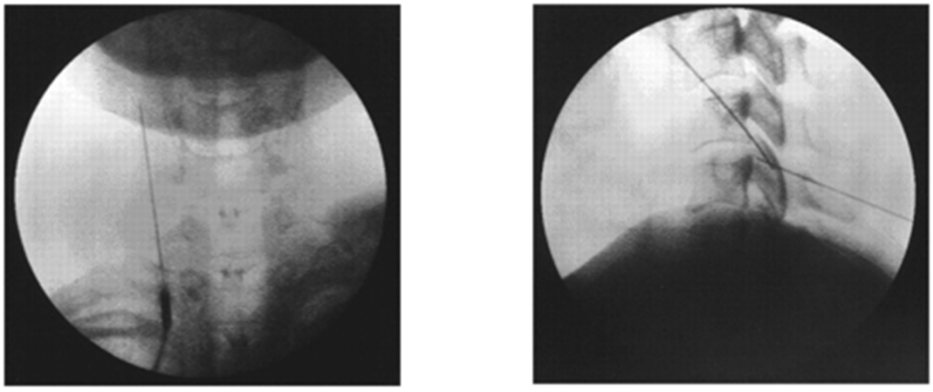
Lord, et al (NEJM ’96)

- **Rigorous Screening**:
  - **Relief** with dual diagnostic blocks
- Treatment (80 C x 90 seconds, 2-3 lesions with each pass) versus sham (37C)
- 12 patients in each group

Lord, et al (NEJM ’96)

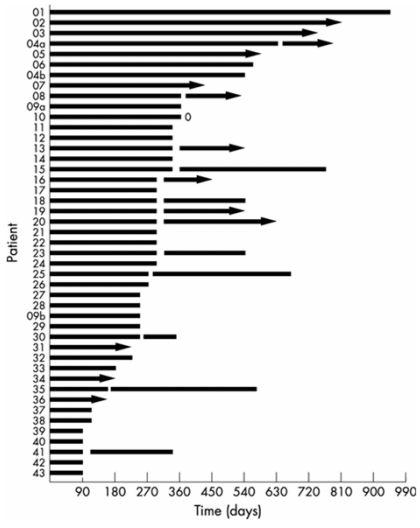
- Mean duration of relief: **263 days** vs. 8
- Follow-up study: 18/28 (64%) demonstrated **complete relief for a median duration of 421.5 days**
  - Complete relief possible with repeat denervations

Lord, et al (NEJM ’96)



Lateral (Panel A) and Anteroposterior (Panel B) Radiographs Showing the Insertion of the Electrode along a Parasagittal Plane to Make Lesions over the Lateral Aspect of the Articular Pillar.

The duration of response of patients who obtained complete relief of headache following radiofrequency neurotomy.



J Govind, W King, B Bailey, N Bogduk
Radiofrequency, J Neurol Neurosurg Psychiatry 2003;74:88-93

-Of the 49 patients, 43 ***(88%)*** achieved a successful outcome.
median duration of relief =297 days, with eight patients continuing to have ongoing relief.
-Fourteen patients underwent a repeat neurotomy to reinstate relief, with 12 (86%) achieving a successful outcome.

- Median duration of relief =217 days, with six patients having ongoing relief.
- No side effects required intervention, and they were tolerated by the patients in exchange for the relief of

Facet RFA (Neurotomy) is THE most effective non-surgical treatment for spinal pain arising from the Facet Joints

Key Points:

- 1. Facet RFA is EFFECTIVE when patients are properly selected with correct procedural technique utilized.
- 2. Multisociety Pain Workgroup has recently reviewed the supportive evidence and made recommendations on proper patient selection and procedural technique. CMDs have made further comments on physician qualifications.
- 3. Spectrum report demonstrates lack of basic knowledge of the procedure analyzed and therefore highlights flaws in the report analysis.

Washington State Health Care Authority
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Facet Neurotomy

Clinical Expert

Jason G. Attaman, DO FAAPMR

Disclosure

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X [redacted] 12/5/2013 Jason G Attaman DO

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Curriculum Vitæ

PERSONAL INFORMATION

Jason G. Attaman, DO, FAAPMR

4071 SW Admiral Way #217
Seattle, WA 98116

Phone (206) 395-4422
Email doctorattaman@gmail.com
Web www.jasonattaman.com

EDUCATION

1997–2002	Doctor of Osteopathic Medicine Chicago College of Osteopathic Medicine, Downers Grove, Illinois
1991–1994	Bachelor of Arts in English, Graduated with Honors University of Michigan, Ann Arbor, Michigan

POSTDOCTORAL TRAINING

2006–2007	ACGME accredited Fellowship; **Pain Medicine** Department of Anesthesiology Wayne State University School of Medicine, Detroit, Michigan
2003–2006	ACGME accredited Residency; **Physical Medicine and Rehabilitation** Department of Physical Medicine and Rehabilitation University of Michigan Health System, Ann Arbor, Michigan
2002–2003	AOA accredited Internship; **Osteopathic Traditional Rotating** Department of Post-Doctoral Training St. Francis Hospital, Evanston, Illinois

WORK EXPERIENCE

2010-2011 Dr. Attaman, PLLC; Seattle, Bellevue, and Auburn, Washington
Pain Medicine Physician

- Owner, private practice Interventional Pain Management Clinic

2008-2010 Pacific Medical Centers; Seattle, Washington
Pain Medicine Physician

- First and only Pain Medicine subspecialist in a multi-specialty clinic of 144 health care professionals
- Built and developed the Pain Medicine department
- Specified, built and developed an interventional fluoroscopy suite in the ambulatory surgery center (ASC)
- Supervised and trained staff including an ARNP, RNs, MAs, and scheduler
- Wrote departmental policies
- Exceeded productivity goals

BOARD CERTIFICATION

2007 ***Diplomate & Fellow***, American Board of Physical Medicine and Rehabilitation; certificate #8479
2007 ***Subspecialty Certificate in Pain Medicine,*** American Board of PM&R via the American Board of Anesthesiology; certificate #1123
2007 American Board of Electrodiagnostic Medicine; board eligible

LICENSURE

2003 National Board of Osteopathic Medical Examiners Levels I, II, and III
9/18/2006 Michigan Board of Osteopathic Medicine and Surgery #5101015807
9/18/2006 Michigan Board of Pharmacy Controlled Substance License #5315028991
8/30/2006 DEA Controlled Substance Registration Certificate, schedules 2, 2N, 3, 3N, 4, 5
1/23/2007 Washington Osteopathic Physician & Surgeon Prescriptive License #OP00002165

HOSPITAL AND SURGERY CENTER APPOINTMENTS

2010 Attending Physician, Overlake Hospital, Bellevue, Washington
2010 Attending Physician, Auburn Regional Hospital, Auburn, Washington
2010 Attending Physician, Overlake Surgery Center, Bellevue, Washington
2008 Attending Physician, Swedish Hospital, Seattle, Washington
2008 Attending Physician, Seattle Surgery Center, Seattle, Washington

COMMITTEES

2010 Overlake Surgery Center, Bellevue, Washington
- Medical Executive Committee member

AWARDS

2009 "Excellence in Clinical Team Work and Quality Performance," awarded by the administration of Pacific Medical Centers, Seattle, Washington
2006 "Superstar Physician Award" for outstanding teamwork, awarded by rehabilitation nurses of the University of Michigan Health System, Ann Arbor, Michigan
2004 "Superstar Physician Award" for outstanding patient satisfaction, awarded by inpatients of the University of Michigan Health System, Ann Arbor, Michigan

PROFESSIONAL SOCIETIES

2007 American Academy of Interventional Spine Specialists
2007 American Medical Association
2006 North American Spine Society
2006 International Spinal Intervention Society
2006 American Society of Interventional Pain Physicians
2003 American Academy of Physical Medicine and Rehabilitation
2002 Association of American Physicians and Surgeons
1998 American Association of Orthopædic Medicine
1997 American Osteopathic Association
1997 American Academy of Osteopathy

GRAND ROUNDS

2006 Attaman JG "Neuromodulation for Chronic Pain," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2005 Attaman JG "The Pain-Sleep Nexus," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan

LECTURES

2008 Attaman JG "Overview of Interventional Pain Management Procedures with CME credit," quarterly staff meeting, Pacific Medical Centers, Seattle, Washington
2008 Attaman JG "New Developments in Interventional Pain Management," board of directors meeting, Pacific Medical Centers, Seattle, Washington
2006 Attaman JG "Spinal Cord Vascular Anatomy and Vascular Complications of Spinal Procedures," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Pain M&M: Vascular Uptake During Cervical Medial Branch Blocks," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Radiation Safety for Pain Physicians," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "The Pain-Sleep Nexus," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Spine Anatomy Parts I&II" Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Pain Morbidity and Mortality," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Pain Morbidity and Mortality," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2006 Attaman JG "Pain Morbidity and Mortality," Department of Anesthesiology, Wayne State University, Detroit, Michigan
2005 Attaman JG "Spine Anatomy," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2005 Attaman JG: "Peripheral Nerve Injuries in Musicians," Departments of Physical Medicine and Rehabilitation and Neurology, University of Michigan Health System, Ann Arbor, Michigan
2005 Attaman JG: "Applying to Pain Medicine Fellowships," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2005 Attaman JG, Farhat, RF: "M&M Conference," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2004 Attaman JG: "Occupational Low Back Pain," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2004 Attaman JG: "Dr. Ted Cole Day Lecture: Clinical Predictors of PT Outcomes in Low Back Pain Patients," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2004 Attaman JG: "Traumatic Brachial Plexopathy; Diagnosis, Surgical Intervention, and Rehabilitation," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2003 Attaman JG: "Physiotherapeutic Techniques in Stroke Rehabilitation," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan

LECTURES CONTINUED

2003 Attaman JG: "The History of Ritual Genital Surgery," Department of Obstetrics and Gynecology, St. Francis Hospital, Evanston, Illinois
2003 Attaman JG: "Roentgenographic Characteristics of Achondroplastic Dwarfism," Department of Radiology, St. Francis Hospital, Evanston, Illinois

WORKSHOP TEACHING

2006 Colwell MO, Attaman JG, Farhat RF, et al.: "Resident Chair and Table Trainer: Introduction to Manual Medicine," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2005 Colwell MO, Attaman JG, et al.: "Table Trainer: Introduction to Manual Medicine," Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan

MEDICAL SCHOOL TEACHING

2006 Supervising and teaching fellow to Wayne State University anesthesiology residents and medical students on rotation to the pain medicine service
2004 Attaman JG: "Gait Analysis Workshop for the Medical Student," University of Michigan Medical School, Ann Arbor, Michigan
2004 Supervising House Officer to University of Michigan Medical School students on clinical rotation in the Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, Michigan
2003 Supervising House Officer to University of Illinois Medical School students, Department of General Surgery, St. Francis Hospital, Evanston, Illinois

CONTINUING MEDICAL EDUCATION WORKSHOPS

2010 Depuy Spine: "Vertebral Body Augmentation Training With Cadaver Workshop," San Diego, California. February 4.
2009 Baylis Medical: "Radiofrequency Lesioning: Intervertebral Disc Biacuplasty, Sacroiliac Joint Neurotomy, and Thoracic Z-Joint Neurotomy," San Carlos, California. November 7.
2009 American Academy of Pain Medicine: "AAPM 25th Annual Meeting," Honolulu, Hawaii. January 28–31.
2008 International Spine Intervention Society: "ISIS 16th Annual Scientific Meeting," Las Vegas, Nevada. July 23–26.
2008 International Spine Intervention Society: "ISIS Electroneuromodulation Workshop," British Columbia, Canada. February 16–17.
2007 Wayne State University and University of Michigan Schools of Medicine: "Advanced Regional Anesthesia 2007: Invasive Pain Management Techniques and Ultrasound Guided Regional Anesthesia Hands-on Workshop with Live Models and Cadavers," Detroit, Michigan. May 4–6, 2007.
2006 Advanced Neuromodulation Systems: "Private training in peripheral nerve field stimulation with Dr. Greaser," Fredericksburg, Virginia. October 13.
2006 Advanced Neuromodulation Systems: "Spinal Cord Stimulation Cadaver Workshop," Memphis, Tennessee. October 27-29.
2006 Medtronic: "Spinal Cord Stimulation Cadaver Workshop," Denver, Colorado. November 4-5.

CONTINUING MEDICAL EDUCATION WORKSHOPS CONTINUED

2006 Parallax Medical, Inc.: "Percutaneous Vertebroplasty (with Cadaver and Fluoroscopy) Workshop," Ann Arbor, Michigan.
2004 Parallax Medical, Inc.: "Percutaneous Vertebroplasty (with Cadaver and Fluoroscopy) Workshop," Ann Arbor, Michigan. March 13.
2001 Fédération Internationale de Médecine Manuelle (FIMM): "13th Triennial International Congress of Integrative Manual Medicine and Workshops," Chicago, Illinois. July 23-27.
2001 The Cranial Academy: "Advanced Instructor Workshop with Fred Mitchell, JR, DO, FAAO, FCA," Chicago, Illinois. April 26-29.
2000 American Academy of Osteopathy: "2000 Annual Convocation and Manual Medicine Workshops," Cleveland, OH. March 22-26.
1999 American Academy of Neural Therapy: "German Neural Therapy According to Dr. Huneke Workshop with Robert Kidd, MD," Chicago, Illinois. May 7-8.
1999 American Association of Orthopædic Medicine: "Introduction to Prolotherapy Lectures and Cadaver Workshop," Chicago, Illinois. June 11-12.
1999 American Academy of Osteopathy: "1999 Annual Convocation and Manual Medicine Workshops," St. Louis, MO. March 25-28.
1999 Jim Jealous, DO: "Introduction to Biodynamic Osteopathy," Franconia, NH.
1999 Chicago College of Osteopathic Medicine: "Percussion Hammer Technique Workshop," Chicago, Illinois.
1998 University of Wisconsin Medical School: "The Anatomy, Diagnosis, and Treatment of Chronic Myofascial Pain with Prolotherapy Cadaver and Live Patient Workshop," Madison, Wisconsin. October 12-14.
1998 American Academy of Osteopathy: "1998 Annual Convocation and Manual Medicine Workshops," Colorado Springs, CO. March 26-29.
1998 The Cranial Academy: "Basic Course in Osteopathy in the Cranial Field Workshop," Chicago, Illinois.
1997 Chicago College of Osteopathic Medicine: "Facilitated Positional Release Workshop with Eileen DiGiovanna, DO," Chicago, Illinois.

MENTORING

2002 The Student Doctor Network (click here to visit SDN) (http://forums.studentdoctor.net/forumdisplay.php?f=132)
Advisor for the Pain Medicine and PM&R discussion forums;
- Give career advice for medical students, interns and residents interested in the specialties of Pain Medicine and PM&R:
- Contributor to the Pain Medicine and PM&R frequently asked questions (FAQ) document

BIBLIOGRAPHY

2005 Tong HC, HO SG, Attaman JG, Geisser ME. Central Sensitization of Pressure Pain Thresholds. *Submitted to the European Journal of Pain*.
2005 Farhat RP, Attaman JG, Haig AJ. Electrodiagnostic Evidence of Long Thoracic Mononeuropathy After Cervical Transforaminal Epidural Injection. *Submitted to Spine*.

BIBLIOGRAPHY CONTINUED

2005 Tong HC, Attaman JG, HO SG, Geisser ME. Pain Pressure Threshold at the Low Back and the Deltoid in Subjects with Low Back Pain. Pending submission.

PAIN PROCEDURE COMPETENCY

Head: greater and lesser occipital nerve block, supraorbital nerve block, infraorbital nerve block, gasserian ganglion block, sphenopalatine ganglion block, maxillary nerve block

Neck: cervical medial branch block and radiofrequency lesioning, cervical interlaminar epidural block, cervical epidural catheter, zygapophyseal block, superficial cervical plexus block

Thorax: thoracic interlaminar epidural, thoracic transforaminal block, thoracic paravertebral block, thoracic medial branch block and radiofrequency lesioning (traditional and with Baylis ThoraCool system), thoracic intraarticular zygapophyseal joint blocks, intercostal nerve block under fluoroscopy with contrast, intercostal neurolysis and radiofrequency lesioning

Lumbar Region: transforaminal epidural blocks, selective nerve root blocks, interlaminar epidural blocks, transforaminal lateral recess blocks, medial branch blocks and radiofrequency lesioning, intraarticular zygapophyseal joint blocks, pulsed radiofrequency of the dorsal root ganglion, pars defect blocks, hardware screw blocks, discography, functional anesthetic discography,

Baylis TransDiscal cooled radiofrequency biacuplasty, percutaneous intradiscal coblation nucleoplasty, caudal epidural block, lumbar epidurolysis (Racz technique), sacroiliac joint injection and radiofrequency lesioning (traditional and Baylis SInergy system)

Joint Injections: shoulder joint injection, subacromial injection, olecranon bursa injection, hip injection under fluoroscopy, knee injection, trochanteric bursa injection under fluoroscopy, ischial bursa injection, knee injection, ankle joint injection, acromioclavicular joint block, pubic symphysis block under fluoroscopy, xiphisternal block under fluoroscopy

Peripheral Nerve Blocks: suprascapular nerve block and pulsed radiofrequency, median nerve block at the wrist, ulnar nerve block at the wrist, digital nerve block, axillary block with nerve stimulation and ultrasonic guidance, superficial cervical plexus block, ilioinguinal nerve block and pulsed radiofrequency, lateral femoral cutaneous block, genitofemoral nerve block, common peroneal nerve block, genital nerve block, saphenous nerve block, ankle block

Sympathetic System: stellate ganglion block, T2 and T3 thoracic sympathetic block, splanchnic block and neurolysis, celiac plexus block and neurolysis, lumbar sympathetic block and radiofrequency lesioning, hypogastric plexus block and neurolysis, ganglion impar block

Implantable Devices: spinal cord and peripheral nerve field stimulator percutaneous trial and surgical implantation, intrathecal pump trial and surgical implantation, tunneled epidural and intrathecal catheters, continuous peripheral nerve catheters

Platelet Rich Plasma injection therapy under image guidance

Prolotherapy under image guidance

ELECTRODIAGNOSTIC PROCEDURES

Electromyography
Nerve Conduction Studies
- Over 200 *complete* electrodiagnostic studies performed during residency
- All studies supervised by Diplomates of the American Board of Electrodiagnostic Medicine

MISCELLANEOUS

Born in Rochester, Michigan

Washington State Health Care Authority

Agency Medical Director Comments

Facet Neurotomy

Gary Franklin, MD, MPH/ Medical Director
Lee Glass, MD, JD/ Associate Medical Director
Washington State Department of Labor & Industries
March 21, 2014

Medial Branch Blocks(MBB) +/- Facet Neurotomy

- MBB*- Diagnostic anesthetic - look for 50-80% pain relief
- Facet neurotomy - usually radiofrequency ablation

*Almost no one uses intra-articular injections.

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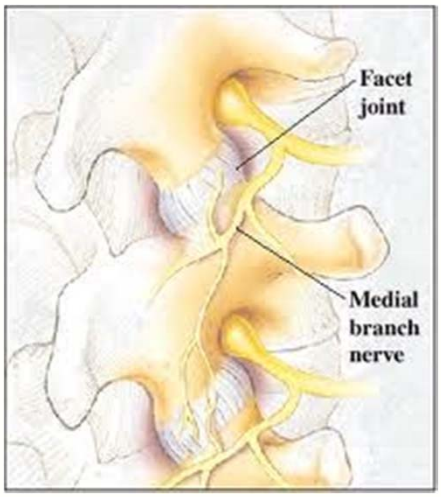
Outcome Anatomy

Typical anatomy:



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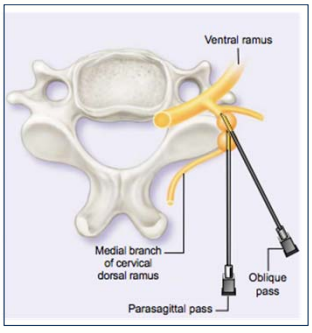
Approach



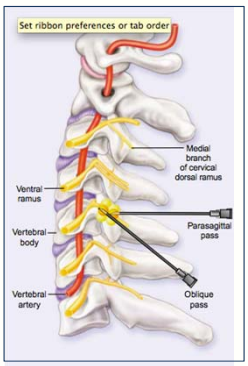


Figure 1. The Use of Electrodes to Coagulate a Medial Branch of a Cervical Dorsal Ramus
Panel A shows a cross section through the C5 vertebra. An oblique pass is used to reach the Nerve over the anterolateral aspect of the articular pillar. A parasagittal pass is used to reach The nerve over the lateral aspect of the pillar. With each pass, lesions are placed at, above, and Below the cephalocaudad center of the pillar (Panel B)

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Agency Medical Directors' Concerns

Primary Criteria Ranking
Initial *(Current)*

Safety = **High *(Low-Medium)***
Efficacy = **Medium**
Cost = **Medium**

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O'Neill and Owens, Spine J; 2009: 9:619-22 Editorial

"Anesthetic blocks were a valiant attempt to provide objective criteria to diagnose a vague syndrome. However, it is time to recognize that 1) anesthetic blocks are not a valid test to diagnose facet joint pain and 2) the treatment effect (impact on outcomes of neurotomy) and cost-effectiveness of anesthetic medial branch blocks are unknown."

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Facet Neurotomy

O'Neill and Owens, Spine J; 2009: 9:619-22 Editorial

Reanalysis of comparative block data (Lord SM, et al)		
Concordant response	18% (3/16)	±18.83%; −0.83%–36.83%
Discordant response	35% (6/17)	±22.67%; 12.33%–57.67%

Likely that spread of anesthetic creates false positive responses.

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Evidence of Efficacy

RCT's of Facet Neurotomy in Lumbar Pain

- **Neurotomy vs sham neurotomy**
  - Short term pain (1-6 mos): 4/6 RCTs no difference
  - Function: Mixed results
- **Neurotomy vs therapeutic facet injection**
  - No difference in pain or function
- **Repeat neurotomies**
  - Case series evidence
- **Strength of evidence is low overall**
  - No single RCT ranked higher than "low" in quality of evidence

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Safety Issues

- **Numbness in the area of the treated nerves in the cervical spine**
  - 38% in the RF neurotomy group experienced numbness in the area of the coagulated nerves in the postoperative period, compared with no patients in the sham neurotomy group (*P* = 0.0139)
  - Potential anatomic changes following facet neurotomy understudied:
    - Smuck et al, Spine J 2013, Nov 14-retrospective series using pre-post MRI suggests greater disc degeneration at neurotomy levels (14.9%) compared to non-intervention levels (4.6%, p<.05)
    - Ahmed et al, Spine J 2012; Epub Oct 12, 2012-Case report of multilevel cervical facet neurotomies-within days patient developed head drop and emg evidence of denervation of paraspinous muscles-fixed kyphotic deformity after a few years.

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Evidence of Efficacy

Lumbar Facet Neurotomy

- **Nath et al, Spine 2008; 33: 1291-7**

  N=376 with paravertebral tenderness screened with medial branch blocks (0.5% bupivicaine)
  - N=115 negative (30.5%)
  - N=261 with at least 80% relief of at least a component of their pain by the screening block
    - N=45 negative in controlled (repeated) blocks
    - N=105 with prolonged responses in controlled blocks
    - 115+45+105/376=70.4% ineligible due to inadequate response to either the screening and the controlled blocks
  - N=53 removed* and N=18 withdrew
  - N=40 randomized

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Facet Neurotomy

Costs of MBBs

- Significant costs likely incurred for high rate of "true" negatives per Nath et al screening out rate of 70%
- The L&I data (slide20) show that on average the diagnostic injections cost $778 per FN procedure

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MBB & FN:
Risks & Benefits

Cost-Effectiveness

- No good cost-effectiveness data
- Cohen et al, Anesthesiology 2010;113:395-405
  - Suggests doing a lot of blocks not cost-effective
  - **BUT**, overall, no matter how many blocks, the average number of levels of neurotomy was 3, with 60-75% of these bilateral (ie, average = 6 neurotomies/patient)
  - With blocks, cost/successful treatment $14-16,000

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Facet Neurotomy

Current State Agency Policy

Description	Medicaid	UMP	DOC	LNI
Diagnostic Medial Branch Nerve Blocks	PA	PA	PA	PA
Facet Neurotomy	PA	PA	PA	PA

C: Covered
NC: Not covered
PA: Prior authorization required

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Facet Neurotomy

Other Centers, Agencies & HTAs

- **CMS NCD for induced lesions of nerve tracts160.1:** Longstanding, no effective date. Indications and Limitations of Coverage: Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurred in by contractor's medical staff) to treat chronic pain.
- **UK-National Institute for Health and Care Excellence-Guidance May, 2009 (last updated 2/24/14):**

  "Do not refer people for radiofrequency facet joint denervation"

  http://www.nice.org.uk/usingguidancedonotdorecommendations/detail.jsp?action=details&dndid=408

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State Agency Utilization

Facet Neurotomy

All Agencies Facet Neurotomies, Paid $	2009	2010	2011	2012	4 Yr Overall Total
Facet Neurotomy Patients	611	602	606	236	1785
Facet Neurotomy Procedures (encounters)	769	773	814	274	2630
Avg Encounters per Patient	1.3	1.3	1.3	1.2	1.5
Total Paid	**$1,332,995**	**$1,154,223**	**$1,233,502**	**$489,296**	**$4,210,015**
Avg Paid per Procedure	$1,733	$1,493	$1,515	$1,785	$1,600

State Agency Utilization

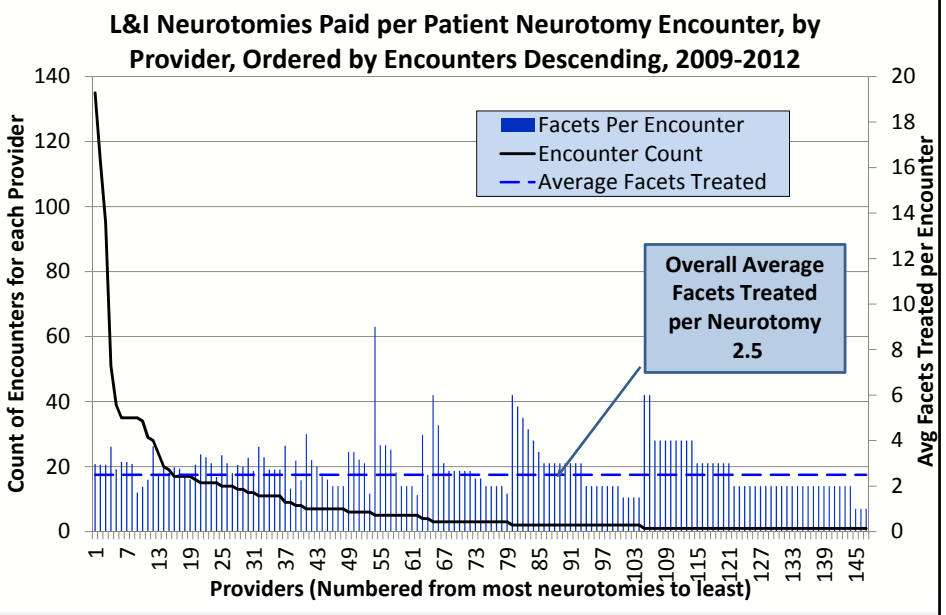
Facet Neurotomy

Overall (4 year) Averages by Agency	PEB/UMP Primary	L&I	Medicaid (Non-Medicare)
Average Paid per Encounter	$2,799	$2,507	$844
Average Encounters per Patient	1.6	1.3	1.5
Average Facets per Encounter	2.7	2.5	2.4

State Agency Utilization

Top 4 Diagnoses by Agency, Allowed $ Descending		Allowed $	% of Total
PEB/UMP	**Overall Allowed Total:**	**$1,214,721**	
Lumbosacral spondylosis		$456,063	37.5%
Lumbago		$157,157	12.9%
Cervical spondylosis		$154,892	12.8%
Other back symptoms		$85,669	7.1%
L&I	**Overall Allowed Total:**	**$1,333,133**	
Lumbosacral spondylosis without myelopathy		$241,941	18.1%
Lumbar sprain and strain		$247,025	18.5%
Other symptoms referable to back		$136,023	10.2%
Lumbago		$118,548	8.9%
Medicaid	**Overall Allowed Total:**	**$731,903**	
Lumbosacral spondylosis		$312,280	42.7%
Lumbago		$96,163	13.1%
Chronic pain NEC		$81,529	11.1%
Cervical spondylosis		$57,982	7.9%

State Agency Utilization



State Agency Utilization

Repeated Facet Neurotomy Use 2009-2012

PEB/UMP Neurotomy Encounters	Patient Count	% Total Patients
10	1	0.2%
6	5	0.8%
5	10	1.5%
4	16	2.5%
3	39	6.0%
2	156	23.9%
1	425	65.2%

Medicaid Neurotomy Encounters	Patient Count	% Total Patients
13	1	0.2%
6	7	1.3%
4	9	1.6%
3	27	4.9%
2	129	23.2%
1	380	68.5%

L&I Neurotomy Encounters	Patient Count	% Total Patients
5	1	0.2%
4	4	0.6%
3	8	1.2%
2	182	28.1%
1	452	69.9%

State Agency Utilization

Per Procedure Avg Allowed Charges by Agency, Setting and Payer (Non-Medicare)	PEB/UMP Primary (n=435*)	L&I (n=815*)	Medicaid Non-Medicare (n=718*)
Breakdown 1			
Professional Services	$649	$1,307	$224
Facility/Other	$1,246	$1,090	$689
Breakdown 2			
Neurotomy	$1,739	$1,494	$838
Imaging/Guidance	$71	$61	$3
Diagnostic Injections*	$62	$778	$56
Other	$22	$64	$16
Avg Allowed/Procedure	**$1,895**	**$2,397**	**$913**

Facet Neurotomy

Department of Labor & Industries Guideline

- Convened group of interventional anesthesiologists
- Developed guideline
- Started paying for cervical and lumbar MBBs and facet neurotomies
- Method:
  - 2 differential blocks
  - Placebo control at physician's discretion
  - At least 80% pain relief
  - Last procedure necessary for injured worker to be at maximum medical improvement (MMI)

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Facet Neurotomy

International Spine Intervention Society (ISIS) Criteria

ISIS criteria on diagnostic medial branch blocks

- At least 80% of relief of index pain from medial branch blocks should be recognized as a pretext for further investigation
- Less than 80% relief should be regarded as non-positive; and further medial branch blocks should not be pursued
- At least 80% relive of index pain following comparative or placebo-controlled blocks should become the only indication for medial branch neurotomy

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Facet Neurotomy

Pain Log

Medical Treatment Guidelines

Washington State Department of Labor and Industries

Facet neurotomy workup pain relief report form

Directions: This form is to be completed by the patient, or someone recording the patient's responses, in "real time" following the administration of a facet block. **Pain relief level should be recorded while doing activities that previously caused pain.**

Please fill in the date and time of your block was performed, then circle the time the block was completed on the time chart. Every 15 minutes put a check mark in the time chart box that most accurately describes the degree of your pain relief. Continue to put check marks in the appropriate time chart box **every fifteen minutes for a full 6 hours** following the block. This form needs to be returned to the physician who performed your block at your next scheduled visit, since it will become part of your medical record.

Name: _____ Date of block: _____

Time of block _____

My pain is: Time (Circle the time of the block)	100% Totally gone	80% Pretty much gone	50% Half way gone	20% Barely gone	0% Usual level, no relief	Time	100% Totally gone	80% Pretty much gone	50% Half way gone	20% Barely gone	0% Usual level, no relief
8:00 am						4:00 pm					
8:15						4:15					
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State Agency Experience

Facet Neurotomy Outcomes

- 2/3 of the claims with FN in the 2008 to 2013 period were still disabled on 4/15/2013,
- Is there a correlation between experience performing MBB or FN and a case moving to vocational rehab?

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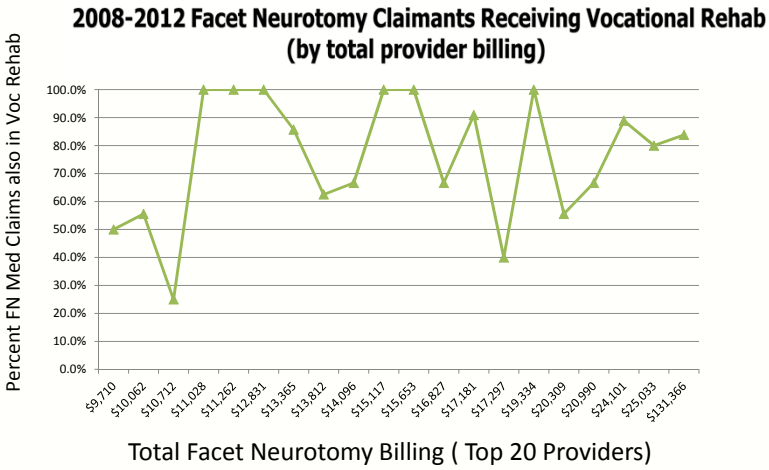
% FN in Voc vs. Billed Amounts



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Summary:

- Low quality evidence of short term benefit for part of the painful condition: cervical>lumbar
- No “gold standard” for diagnosis and localization of facet joint pain

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Facet Neurotomy

State Agency Recommendation:

- Non-coverage

  OR

- Coverage with conditions:

  e.g. Facet neurotomy is payable only if:

  - 100% pain relief from local anesthetic medial branch block; and
  - No relief from placebo control medial branch block.
  - One level/side and not more than 6 months if evidence supports (GHC: http://www.ghc.org/all-sites/clinical/criteria/pdf/radiofrequency_neurotomy.pdf)

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Facet Neurotomy

Current L&I Criteria

- Failure of 6 months of non-invasive therapy
- Clinical findings:
  - Non-radicular neck or back pain
  - Segmental pain or tenderness at the level of the potentially involved facet and not more than 2 joint levels bilaterally or 3 joint levels unilaterally
  - Neurologically intact for the region involved
  - If neurologic deficit is present, it should be addressed in the treatment plan
- Diagnostic tests:
  - Diagnostic testing to rule out any correctable structural lesion to include CT or MRI
  - At least 2 differential local anesthetic blocks and minimum of 80% pain relief following each block while performing activities that previously provoked pain

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Questions?

More Information:

http://www.hca.wa.gov/hta/Pages/neurotomy.aspx

Gary Franklin, MD, MPH
Medical Director
Washington State Department of Labor & Industries
FRAL235@LNI.WA.GOV

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Facet neurotomy

March 21, 2014

HEALTH TECHNOLOGY ASSESSMENT
prepared by:

Robin Hashimoto, PhD
Haley Holmer, MPH
Ned Sherry, BS
Andrea Skelly, PhD, MPH

Spectrum Research, Inc., Tacoma, WA

Background:
Facet joint

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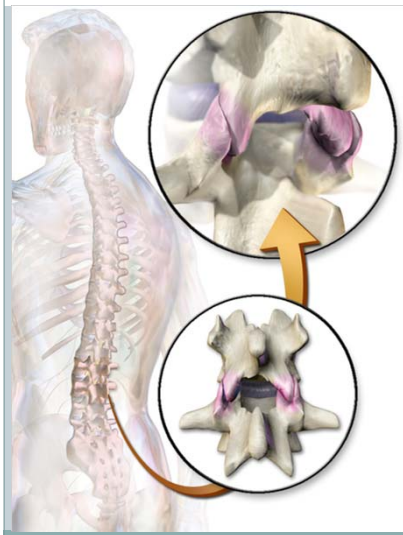

Facet arthropathy:
- Progressive
- More common in older patients

- Primary physical sign: paraspinal tenderness at affected joints
- Primary symptom: axial spinal pain
- Other symptoms include radiating pain, pain with twisting or bending

Whiplash can also lead to facet pain in the cervical spine

Diagnosis of facet joint pain

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- Physical examination
- Imaging may be used to rule out other pathologies
- Diagnostic blocks:
  - **Medial branch block anesthetizes the medial branch nerve**
  - **Intra-articular block anesthetizes the entire joint cavity**
- Pain relief following diagnostic block indicates facet joint is likely source of pain

Diagnosis of facet joint pain

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- Some possible causes of false positive blocks:
  - **placebo response, excess superficial local anesthetic, sedation, infiltration of anesthetic, inadequate anesthetic dose, vascular uptake of anesthetic, procedure-related pain**
- Risk of false positive blocks may be decreased with:
  - **Use of controlled or comparative blocks (instead of a single block)**
  - **Requiring higher levels of pain relief following diagnostic block (i.e., 80% instead of 50% pain relief required)**
- No gold standard for diagnosing facet joint pain

Technology: facet neurotomy

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- Lesioning of the nerves at the affected joint(s) used to disrupt pain signals and thus achieve pain relief (6-12 months)
- Outpatient procedure
- Needle positioned using fluoroscopic guidance
- Correct positioning tested with initial pulse
- Energy (usually RF) applied to medial branch nerves
- Larger lesion volumes may help ensure procedural success (larger electrodes, higher temps, longer lesion times may be used)

Key Questions

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- **KQ1.** Effect of diagnostic blocks on neurotomy efficacy and effectiveness
- **KQ2.** Comparative efficacy and effectiveness
- **KQ3.** Safety
- **KQ4.** Differential efficacy or safety issues in subpopulations
- **KQ5.** Cost effectiveness

Inclusion criteria (PICO)

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- **Participants.** Adults being considered for facet neurotomy due to suspected facet joint pain
- **Intervention.** Facet neurotomy using FDA approved devices or other ablation techniques
- **Comparators.** Sham neurotomy, therapeutic spinal injections (e.g., intra-articular injections, medial branch blocks), medical therapy

Inclusion criteria (PICO)

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- **Outcomes.**
  - **Efficacy and effectiveness:**
    - Primary outcomes: pain relief, functional improvement
      - Clinically meaningful improvement in pain:
        - Moderate : 30% pain relief
        - Substantial: 50% pain relief
    - Secondary outcomes: health-related quality of life, return to work, patient satisfaction, opioid use
  - **Safety:**
    - Complications and adverse events

Literature search

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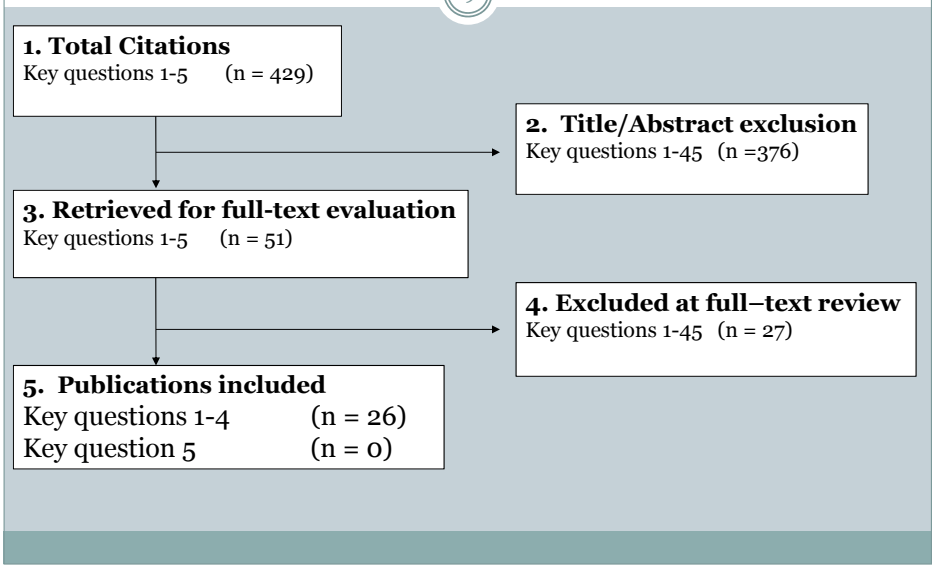

Overall quality of evidence (GRADE)

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Quality rating	Interpretation
High	High confidence that the evidence reflects the true effect.
Moderate	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.
Low	Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Insufficient	Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.

Results: KQ1

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KQ1. What is the evidence that the use of diagnostic blocks to select patients improves clinical outcomes following FN? Consider:

a. **diagnostic block versus alternative diagnostic test**
b. **type of diagnostic block**
c. **single versus controlled diagnostic blocks**
d. **degree of pain relief from diagnostic block**
e. **unilateral versus bilateral diagnostic block**
f. **single vs. multiple level diagnostic block**

KQ1a: Patient selection

(Lumbar: FN following selection by MBB versus clinical exam)

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Short-term pain	Studies N	F/U	Diagnostic Method (% pain relief required for FN)	MBB (% patients)	Clinical exam (% patients)	Overall QoE	Favors
"Success" composite (VAS, GPE) following RFN	1 RCT N = 70	3 mos.	MBB (≥50%) Clinical exam (none)	39%	33%	Low	neither

RR (95% CI): 1.07 (0.58, 2.34)
RD (95% CI): 0.06 (-0.20, 0.32)

KQ1b: Patient selection
(Lumbar: FN following selection by MBB versus pericapsular block)

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Short-term pain & function	Studies N	F/U	Diagnostic Method (% pain relief required for FN)	MBB	Peri-capsular block	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100) following cryodenervation	1 RCT N = 26	6 mos.	MBB (≥50%) Pericapsular block (≥50%)	47 (64%)	40 (57%)	Low	neither
Function (MacNab, 0-3) following cryodenervation	1 RCT N = 26	6 mos.	MBB (≥50%) Pericapsular block (≥50%)	1.2	1.0	Low	neither

KQ1c: Patient selection
(Lumbar: FN following selection by single versus controlled blocks)

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Short-term pain & function	Studies N	F/U	Diagnostic Method (% pain relief required for FN)	1 MBB	2 comp. MBBs	Overall QoE	Favors
				% patients			
"Success" composite (VAS, GPE) following RFN	1 RCT N = 33	3 mos.	1 MBB (≥50%) 2 comparative MBBs (≥50%)	39%	64%	Low	neither

RR (95% CI): 0.60 (0.30, 1.22)
RD (95% CI): -0.25 (-0.59, 0.08)

KQ1d: Percentage of pain relief
(Lumbar: FN following selection by diagnostic block)

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Short-term pain & function	Studies N	F/U	Diagnostic Method	50-79% pain relief (% patients)	≥80% pain relief (% patients)	Overall QoE	Favors
Back pain "success" (≥50% pain relief)	2 retro cohort studies N = 313	6 mos.	MBB	52-54%	56-84%	**Insufficient**	**≥80% pain relief from block in 1/2 studies**
"Success" composite (VAS, GPE) following RFN	2 cohort (1 prosp, 1 retro) studies N = 113	3 mos.	MBB	35-67%	56-76^	**Insufficient**	**≥80% pain relief from block in 1/2 studies**
Function "success" (≥50% improvement in activity levels)	1 retro cohort study N = 51	6 mos.	MBB	33%	76%	**Insufficient**	**≥80% pain relief from block**

Summary: Patient selection (KQ1)

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KQ	Summary	Result	Overall Quality of Evidence	Evidence basis
KQ1a	Diagnostic block versus physical exam (lumbar spine)	**No difference** in pain relief "success" between groups.	**Low**	1 RCT N = 70 3 months
KQ1b	MBB versus pericapsular block (lumbar spine)	**No difference** in pain or function between groups.	**Low**	1 RCT N = 26 6 months
KQ1c	1 MBB versus 2 comparative MBBs (lumbar spine)	**No difference** in pain between groups.	**Low**	1 RCT N = 33 3 months
KQ1d	Threshold of pain relief (50-79% versus ≥80%) following block (lumbar spine)	**Inconclusive;** no difference OR favors ≥80% pain relief	**Insufficient**	2 retro cohorts N = 313 6 mos.

Results: KQ2

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KQ2. What is the evidence of efficacy and effectiveness of facet neurotomy compared with alternatives (e.g., sham neurotomy, therapeutic medial branch blocks, etc.)?

KQ2: Efficacy

(Lumbar spine: RF versus sham neurotomy)

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Evidence base: 6 RCTs

N = 292 patients total (31 – 81 per study)

Intervention:

Radiofrequency (RF) versus sham neurotomy

RCT	N	Follow-up	Duration of symptoms	Diagnostic Block	% pain relief required for FN	Outcomes blinded?
Van Kleef (1999)	31	2 mos.	25 (12-120) mos.	1 MBB	≥ 50% pain relief	yes
Leclaire (2001)*	70	3 mos.	> 3 mos.	1 IAB	"significant" response	yes
van Wijk (2005)	81	3 mos.	> 6 mos.	2 IABs	≥ 50% pain relief	yes
Gallagher (1994)	30	6 mos.	> 3 mos.	1 IAB	"good" response	yes
Nath (2008)	40	6 mos.	≥ 24 mos.	2 MBBs	≥ 80% pain relief	yes
Tekin (2007)	40	6 mos. 12 mos.	> 72 mos.	1 MBB	≥ 50% pain relief	yes

KQ2: Efficacy
(Lumbar spine: RF versus sham neurotomy)

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Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	6 RCTs N = 292	2-6 mos.	Varied (varied)	-0.4 to 42.0 (-1 to 65%)	2.0 to 19.4 (3 to 54%)	**Low**	**neither** (4/6 studies)
McGill pain (0-50)	1 RCT N = 30	6 mos.	1 IAB ("good" response)	3 ± 5.5	2 ± 1.9	**Low**	**neither**
Leg pain (VAS, 1-100)	2 RCTs N = 121	3-6 mos.	Varied (varied)	16 to 21 (37 to 50%)	1 to 16 (5 to 25%)	**Low**	**RFN**
Generalized pain (VAS, 1-100)	1 RCT N = 40	6 mos.	2 MBBs (≥80%)	19.3 (32%)	3.7 (9%)	**Low**	**RFN**

KQ2: Efficacy
(Lumbar spine: RF versus sham neurotomy)

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Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				% patients			
Back pain "success" (VAS, ≥50% pain relief)	1 RCT N = 81	3 mos.	2 IABs (≥50%)	33%	34%	**Low**	**neither**
Back pain "success" (GPE, ≥50% improvement)	1 RCT N = 81	3 mos.	2 IABs (≥50%)	62%	39%	**Low**	**RFN (marginally)**
Leg pain "success" (VAS, ≥50% pain relief)	1 RCT N = 81	3 mos.	2 IABs (≥50%)	50%	37%	**Low**	**neither**

KQ2: Efficacy
(Lumbar spine: RF versus sham neurotomy)

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Short-term Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Function (ODI, 0-100)	3 RCTs N = 141	2-6 mos.	Varied (varied)	4.7 to 14.1 (12 to 36%)	-1.7 to 11.2 (-4 to 28%)	Low	RFN (2/3 studies)
Function (Roland-Morris, converted to 0-100)	1 RCT N = 70	3 mos.	1 IAB ("significant" response)	9.8 ± 19.5 (19%)	7.2 ± 17.0 (14%)	Low	neither
Disability (Waddell, 0-24)	1 RCT N = 31	2 mos.	1 MBB (≥50%)	0.33	0.07	Low	neither

KQ2: Efficacy
(Lumbar spine: RF versus sham neurotomy)

22

Long-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	41.0 ± 9.1 (63%)	29.0 ± 9.6 (43%)	Low	RFN
Function (ODI, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	11.2 ± 4.8	6.5 ± 3.9	Low	RFN

KQ2: Efficacy
(Lumbar spine: RF versus spinal injection)

23

Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN (Δ from baseline (mean (%))	MBB or IAI (Δ from baseline (mean (%))	Overall QoE	Favors
Back pain (VAS, 0-100)	2 RCTs N = 156	6 mos.	Varied (varied)	19 to 57 (29 to 70%)	16 to 41 (23 to 48%)	**Low**	**neither** (2/2 studies)
				RFN (% patients)	**MBB** (% patients)		
Back pain "success" (VAS)	1 RCT N = 100	6 mos.	NR (NR)	90%	68%	**Low**	**RFN**

RR: 1.32 (1.11, 1.58)
RD: 0.22 (0.07, 0.37)

Evidence base (CoE II): Civelek (N = 100) (vs. MBB); Lakemeier (N = 56) (vs. IAI)

KQ2: Efficacy
(Lumbar spine: RF versus spinal injection)

24

Short-term Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN (Δ from baseline (mean (%))	IAI (Δ from baseline (mean (%))	Overall QoE	Favors
Function (ODI, 0-100)	1 RCT N = 56	6 mos.	1 MBB (≥50%)	12.8 ± 12.0 (31%)	5.7 ± 11.4 (15%)	**Low**	**neither**
Function (Roland-Morris, 0-100)	1 RCT N = 56	6 mos.	1 MBB (≥50%)	3.7 ± 3.7 (19%)	4.2 ± 3.9 (14%)	**Low**	**neither**

Evidence base (CoE II): Lakemeier (N = 56) (vs. IAI)

KQ2: Efficacy
(Lumbar spine: RF versus spinal injection)

25

Long-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	MBB	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	1 RCT N = 100	12 mos.	NR (NR)	56 (68%)	36 (42%)	Low	neither
				RFN	MBB		
				% patients			
Back pain "success" (VAS)	1 RCT N = 100	12 mos.	NR (NR)	88%	62%	Low	RFN

RR: 1.42 (1.12, 1.80)
RD: 0.26 (0.10, 0.42)

Evidence base (CoE II): Civelek (N = 100) (vs. MBB)

KQ2: Efficacy
(Cervical spine: RF versus sham neurotomy)

26

Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Freedom from "accustomed" pain	1 RCT N = 24	6 mos.	3 MBBs (100% with anesthetics, 0% with saline)	58% (7/12)	8% (1/12)	Insufficient	RFN

RR (95% CI): 7.00 (1.01, 48.54)
RD (95% CI): 0.50 (0.18, 0.82)

Evidence base (CoE II): Lord 1996

KQ2: Efficacy
(Cervical spine: RF versus spinal injection)

27

Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN Δ from baseline (mean (%))	GON injection Δ from baseline (mean (%))	Overall QoE	Favors
Headache pain (VAS, 0-100)	1 RCT N = 30	2 mos.	None	30.5 ± 17.3 (45%)	32.4 ± 24.7 (42%)	Low	neither
				RFN % patients	GON injection % patients		
"Success" composite (GPE/VAS)	1 RCT N = 30	2 mos.	None	80%	71%	Low	neither

RR (95% CI): 1.12 (0.79, 1.59)
RD (95% CI): 0.09 (-0.23, 0.40)

Evidence base (CoE II): Haspeslagh (cervicogenic headache)

Results: KQ2a

28

KQ2a-d. What is the evidence of the comparative efficacy and effectiveness of

a. Different types of facet neurotomy?

- **Conventional versus pulsed RFN**
- **RFN versus alcohol ablation**

KQ2a: Efficacy
(Lumbar spine: Conventional versus pulsed RFN)

29

Short-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	Conv. RFN Δ from baseline (mean (%))	Pulsed RFN Δ from baseline (mean (%))	Overall QoE	Favors
Back pain (VAS, 0-100)	2 RCTs N = 66	3-6 mos.	1 MBB (≥50%)	23 to 42 (32 to 65%)	12 to 37 (19 to 56%	Low	neither
Function (ODI, 0-100)	2 RCTs N = 66	3-6 mos.	1 MBB (≥50%)	10.3 to 14.1	2.7 to 14.1	Low	neither

Evidence base (CoE II): Tekin (N = 40), Kroll (N = 26)

KQ2a: Efficacy
(Lumbar spine: Conventional versus pulsed RFN)

30

Long-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	Conv. RFN Δ from baseline (mean (%))	Pulsed RFN Δ from baseline (mean (%))	Overall QoE	Favors
Back pain (VAS, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	41 ± 9 (63%)	31 ± 10 (47%)	Low	Conv. RFN
Function (ODI, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	11.2 ± 4.8	10.9 ± 3.7	Low	neither

Evidence base (CoE II): Tekin (N = 40)

KQ2a: Efficacy
(Lumbar spine: RFN versus alcohol ablation)

31

Short-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Alcohol ablation	Overall QoE	Favors
				Δ from baseline (mean (%))			
"Success" composite (VAS, ODI)	1 RCT N = 40	9 mos.	2 blocks (NR) (previously successful RFN)	85%	100%	Low	neither

RR (95% CI): 0.85 (0.71, 1.02)
RD (95% CI): -0.15 (-0.31, 0.01)

KQ2a: Efficacy
(Lumbar spine: RFN versus alcohol ablation)

32

Long-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Alcohol ablation	Overall QoE	Favors
				Δ from baseline (mean (%))			
"Success" composite (VAS, ODI)	1 RCT N = 40	12 mos.	2 blocks (NR) (previously successful RFN)	25%	100%	Low	Alcohol ablation
		24 mos.		5%	85%	Low	Alcohol ablation

24 months:
RR: 0.06 (0.01, 0.40)
RD: -0.80 (-0.98, -0.62)

Results: KQ2b

33

KQ2a-d. What is the evidence of the comparative efficacy and effectiveness of different types of facet neurotomy?

b. Repeat neurotomy

Insufficient quality of evidence: following successful initial procedure, repeat procedures likely to be similarly successful.

- Lumbar spine: 6 case series
- Cervical spine: 2 case series

Results: KQ2c

34

KQ2a-d. What is the evidence of the comparative efficacy and effectiveness of different types of facet neurotomy?

c. Unilateral versus bilateral neurotomy

- **Insufficient evidence (1 retrospective cohort study, 69 procedures): no difference between treatment groups (mean 6 mos. f/u) in back pain "success"**

Results: KQ2d

35

KQ2a-d. What is the evidence of the comparative efficacy and effectiveness of different types of facet neurotomy?

d. Single versus multiple levels

- **No evidence**

Results: KQ3

36

KQ3. What is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term following facet neurotomy?

KQ3: Safety
(Lumbar spine: RF versus sham neurotomy)

37

	Studies N	RFN (% patients)	Sham (% patients)	RR (95% CI) RD (95% CI)	Overall QoE	Favors
Treatment – related pain (moderate or severe)	1 RCT N = 81	59%	36%	1.40 (0.95, 2.04) 0.09 (-0.01, 0.20)	**Low**	**neither**
Treatment – related sensibility changes	1 RCT N = 81	5%	0%	1.31 (0.74, 2.31) 0.41 (-0.04, 0.13)	**Low**	**neither**
Treatment – related motor changes	1 RCT N = 81	0%	2%	0.0 (NC) -0.02 (-0.07, 0.02)	**Low**	**neither**
Treatment – related adverse events (undefined)	4 RCTs N = 191	0%	0%	NC	**Low**	**neither**

KQ3: Safety
(Lumbar spine: RFN versus spinal injections)

38

	Studies N	RFN (% patients)	Sham (% patients)	RR (95% CI) RD (95% CI)	Overall QoE	Favors
Procedure-related numbness	1 RCT N = 24	38%	0%	NC 0.42 (NC)	**Low**	**Sham**

KQ3: Safety
(Cervical spine: RF versus sham neurotomy)

39

	Studies N	RFN	Sham	RR (95% CI) RD (95% CI)	Overall QoE	Favors
		% patients				
Procedure-related numbness	1 RCT N = 24	38%	0%	NC 0.42 (NC)	**Low**	**Sham**

Results: KQ4

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KQ4. Is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

- **Heterogeneity of treatment effect**
- **Subgroup of studies evaluation comparative efficacy of RFN following selection by MBB**

KQ4: HTE
(Lumbar spine: RF versus sham neurotomy)

41

	Studies N	F/U	Subgroup	RFN	Sham	Overall QoE	Outcome
				% patients who achieved "success" composite			
Sex	1 RCT N = 81	3 mos.	Male	20%	43%	**Low**	**No modification of treatment effect**
			Female	30%	21%		
Age			18-40 years	31%	**33%**		
			>41 years	26%	**28%**		
Duration of pain			2-5 years	32%	33%		
			>5 years	24%	25%		
Employment status			Employed	30%	35%		
			Unemployed	24%	24%		

KQ4: Selection by MBB (50% pain relief)
(Lumbar spine: RF versus sham neurotomy)

42

Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	3 RCTs N = 111	2-6 mos.	1-2 MBBs (≥50% or ≥80%)	21 to 42 (35 to 65%)	4 to 37 (8 to 64%)	**Low**	**RFN** (3/3 studies)
Leg pain (VAS, 1-100)	1 RCT N = 40	6 mos.	1 MBB (≥50%)	16 (37%)	1 (5%)	**Low**	**RFN**
Generalized pain (VAS, 1-100)	1 RCT N = 40	6 mos.	2 MBBs (≥80%)	19.3 (32%)	3.7 (9%)	**Low**	**RFN**

KQ4: Selection by MBB (50% pain relief)
(Lumbar spine: RF versus sham neurotomy)

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Short-term function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Function (ODI, 0-100)	2 RCTs N = 71	2-6 mos.	1 MBB (≥50%)	11 to 14	-2 to 11	Low	RFN (2/2 studies)
Function (Waddell, 0-24)	1 RCT N = 31	2 mos.	1 MBB (≥50%)	0.33	0.07	Low	neither

KQ4: Selection by MBB (50% pain relief)
(Lumbar spine: RF versus sham neurotomy)

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Long-term Pain & Function	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	41.0 ± 9.1 (63%)	29.0 ± 9.6 (43%)	Low	RFN
Function (ODI, 0-100)	1 RCT N = 40	12 mos.	1 MBB (≥50%)	11.2 ± 4.8	6.5 ± 3.9	Low	RFN

KQ4: Selection by MBB (50% pain relief)
(Cervical spine: RF versus sham neurotomy)

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Short-term Pain	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	Sham	Overall QoE	Favors
				Δ from baseline (mean (%))			
Freedom from "accustomed" pain	1 RCT N = 24	6 mos.	3 MBBs (100% with anesthetics, 0% with saline)	58% (7/12)	8% (1/12)	Insufficient	RFN

RR (95% CI): 7.00 (1.01, 48.54)
RD (95% CI): 0.50 (0.18, 0.82)

Evidence base (CoE II): Lord 1996

KQ4: Selection by MBB (50% pain relief)
(Lumbar spine: RFN versus intra-articular injections)

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Short-term	Studies N	F/U	Diagnostic block (% pain relief required for FN)	RFN	IAI	Overall QoE	Favors
				Δ from baseline (mean (%))			
Back pain (VAS, 0-100)	1 RCT N = 56	6 mos.	1 MBB (≥50%)	19 ± 15 (29%)	16 ± 13 (23%)	Low	neither
Function (ODI, 0-100)	1 RCT N = 56	6 mos.	1 MBB (≥50%)	13 ± 12 (31%)	6 ± 11 (15%)	Low	neither
Function (Roland Morris, 0-24)	1 RCT N = 56	6 mos.	1 MBB (≥50%)	4 ± 4	4 ± 4	Low	neither

Results: KQ5

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KQ5. What is the evidence of cost effectiveness of facet neurotomy compared with other treatment options?

Summary and implications

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Summary: Efficacy (KQ2): RFN versus Sham, Lumbar spine

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KQ	Outcome	Result	Overall Quality of Evidence	Evidence basis
KQ2	Short-term back pain (VAS)	**No difference** between groups (4/6 studies)	**Low**	6 RCTs N = 292 2-6 mos.
KQ2	Short-term pain (leg, generalized, GPE "success")	**Favors RFN**	**Low**	≤2 RCTs N ≤ 121 3-6 mos.
KQ2	Short-term pain (VAS back pain "success", leg pain "success", McGill pain)	**No difference** between groups	**Low**	1 RCT each N = 31 or 81 3-6 mos.
KQ2	Short-term function (ODI)	**Favors RFN** (2/3 studies)	**Low**	3 RCTs N = 141 2-6 mos.
KQ2	Short-term function (Roland-Morris, Waddell, physical activity)	**No difference** between groups	**Low**	1 RCT each N = 31-81 2-3 mos.
KQ2	Long-term pain (VAS) & function (ODI)	**Favors RFN**	**Low**	1 RCT N = 40 12 mos.

Summary: Efficacy (KQ2): RFN versus Spinal Injections, Lumbar spine

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KQ	Comparator	Outcome	Result	Overall Quality of Evidence	Evidence basis
KQ2	MBB or IAI	Short-term back pain (VAS)	**No difference** between groups	**Low**	2 RCTs N = 156 6 mos.
KQ2	MBB	Short-term back pain "success"	**Favors RFN**	**Low**	1 RCT N = 100 6 mos.
KQ2	IAI	Short-term function (ODI, Roland Morris)	**No difference** between groups	**Low**	1 RCT N = 56 6 mos.
KQ2	MBB	Long-term back pain (VAS)	**No difference** between groups	**Low**	1 RCT N = 100 12 mos.

Summary: Efficacy (KQ2): Cervical spine

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KQ	Outcome	Result	Overall Quality of Evidence	Evidence basis
RFN versus Sham				
KQ2	Short-term freedom from accustomed pain	**Favors RFN**	**Low**	1 RCT N = 24 6 mos.
RFN versus GON injection				
KQ2	Short-term headache pain (VAS)	**No difference** between groups	**Low**	1 RCT N = 30 2 mos.

Summary: Efficacy (KQ4) with MBB selection RFN versus Sham, Lumbar spine

52

Outcome	Result	Overall Quality of Evidence	Evidence basis
Subgroup of studies from KQ2: patients selected by MBB (≥50% pain relief required)			
Short-term back pain (VAS)	**Favors RFN** (3/3 studies)	**Low**	3 RCTs N = 111 2-6 mos.
Short-term pain (leg, generalized VAS)	**Favors RFN**	**Low**	1 RCT N = 40 6 mos.
Short-term function (ODI)	**Favors RFN** (2/2 studies)	**Low**	2 RCTs N = 71 2-6 mos.
Short-term function (Waddell)	**No difference** between groups	**Low**	1 RCT each N = 31 2 mos.
Long-term pain (VAS) & function (ODI)	**Favors RFN**	**Low**	1 RCT N = 40 12 mos.

Summary: Efficacy (KQ4) with MBB selection

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Outcome	Result	Overall Quality of Evidence	Evidence basis
Subgroup of studies from KQ2: patients selected by MBB (≥50% pain relief required)			
RFN versus sham, cervical spine			
Short-term freedom from accustomed pain	**Favors RFN**	**Low**	1 RCT N = 24 6 mos.
RFN versus therapeutic intra-articular injection, lumbar spine			
Short-term back pain (VAS)	**No difference** between groups	**Low**	1 RCT N = 56 6 mos.
Short-term function (ODI, Roland Morris)	**No difference** between groups	**Low**	1 RCT N = 56 6 mos.

Gaps in the evidence

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KQ	Spinal region	Gaps in evidence
KQ1b	Any	Outcomes following FN in patients selected by MBB vs. IAI blocks
KQ1	Cervical	Comparative studies evaluating outcomes following FN in patients selected by different diagnostic methods
KQ2	Cervical	FN versus IAI or MBB in the cervical spine
KQ4	Any	Differential effectiveness of neurotomy versus spinal injections in subgroups
KQ5	Any	Full economic analyses evaluating the cost-effectiveness of facet neurotomy compared with other treatment options
All	Thoracic	Comparative studies evaluating the efficacy, effectiveness, or safety of facet neurotomy


Thank you.
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Questions?

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.
- 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

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

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.

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[4] 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.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: 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.

Medicare Coverage and Guidelines

From pages 120-125 of the evidence report

Table 5. Overview of payer technology assessments and policies for facet neurotomy

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
CMS	None	None	None	• There are currently no National Coverage Decisions (NCDs) published from the Centers for Medicare and Medicaid Services (CMS).
Aetna (2013) *Clinical Policy Bulletin: Back Pain - Invasive Procedures* POLICY #: 0016 Effective Date: 07/31/1995 Last Review Date: 03/19/2013 Next Review Date: 01/09/2014	NR	NR ("Various Studies")	Non-pulsed radiofrequency facet denervation (also known as facet neurotomy, facet rhizotomy, or articular rhizolysis) is considered medically necessary for treatment of members with intractable cervical or back pain with or without sciatica in the outpatient setting when *all* of the following are met: • Member has experienced severe pain limiting activities of daily living for at least 6 months; *and* • Member has had no prior spinal fusion surgery; *and* • Neuroradiologic studies are negative or fail to confirm disc herniation; *and* • Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; *and* • Member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants); *and* • Trial of facet joint injections has been successful in relieving the pain.	• Only 1 treatment procedure per level per side is considered medically necessary in a 6-month period. *Radiofrequency Facet Denervation* • Percutaneous radiofrequency facet denervation, also known as radiofrequency facet joint rhizotomy or facet neurotomy, involves selective denervation using radiofrequency under fluoroscopic guidance • *Facet Chemodenervation/Chemical Facet Neurolysis and Laser Facet Denervation* • The use of chemical facet injections such as alcohol, phenol and hypertonic saline has been proposed as an option for lumbar facet pain. However, there is a lack of published data to support the safety and effectiveness of this technique.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			Non-pulsed radiofrequency facet denervation is considered experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established. Aetna considers *any* of the following injections or procedures experimental and investigational: • Facet chemodenervation/ chemical facet neurolysis • Laser facet denervation	
Aetna (2012) *Clinical Policy Bulletin: Pulsed Radiofrequency* POLICY #: 0735 Effective Date: 08/21/2007 Last Review Date: 12/07/2012 Next Review Date: 09/23/2013		This policy is based upon references including RCTs, systematic reviews, retrospective Cohort study, case series study	Aetna considers pulsed radiofrequency experimental and investigational for all indications, including those in the following list, because its effectiveness has not been established. • Facet joint arthropathy • Zygapophyseal joint pain.	• Radiofrequency procedures have been reported to be associated with high number of complications compared with other ablative neurosurgical techniques. Furthermore, conventional (continuous) RF treatment occasionally results in worsening and even new onset of pain. The use of pulsed radiofrequency (PRF, also known as cold RF), a non- or minimally-neurodestructive and thus less painful technique, serves as an alternative to conventional RF therapy. Pulsed radiofrequency treatment, performed under fluoroscopic guidance, entails the use of pulsed time cycle that delivers short bursts of RF energy to nervous tissue.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments

Cigna (2012)
 	
Minimally Invasive Treatment of Back and Neck Pain
 	
POLICY #: 0139
 	
Effective Date: 7/15/2012
 	
Next Review Date: 7/15/2013
	NR	This policy is based upon references including RCTs, systematic reviews, retrospective Cohort study, case series study, Meta-analysis and ASIPP practice guideline	• Cigna covers initial radiofrequency denervation of paravertebral facet joint nerves (also referred to as radiofrequency neurolysis, neurotomy, facet rhizotomy) (CPT codes 64633-64636) for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:
			
			  • Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
			  • There is severe pain unresponsive to at least six months of conservative medical management. (e.g., pharmacological therapy, physical therapy, exercise)
			  • Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in elimination or marked decrease in intensity of pain
			  • Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)
			
			• Cigna covers repeat radiofrequency denervation of paravertebral facet joint nerves at the same level for the treatment of chronic back or neck pain as medically necessary when BOTH of the following criteria are met:
			
			  • At least six months have elapsed since the previous radiofrequency ablation/neurolysis of paravertebral facet joint nerves
			  • More than 50% relief is obtained, with associated functional improvement, for at least ten weeks following the previous treatment
				• Radiofrequency denervation of facet joints has been used to treat spinal pain presumed to be of facet origin. RFA was also been explored for the treatment of SI joint pain.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			• Cigna does not cover long-term or maintenance denervation of paravertebral facet joint nerves for any indication because it is considered not medically necessary. • Cigna does not cover ANY of the following ablative procedures for the treatment of back or neck pain because each is considered experimental, investigational or unproven (this list may not be all-inclusive); • Pulsed radiofrequency (CPT code 64999) • Cryoablation/cryoneurolysis/cryodenervation (CPT code 64999) • Chemical ablation (e.g., alcohol, phenol, glycerol) (CPT codes 64622-64627) • Laser ablation (CPT code 64999) • Sacroiliac (SI) joint nerve ablation by any method (CPT code 64640)	
Health Net (2012) *Facet Joint Denervation* POLICY #: NMP43 Effective Date: 10/2003 Last Review Date: 1/2012	PRF- Updated 1/2012 PRF (facet neurolysis)- Updated 7/2009	This policy is based upon references including RCTs, systematic reviews, cohort and retrospective studies	Facet Joint Denervation (also referred to as neurolysis, lesioning, facet neurotomy, facet rhizotomy, or articular rhizolysis) by either injecting neurolytic substances (alcohol 50-100% or phenol) or utilizing radiofrequency thermoneurolysis (e.g. radiofrequency ablation, radiofrequency neurolysis, and/or radiofrequency thermoablation) or cryoneurolysis is medically necessary for treatment of patients with intractable chronic zygapophyseal cervical or lumbar joint pain with or without neurological compression symptoms when all of the following are met: • Trial of facet joint injections using local anesthetic has been successful in relieving the pain or, at least, a > 50% reduction of pain; and • Severe low back pain or cervical neck pain limiting activities of daily living has been present for at least 6 months; and	• Note - Caution is recommended for RFA treatment in patients with diabetes mellitus and in those who have undergone prior back surgery at the pain site. Scientific Rationale – Update April 2008 (2007) American Society of Interventional Pain Physicians states: • "Among the diagnostic interventions, the accuracy of facet joint nerve blocks is strong in the diagnosis of lumbar and cervical facet joint pain."

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			• No prior spinal fusion surgery in the same area of the spine that is to undergo radiofrequency treatment; and • Neuroradiologic studies are negative or fail to confirm disc herniation; and • Patient has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and • Patient has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g. anti-inflammatory agents, analgesics and muscle relaxants. <u>Relative or Absolute Contraindications to Radiofrequency Ablation</u>: • Neurologic abnormalities; • Definitive clinical and/or imaging findings; • Proven specific causes of low back pain, including herniation, spondylolisthesis, spondylosis ankylopoetica, spinal stenosis, discogenic or stenotic compression, extensive multilevel spondylosis, clinical radiculopathy, multiple sclerosis, coagulation disorders, pregnancy, malignancy, infection, and trauma; • Allergy to radiopaque contrast or local anesthetic; • More than one pain syndrome; • Lack of response to diagnostic nerve blocks; • Psychiatric disorders. <u>Pulsed Radiofrequency Ablation</u> • Health Net, Inc. considers pulsed radiofrequency ablation investigational. The available evidence on the effectiveness of pulsed radiofrequency in the treatment of patients with various chronic pain syndromes is largely based on retrospective, case series studies. Its clinical value needs to be examined in well-designed,	

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			randomized controlled trials with large sample size and long-term follow-up. Studies on pulsed radiofrequency ablation continue to be done.	

From pages 84- 92 of the evidence report

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
American Pain Society Clinical (2009) *Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain An Evidence-Based Clinical Practice Guideline From the American Pain Society.*	NR	Facet neurotomy, radiofrequency denervation	RCTs	Criteria and grading system adapted from methods developed by the US Preventative Services Task Force* **Diagnostic:** There is insufficient evidence to evaluate validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy. • No reliable data exist on the diagnostic accuracy or clinical utility of diagnostic facet joint, medial branch, or selective nerve root blocks. Correlation with imaging findings is variable and difficult to interpret in the absence of reliable reference standards for identifying "true" facet joint pain. Although positive responses are less frequent with controlled rather than uncontrolled facet joint blocks, it is not possible to determine whether this finding is due to	I I	Poor Poor

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
				fewer true- or false-positive cases. Some studies have evaluated the association between findings on invasive diagnostic tests and surgical outcomes, but no studies have investigated the effects of using facet joint, medial branch, or selective nerve root block to guide choice of therapy or how use of these tests affects subsequent patient outcomes, compared with selective therapy without using the invasive diagnostic test. **Therapeutic:** In patients with persistent nonradicular low back pain, there is insufficient evidence to adequately evaluate benefits of radiofrequency denervation. • Trials of radiofrequency denervation reported inconsistent results between small numbers of higher quality trials and (in the case of radiofrequency denervation) technical or methodologic shortcomings making it difficult to reach conclusions about benefits.		
National Institute for Health and Clinical Excellence/ National Collaborating Centre for Primary Care (2009) *Low back pain: early management of persistent non-*		Radiofrequency facet joint denervation	NR	Evidence levels are based on the guidelines manual developed by the National Institute for Health and Clinical Excellence[†] <u>Do not refer people for any of the following procedures</u> • The role of specific therapeutic interventions remains unclear: Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomized	NR	1+, 1–

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
specific low back pain Full Guideline.				controlled trials give conflicting evidence.		
American College of Occupational and Environmental Medicine (2007/2011) *Low back disorders Evaluation and management of common health problems and functional recovery in workers.*	1966 – 2010	Radiofrequency neurotomy, neurotomy, and facet rhizotomy	NR	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§] <u>Acute Low Back Pain, Subacute Low Back Pain, Radicular Pain Syndromes and Spinal Stenosis:</u> Radiofrequency neurotomy, neurotomy, and facet rhizotomy are not recommended. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence. <u>Chronic Low Back Pain:</u> Radiofrequency neurotomy, neurotomy, or facet rhizotomy for patients with chronic LBP confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment – no recommendation. The evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.	Not recommended No recommendation	C I

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
American Society of Interventional Pain Physicians (2003/2009) *Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain.*	1966 – Dec 2008	Facet or zygapophysial joint blocks, medial joint blocks, radiofrequency neurotomy	NR	Grading recommendations adapted from Guyatt et al. (2006)[††] Quality of Evidence modified from the grading system developed by the U.S. Preventive Services Task Force[**] **Diagnostic:** <u>Low Back Pain:</u> Diagnostic lumbar facet joint nerve blocks are recommended in patients suffering from somatic or non-radicular low back and lower extremity pain (avg. > 6 on scale of 0 – 10), with duration of pain of at least 3 months. <u>Neck Pain:</u> Diagnostic cervical facet joint nerve blocks are recommended in patients suffering from somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain (avg. > 6 on scale of 0 – 10) of at least 3 months. <u>Thoracic Pain:</u> Facet or zygapophysial joint blocks are recommended in patients suffering from somatic or nonradicular upper back or mid back pain (avg. > 6 on scale of 0 – 10) of at least 3 months. **Therapeutic:** Based on Guyatt et al.'s, (2006) criteria for cervical radiofrequency neurotomy and lumbar radiofrequency neurotomy, the recommendation is strong.	NR NR NR 1C	I or II-I I or II-I II-I II-1 to II-3

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
Colorado Division of Workers' Compensation (2011) *Chronic pain disorder medical treatment guidelines.*	2001 – 2010	Radiofrequency medial branch neurotomy/facet rhizotomy	NR	RF medial branch neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. This treatment is indicated for patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.	NR	NR
American College of Occupational and Environmental Medicine (2008) *Chronic pain.*	1966 – 2008	Radiofrequency neurotomy, neurotomy, or facet rhizotomy	RCTs	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§] <u>Chronic Low Back Pain:</u> There is no recommendation for radiofrequency neurotomy, neurotomy, or facet rhizotomy for cervicogenic spinal conditions. The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. Radiofrequency neurotomy, neurotomy, or facet rhizotomy for lumbar spinal conditions is not recommended. The EBPP found at least moderate evidence that harms and costs exceed benefits based on limited evidence.	No recommendation Not recommended	I C

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
American College of Occupational and Environmental Medicine (2011) *Cervical and thoracic spine disorders.*	NR	Use of radiofrequency neurotomy, neurotomy, and facet rhizotomy	NR	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§] <u>Chronic Cervicothoracic Pain:</u> There is no recommendation for the use of radiofrequency neurotomy, neurotomy, and facet rhizotomy for chronic cervicothoracic pain confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment. The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. <u>Cervicogenic Headache:</u> Radiofrequency neurotomy is moderately not recommended. Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or costs outweigh benefits.	No recommendation	I
					Not recommended	B
Institute of Health Economics (2009/2011) *Guideline for the evidence-informed primary care*	Jan 1996 – Dec 2010	Medial branch neurotomy	Systematic review (IHE) presenting consistent evidence to support the action.	Recommendation rating developed by the GDG[§§] <u>Chronic Low Back Pain:</u> Medial branch neurotomy is recommended for chronic low back pain.	Do	NR

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
management of low back pain.						
Work Loss Data Institute (2003/2008/2011) *Neck and upper back (acute & chronic).*	2003 – 2011	Facet joint radiofrequency neurotomy/facet rhizotomy	NR	Diagnostic facet blocks are recommended for patients with disorders of the neck and upper back, except those whom a surgical procedure is anticipated and in those who have had a previous fusion procedure at the planned injection level. Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.	NR NR	NR NR
Institute for Clinical Systems Improvement (ICSI) (2009/2011) *Assessment and management of chronic pain.*	Aug 2008 – Aug 2011	Percutaneous radiofrequency neurotomy	NR	Evidence grades determined by the ICSI[***] Percutaneous radiofrequency neurotomy is recommended as a commonly used Level I therapeutic procedure for patients with neck and back pain generated by facet joints.	NR	I
Work Loss Data Institute (2003/2008/2011) *Low Back-lumbar & thoracic (acute & chronic).*	NR	Facet joint radiofrequency neurotomy/facet rhizotomy	NR	Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.	NR	NR
American Society of Regional Anesthesia and Pain Medicine	1944 – 2009	Chemical denervation, Radiofrequency ablation, radiofrequency ablation	NR	Chemical denervation (e.g., alcohol, phenol, or high concentration local anesthetics) is not recommended for routine care of patients with chronic non-cancer pain.	NR	NR

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
(1997/2010) *Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine.*		(facet joint)		<u>Radiofrequency ablation:</u> Conventional (e.g., 80°C) or thermal (e.g., 67°C) radiofrequency ablation of the medial branch nerves to the facet joint is recommended for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. Conventional radiofrequency ablation may be performed for neck pain. Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain.	NR	NR

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

Safety Outcomes	Safety Evidence
Treatment related pain	
Treatment related sensibility changes	
Treatment related motor changes	
Adverse events	
Procedure related numbness	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Success (composite with pain, other measures)	
Back Pain	
Function	
Function success	
Leg pain	
Generalized pain	
Disability	
“accustomed” pain	
Headache pain	

Special Population / Considerations Outcomes	Special Population Evidence
Sex	
Age	
Duration of pain	
Employment status	
Race	
Gender	
Back pain severity	
Leg pain severity	
Generalized pain severity	
Function level	
Cost	**Cost Evidence**
Cost effectiveness	

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:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

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?

Clinical Committee Findings and Decisions

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.

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?