Peripheral nerve ablation for limb pain

Clinical Expert

Brett R. Stacey

Medical Director – University of Washington, Center for Pain Relief

Professor, Anesthesiology and Pain Medicine, UW School of Medicine
1. **Business Activities**

(a) If you or a member of your household was *an officer or director of a business* during the immediately preceding calendar year and the current year to date, provide the following:

<table>
<thead>
<tr>
<th>Title</th>
<th>Business Name &amp; Address</th>
<th>Business Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

(b) If you or a member of your household *did business under an assumed business name* during the immediately preceding calendar year or the current year to date, provide the following information:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Business Type</th>
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<tbody>
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</table>

2. **Honorarium**

If you *received an honorarium of more than $100* during the immediately preceding calendar year and the current year to date, list all such honoraria:

<table>
<thead>
<tr>
<th>Received From</th>
<th>Organization Address</th>
<th>Service Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Wisconsin</td>
<td>OCPD in Medicine &amp; Public Health, 750 Highland Ave Room 1171 HSLC, Madison, WI 53705</td>
<td>Develop and Deliver Review Course/CMD information</td>
</tr>
<tr>
<td>Teva Pharmaceuticals</td>
<td>North Wales, PA</td>
<td>Consulting for research project</td>
</tr>
<tr>
<td>Innovations Consulting</td>
<td>3119 51st Place NW, Washington DC 20016</td>
<td>Attend meeting on acute pain</td>
</tr>
</tbody>
</table>

3. **Sources of Income**

(a) Identify *income source(s) that contributed 10% or more of the combined total gross household income* received by you or a member of your household during the immediately preceding calendar year and the current year to date.

<table>
<thead>
<tr>
<th>Source Name &amp; Address</th>
<th>Received By</th>
<th>Source Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Washington/Association University Physicians</td>
<td>Me</td>
<td>Salary</td>
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</tbody>
</table>
(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☐ No

If “yes”, describe:

My UW salary relates primarily to clinical care and some of that clinical care involves patients with limb pain

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If “yes”, describe:

4. Business Shared With a Lobbyist

If you or a member of your household shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist, were employed by, or employed, a paid lobbyist during please list the following:

( Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

<table>
<thead>
<tr>
<th>Lobbyist Name</th>
<th>Business Name</th>
<th>Type Business Shared</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Provide the information requested in items 5, 6, and 7 below only if:

(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.

(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (not amounts) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

<table>
<thead>
<tr>
<th>Income Source</th>
<th>Address</th>
<th>Description of Income Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Dept Justice</td>
<td>1000 SW 3rd Ave, Suite 600 Portland, OR 97204</td>
<td>Consulting work, legal case</td>
</tr>
<tr>
<td>MCE Conferences</td>
<td>7220 Trade St. #201, San Diego, CA 92121</td>
<td>Preparing, delivering CME content</td>
</tr>
<tr>
<td>Kineta</td>
<td>307 Westlake Ave. N, Seattle, WA 98109</td>
<td>Consulting innovative pharmaceuticals</td>
</tr>
<tr>
<td>Consulting Medical Associates</td>
<td>360 3rd St, Suite 425, San Francisco, CA 94107</td>
<td>Medical records/opinion review</td>
</tr>
<tr>
<td>Australian Victorian Govt</td>
<td>PO Box 4356 Melbourne, VIC 3001 AU</td>
<td>Consulting on Australian Medical Board Case</td>
</tr>
</tbody>
</table>
6. **Business Investments of More Than $1,000**

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Description of Business</th>
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7. **Service Fee of More Than $1,000**

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each *person for whom you performed a service for a fee of more than $1,000* in the immediate preceding calendar year or the current year to date.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description of Service</th>
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I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name  Brett R Stacey

Check One:  ☐ Committee Member  ☐ Subgroup Member  ☐ Contractor

Signature  Date  12/6/2018
UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE
CURRICULUM VITAE

Brett R. Stacey, M.D.

Personal Data:
Place of birth: Oklahoma City, OK
Date of birth: 09/29/1959
Citizenship: US

Education:
1982-1986 University of Michigan School of Medicine, Ann Arbor, Michigan M.D.

Postgraduate Training:
1986-1987 Henry Ford Hospital, Detroit, Michigan Internship
1987-1990 University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania Residency Anesthesiology
1989-1990 Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania CA-3 year Pain Management

Faculty Positions Held:
1990-1996 Assistant Professor, Anesthesiology/Critical Care Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania
1996-1998 Assistant Professor, Anesthesiology & Perioperative Medicine, Oregon Health & Science University, Portland, Oregon
1998-2009 Associate Professor, Anesthesiology & Perioperative Medicine, Oregon Health & Science University, Portland, Oregon
2009-2014 Professor, Anesthesiology & Perioperative Medicine, Oregon Health & Science University, Portland, Oregon
2014- Professor, Anesthesiology & Pain Medicine, University of Washington, Seattle, Washington

Administrative Positions Held:
1990-1996 Staff Anesthesiologist, Presbyterian University Hospital, Pittsburgh, Pennsylvania
1991-1992 Acting Medical Director, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
1992-1996 Medical Director, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
1993-1996 Director, Accreditation Council for Graduation Medical Education (ACGME) Approved Pain Fellowship, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
1996-1998 Director, Pain Fellowship, Oregon Health & Science University, Portland, Oregon
1996-2014 Medical Director, Comprehensive Pain Center (formerly Pain Management Center), Oregon Health & Science University, Portland, Oregon
2003-2014 Division Chief, Pain Medicine, Oregon Health & Science University, Portland, Oregon
2012-2014 Program Director, ACGME Accredited Fellowship, Oregon Health & Science University, Portland, Oregon
2014- Medical Director, UW Center for Pain Relief, Seattle, Washington

Honors:
1977 National Merit Finalist
1979 Alpha Lambda Delta, Freshman Honor Society
1979-1982 Dean’s List
1982 Graduated Magna Cum Laude from The Colorado College
1982 Phi Gamma Nu, Social Science Honor Society
1982 Phi Beta Kappa
2010 Top Doctor, Pain Medicine, Portland Monthly Magazine
2013 Top Doctor, Pain Medicine, Portland Monthly Magazine
2017 Top Doctor, Pain Medicine, Seattle Met Magazine

Certifications:
1987 National Board of Medical Examiners
1986, 2013 Advanced Cardiac Life Support
1990, 1994 Advanced Trauma Life Support
1991 American Board of Anesthesiology (ABA), Certificate #19846
1993, -- 2023 Certification in Pain Medicine (formerly Certificate of Added Qualifications in Pain Management)
1995 Diplomate – American Board of Pain Medicine

License to Practice:
1987 Pennsylvania, inactive
1996 Oregon, inactive
2014 Washington, active

Professional Societies:
International Anesthesia Research Society
American Society of Regional Anesthesia
American Pain Society
International Association for the Study of Pain
International Spinal Injection Society
American Academy of Pain Medicine
Association of University Anesthesiologists

Editorial Boards:
2007 The Pain Clinic
2018- Clinical Journal of Pain, Associate Editor
Ad Hoc Editorial Review Activities:

1998  Anesthesia and Analgesia
2002  European Journal of Pain
2003-2004  Clinical Journal of Pain
2004  Diabetic Medicine
2004  Pain Medicine
2005  Oregon DUR Board Newsletter, Annual Review
2005  The Journal of Diabetes and Its Complications
2007  IASP Press
2008  Clinical Journal of Pain
2011  Drug Effectiveness Review Project (DERP), OHSU

Committees:

International/National
2000-2003  Member, Board of Directors of the American Board of Pain Medicine
2005-2008  International Association for the Study of Pain Neuropathic Pain Special Interest Group, Clinical Guidelines Committee
2016-2017  Nominating Committee Member, American Pain Society

Regional
2000-2004  Advisory Committee for the Oregon Center for Complementary and Alternative Medicine Research in Craniofacial Disorders (OCCAM), NCCAM supported research center

Institutional
1996  Committee Member, Medical Ethics Committee, University of Pittsburgh Medical Center
2000-2002  Member, OHSU Pain Initiative Committee
2003-2006  Member, Spine Center Advisory Board, Oregon Health & Science University
2005  Member, Safe Pain Management in the Post-operative Period, Oregon Health & Science University ad hoc committee
2006  Member, Post-operative Nausea and Vomiting (PONV) Summit, Oregon Health & Science University ad hoc committee
2008-2014  Oregon Brain Institute, Clinical Leadership Committee
2015-present  EpicCare Operations Committee (EOC)

Departmental
1990-1996  Faculty Advisor, University of Pittsburgh Medical Center
1991-1996  Clinical Coordinator, Clinical Coordinators Committee, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center
1991-1996  Executive Committee, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center
1991-1996  Committee Member, Quality Assurance Committee, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center
1992  Tutor for Special Needs Housestaff, Department of Anesthesiology, University of Pittsburgh Medical Center
1993-1996  Committee Member, Anesthesia Chief's Committee, University of Pittsburgh Medical Center
1993-1996  Committee Member, Executive Committee, Department of Anesthesiology, University of Pittsburgh Medical Center
1994-1996  Committee Member, Promotions and Reappointment, Department of Anesthesiology, University of Pittsburgh Medical Center
1997-1998  Member, University Anesthesiologists, PC Board, Department of Anesthesiology, Oregon Health Sciences University
1999  Vice-President, University Anesthesiologists, PC Board, Department of Anesthesiology, Oregon Health Sciences University
1999  Board Member, Research and Education Society, Department of Anesthesiology, Oregon Health Sciences University
1997-2007  Member, Resident Evaluation and Clinical Competence Committee, Department of Anesthesiology, Oregon Health & Science University
2000-2002  Member, Excellence in Epidural Analgesia task force, Oregon Health & Science University
2001  Member, Equipment and Technology Committee, Department of Anesthesiology, Oregon Health & Science University
2003-2007  Member, Executive Committee, Department of Anesthesiology, Oregon Health & Science University
2002-2014  Member, Promotions and Tenure Committee, Department of Anesthesiology, Oregon Health & Science University

Research Funding:

Federal


Other Support

Double-Blind, Randomized, Placebo-Controlled, Parallel Groups, Multi-Center Trial to Determine the Efficacy and Safety of Neurontin (gabapentin) in Subjects with Peripheral Neuropathy (post-herpetic neuralgia). J.D. Sinclair, M.D., Principal Investigator; BR Stacey, M.D., Co-Principal Investigator; SC Levin, M.D., Co-Investigator. Parke-Davis, $54,000, 1996–1997.

Double-Blind, Randomized, Placebo-Controlled, Parallel Groups, Multi-Center Trial to Determine the Efficacy and Safety of Neurontin (gabapentin) in Subjects with Peripheral Neuropathy (post-herpetic neuralgia). BR Stacey, M.D., Principal Investigator; V Fiks, M.D., Co-Investigator. Parke-Davis, $54,000, 1997.

Double-Blind, Placebo-Controlled Trial of Pregabalin for Treatment of Painful Diabetic Peripheral Neuropathy. BR Stacey, M.D. and D Sibell, M.D., Co-Investigators; J Laidler, M.D., C Roberts, M.D., and J Robertson, M.D., Sub-Investigators. Parke-Davis, $120,000, 1998.


Multicenter, Double-Blind, Randomized, Placebo-Control, Parallel-Group Study to Evaluate the Safety and Efficacy of Trileptal in Patients with Neuropathic Pain due to Radiculopathy. DM Sibell, M.D., Principal Investigator; BR Stacey M.D., Co-Investigator. Novartis, Inc. September 2001.

A 15-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Study of Neurontin (gabapentin) for Efficacy and Quality of Life in Patients with Painful Diabetic Peripheral Neuropathy (Protocol A945-1008). BR Stacey M.D., Principal Investigator. Pfizer, Inc. April 2002.


Validation of a Neuropathic Pain Screening Tool (NPST) (Protocol NRA9450010). BR Stacey, M.D., Principal investigator. Pfizer, Inc. $18,000, February 2004.

A Double-Blind Randomized Placebo-Controlled Trial of the Time to Onset of Meaningful Pain Relief in Subjects with Postherpetic Neuralgia (PHN) Treated with Pregabalin (150-600 mg/day) Flexible Optimized Dose or (300 mg/day) Fixed Dose or Placebo (Protocol A0081004-1024). BR Stacey, M.D., Principal Investigator. Pfizer, Inc. November 2004.


CREATE-1 Study: A Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of AXS-02 (Disodium Zoledronate Tetrahydrate) Administered Orally to Subjects with Complex Regional Pain Syndrome Type I (Protocol AXS02-301). BR Stacey, M.D., Principal Investigator, Axsome Therapeutics, Inc. $88,517, 8/30/16-6/30/2018.


A Phase 2, Randomized, Double-blind, Placebo-Controlled, 6-Week, Parallel-design Study of the Efficacy and Safety of VX-150 in Treating Subjects With Pain Caused by Small Fiber Neuropathy (Protocol: VX16-150-102). BR Stacey, M.D., Principal Investigator, Vertex Pharmaceuticals, Inc. $126,911, 11/7/17-present
BIBLIOGRAPHY

Manuscripts in Refereed Journals:


32. Darnall BD, Stacey BR. Sex Differences in Long Term Opioid Use: Cautionary Notes for Prescribing in Women. Archives of Internal Medicine, 2012;172(5):431-432.


Book Chapters:


**Reviews:**


**Other Publications:**


13. Dworkin R; O'Connor AB; Kent J; Mackey SC; Raja SN; **Stacey BR;** Levy RM; Backonja MM; Baron R; Harke H; Loeser JD; Treede R-D; Turk DC; Wells CD. Interventional management of neuropathic pain: where we are and what we need to do (letter), Pain. 2014 May;155(5):1045-6

Abstracts:

1. Stacey BR, Brody MC, Burke DF. Patients with a substance abuse history can effectively use PCA. Anesthesiology. 1990;72:A760.


24. Stacey BR. Gabapentin improves both pain and health status in post-herpetic neuralgia (PHN): a pooled analysis of three clinical trials. Poster presented at the 22nd Annual Scientific Meeting of the American Pain Society; 2003 Mar 20-23; Chicago IL.
27. Dworkin, R, Stacey B, Martin S, Young J, LaMoreaux L, Sharma U. Pregabalin improves health-related quality of life in patients with postherpetic neuralgia as evaluated in three randomized trials. Abstract presented at the 2nd Joint Scientific Meeting of the American Pain Society and Canadian Pain Society; 2004 May 6-9; Vancouver, BC.
31. Stacey BR. Treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN) in treatment-refractory patients: findings from a long-term open-label trial of Pregabalin. Poster presented at the 8th International Conference on the Mechanisms and Treatment of Neuropathic Pain; 2005 Nov 3-5; San Francisco, CA.

International and National Invitational Lectures:
47. “Assessing opioid use and opioid outcomes (e.g., dosage, time to event, duration of use).” IMMPACT XXI, Washington, DC, July 26, 2018.

Regional and Local Invitational Lectures:

10. “Chronic Pain,” Presbyterian Hospital Aid Society, Presbyterian University Hospital, Pittsburgh, PA, April 1995.
11. “Pharmacologic Management of Chronic Pain,” Medical Rounds, St. Margaret Memorial Hospital, Pittsburgh, PA, October 1995.
12. “Regional Anesthesia and Acute Pain Management,” Rockford Memorial Hospital, Rockford, IL, May 1996.
41. “Neuropathic Pain: Overview and Treatment Options,” Hilo Medical Center CME, Hilo, HI, April 29, 2006.
42. “Post-operative Pain Management,” St. Charles Medical Center, Bend, OR, June 2, 2006.
43. “Update on Neuropathic Treatment Options,” CME lecture at Veterans Administration Hospital, Vancouver, WA, December 5, 2006.
47. “Neuropathic Pain,” Western Pain Society Annual Conference, Portland, OR, April, 2008.
52. “Opioids, Diversion, and Chronic Pain” Community Action To Reduce Substance Abuse quarterly meeting, Portland, OR, January 5, 2011.
55. Debate: “Spinal Injections are Worthwhile—Pro” 2011 Annual Musculoskeletal Update for Primary Care: Urgencies & Emergencies in Musculoskeletal Medicine; Sunriver, OR, March 26, 2011.
58. “Chronic Pain, Neuropathic Pain and Yoga” Yoga of Awareness for Chronic Pain Teacher Training Course, OHSU, June 6, 2011.
60. “Multidisciplinary Management of Chronic Pain” Clinical Neuroscience at the Oregon Coast, OHSU Brain Institute, Gleneden Beach, OR, September 23, 2011.
64. “What is Chronic Pain? What to do about it?” VA Medical Center, Portland OR, NW Pain Lecture Series, April 26, 2012.
71. “Chronic Pain and Opioids” Columbia Memorial Medical Center Grand Rounds, Astoria, OR, November 12, 2013.
TEACHING

Overview of my Role as an Educator:
At the University of Pittsburgh: I served as the Director of Pain Education for the Department of Anesthesiology. I established the curriculum, educational materials, and documentation to have the pain fellowship become certified by the Accreditation Council for Graduation Medical Education (ACGME). I was responsible for all aspects of resident and fellow education in pain for a very large department. We educated 4-5 fellows/year. I initiated institution wide standards for postoperative pain care and published a guideline for use by all trainees at the University of Pittsburgh Medical Center in managing pain and Patient Controlled Analgesia (PCA). I organized an all-day course on pain management for 4th year medical students.

At Oregon Health & Science University: Upon my arrival in 1996 I became fellowship director and in charge of resident pain education during their mandated pain rotation. Within my first month of arrival, I prepared for an ACGME site visit and recertification. During my time as fellowship director I increased the size of the fellowship (expanded from 1 to 2 fellows) and formalized the curriculum, lecture schedules, and evaluation process. In 2012, I resumed my role as fellowship director. I regularly participate in all levels of education in pain medicine: fellow, resident, medical student. Every lecture is not listed here.

SCHOLARSHIP OF TEACHING
Curriculum Development:

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991-1996</td>
<td>Established ACGME-accredited pain fellowship with first-time written curriculum, University of Pittsburgh Medical Center</td>
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<tr>
<td>1996-1998</td>
<td>Revamped curriculum for ACGME-accredited pain fellowship</td>
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<td></td>
</tr>
<tr>
<td>2002-2005</td>
<td>Member, Complementary and Alternative Medicine (CAM) Science Curriculum Task Force, Oregon Health &amp; Science University</td>
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<tr>
<td>2003-2005</td>
<td>Third Year Students' Continuity Curriculum Task Force, Oregon Health &amp; Science University</td>
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</tbody>
</table>

Educational Publications:

Educational Conference Presentations:
“Pharmacologic Management of Pain,” Organized all-day 4th year medical student course, University of Pittsburgh Medical Center, April 1996.
“Chronic Pain”, Course Director, Sitka Community Hospital, Sitka, AK, July 29th, 2016.

EDUCATIONAL ACTIVITIES
Medical Student Education:
“Local Anesthetics and Regional Anesthesia,” University of Pittsburgh medical students, 1989.
“Clinical Skills,” 2nd year medical student lecture, University of Pittsburgh Medical Center, April 1994.
“Pain Management,” anesthesia lecture to medical students, Oregon Health Sciences University, November 1996.
“Opioids and Acute Pain,” medical student lecture, Department of Anesthesiology and Peri-Operative Medicine, Oregon Health & Science University, January 2004.
“Neuropathic Pain,” Pain Elective, medical student lecture, Oregon Health & Science University, April 2004.
Principles of Clinical Medicine, preceptor to medical students, Oregon Health & Science University: 1998-99 spring & fall, 1999-00 fall, winter & spring (2 students in the spring), 2000-01 fall, winter & spring, 2001-02 fall, winter & spring, 2002-03 fall, winter & spring, 2003-04 fall & winter, 2004-05 winter, 2005-06 winter and spring, 2006-07 fall, winter, & spring, 2007-08 fall and spring, 2008-09 fall, winter, & spring, 2009-2010 winter term and spring term, 2010-11 fall, winter, and spring, 2013-2014 fall and winter.
“Neuropathic Pain with a focus on Painful Diabetic Neuropathy and Post Herpetic Neuralgia,” Physiology and Pharmacology of Pain course for 2nd year medical students, Oregon Health & Science University, March 31, 2003.
“Neuropathic Pain: Postherpetic Neuralgia and Post-Stroke Pain,” lecture and discussion for Physiology and Pharmacology of Pain course, 1st and 2nd year medical students, Oregon Health & Science University, March 13, 2008.
“Neuropathic Pain” lecture and discussion. PHPH 614: Neurophysiology and Pharmacology of Pain, Oregon Health & Science University, May 28, 2009.
“Opioids” Analgesic Drugs Small Group Discussion, OHSU 1st yr medical students, OHSU, January 11, 2011

House Staff Education:

“Anesthesia for TURP,” CA-2 Resident Lecture Series, University of Pittsburgh Medical Center, April 1989.
CA-3 Resident Conferences; CA-3 Mock Oral Exam Conferences, University of Pittsburgh Medical Center, January 1992.
“Regional Anesthesia,” CA-1 residents – 20 day program, University of Pittsburgh Medical Center, July 1992.
“Regional Anesthesia Workshops I,” lecture/demonstration to CA-1 residents, University of Pittsburgh Medical Center, May 1993.
“Regional Anesthesia Workshops II,” lecture/demonstration to CA-1 residents, University of Pittsburgh Medical Center, May 1993.
“Principles of Interdisciplinary Pain Management,” Fellowship Didactic Series, University of Pittsburgh Medical Center, August 1993
“Principles of Pain Management,” lecture to Internal Medicine Residents, University of Pittsburgh Medical Center, April 1994.
“Regional Anesthesia Workshop–Upper Extremity,” lecture/demonstration to CA-1 residents, University of Pittsburgh Medical Center, May 1994.
“Regional Anesthesia Workshop–Lower Extremity,” lecture/demonstration to CA-1 residents, University of Pittsburgh Medical Center, May 1994.
“Pain Anatomy and Physiology,” Fellowship Didactic Series, University of Pittsburgh Medical Center, July 1996.
“Neuraxial Blocks,” lecture to CA-1 residents, Oregon Health Sciences University, November 1996.
“Acute Pain Management,” Residents’ Case Conference, Oregon Health Sciences University, November 1996.
“Hypoxemia,” lecture to Anesthesiology Residents, Oregon Health Sciences University, April 1997.
“Chronic Pain Syndromes,” lecture to CA-2 residents, Oregon Health Sciences University, November 1999.
“Spinal and Epidural Anesthesia,” lecture to CA-1 residents, Oregon Health Sciences University, February 2000.
“Chronic Pain Procedures,” lecture to CA-2 residents, Oregon Health Sciences University, September 13, 2000.
“Chronic Pain Management,” lecture to CA-2 residents, Oregon Health & Science University, September 12 & 19, 2001.
"PCA orders, IV vs. PO, Epidurals," orientation lecture for incoming residents and fellows, Oregon Health & Science University School of Medicine, Graduate Medical Education, June 24, June 30, and July 14, 2004.
"Fibromyalgia & other Mysteries," Fellowship Didactic Lecture, June 12, 2006.
"Optimizing Chronic Pain Medications," Fellowship Didactic Lecture, October 27, 2008.
“Central Sensitization and specific pain syndromes,” Fellowship Didactic Lecture, 2/7/11.
“Chronic Pain and Opioids,” Fellowship Didactic Lecture, 7/28/2011
“Neuropathic Pain Overview,” Fellowship Didactic Lecture, 9/19/2011
“CRPS, Fellowship Didactic Lecture,” 10/17/2011
“Trigeminal Neuralgia and Facial Pain,” Fellowship Didactic Lecture, 4/2/2012
“Acute Pain,” CA-1 lecture June 18, 2012
“Pain Modalities” OHSU Orthopaedic educational lecture series, 4/13/2012.
“Acute Pain: Role of the Anesthesiologist,” CA-1 lecture, 6/18/2012.
“Neuropathic Pain,” OHSU Pain Fellowship Didactic Lecture, 8/6/2012.
“Painful Diabetic Peripheral Neuropathy” OHSU Pain Fellowship Didactic Lecture, 1/7/2013.
“Pain Research Issues” OHSU Pain Fellowship Didactic Lecture, May 13, 2013
 “Neuropathic Pain,” University of Washington Medical Center, Anesthesiology and Pain Medicine, 7/10/15, 8/6/15, 10/16/15, 11/6/15, 2/4/16, 4/1/16, 4/19/16, 7/22/16, 8/4/16
Journal Club, University of Washington Medical Center, Anesthesiology and Pain Medicine, 8/25/16, 11/10/16

**Nurse Anesthetist/Nursing Education:**

“Regional Anesthesia and Pain,” senior nurse anesthesia students, University of Pittsburgh Medical Center, December 1992, November 1993.
“Regional Anesthesia,” senior nurse anesthesia students, University of Pittsburgh Medical Center, November 1994.
“Acute Pain Management,” nurse practitioner students, Oregon Health Sciences University School of Nursing, May 2000.
“An Overview of Pain Management,” clinical specialists graduate students, Oregon Health & Science University School of Nursing, October 12, 2000.
“Chronic Pain, Opioids, and Acute Pain” 9k Education day, Oregon Health & Science University, April 2, 1013

**Undergraduate Teaching:**

Preceptor to pre-med student, Health Careers Opportunity Program (HCOP), Summer and Fall 2005.

**OTHER TEACHING ACTIVITIES**

**Departmental Lectures:**

“Complications of Regional Anesthesia,” monthly morning lecture, Presbyterian University Hospital, October 1989.


"Peripheral Opioids," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, February 1993.


"Acute Pain Management," Magee Women's Hospital – Anesthesia Department, November 1993.


"Succinylcholine in Children," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, November 1994.

"Acute Pain - Case Presentation," Anesthesia Grand Rounds (Guest Moderator), University of Pittsburgh Medical Center, February 1995.

"Peripheral Opioid Analgesia," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, September 1995.


"Pharmacologic Management of Chronic Pain," Department of Anesthesiology, January 1996.

"Thoracic Epidural Analgesia," Eye and Ear Anesthesia, University of Pittsburgh Medical Center, Inservice, January 1996.

"Complications of Post-Operative Epidural Management," Presbyterian University Hospital Anesthesia Department, May 1996.

"The New Oregon Health & Science University Pain Management Center," Department of Anesthesiology, Oregon Health Sciences University, 50th Anniversary Seminars, June 1998.

"Low Molecular Weight Heparin and Neuraxial Anesthesia," Anesthesia Case Conference, Oregon Health Sciences University, February 1998.

"Post-Op Pain Management," Post-Anesthesia Care Unit Staff, Oregon Health Sciences University, January 2000.


"Epidural Quality Improvement," Department of Anesthesiology Morbidity & Mortality Case Conference, Oregon Health & Science University, February 4, 2002.

Moderator, Department of Anesthesiology Morbidity and Mortality Conference, Oregon Health & Science University April 1, 2002.

"Epidural Steroid Complications," Moderator, Department of Anesthesiology Morbidity and Mortality Conference, Oregon Health & Science University, April 1, 2002.

"Medication Errors," Moderator, Department of Anesthesiology Morbidity and Mortality Conference, Oregon Health & Science University, July 29, 2002.

"Intrathecal Catheter Disruption" and “Dermatomal Tidbits,” presenter and moderator, Department of Anesthesiology Morbidity and Mortality Conference, Oregon Health & Science University, December 2, 2002.

"Functional Neuroimaging Applied to Pain and Anesthesia," Moderator of presentation by visitor Dr. Sean Mackey, Department of Anesthesiology Morbidity and Mortality Conference, Oregon Health & Science University, April 26, 2003.


What’s New in Pain Management?,” lecture at Oregon Health & Science University Anesthesia Alumni Reunion CME program, Department of Anesthesiology and Peri-Operative Medicine, June 25, 2005.

"Extracting Meaning from Clinical Trials," Clinical Research-in-Progress Roundtable, Oregon Health & Science University Department of Anesthesiology and Peri-Operative Medicine, October 18, 2005.


"Neuropathic Pain,” Grand Rounds, Department of Anesthesiology, Oregon Health & Science University, March 31, 2008.

"Knotted Infraclavicular Catheter,” Morbidity and Mortality Conference, Department of Anesthesiology, OHSU, August 4, 2008.

"Postamputation Pain,” APOM Grand Rounds, speaker and moderator, January 10, 2011.
“Chronic Neuropathic Pain and Spinal Cord Stimulation” University of Washington, Department of Anesthesiology and Pain Medicine, Grand Rounds, Seattle, WA, June 3, 2015.

"Invasive Pain Management: 2 hours to review my specialty," speaker, CA1 resident lecture. University of Washington, Department of Anesthesiology and Pain Medicine, Seattle, WA, October 17, 2018.

**Institutional Extradepartmental Lectures:**


“Chronic Pain and the Pain Institute,” University of Pittsburgh Medical Center Social Work Department, February 1993.


“Chronic Pain Research at the Pain Institute: Interdisciplinary Approaches”; Research Minisymposium; Montefiore University Hospital, Pittsburgh, PA, May 1995.


“Anesthesia & Analgesia and Surgical Outcome,” Department of Surgery Grand Rounds, Oregon Health Sciences University, April 1997.


“Pharmacologic Management of Neuropathic Pain,” Videotape Series, Oregon Health Sciences University, Donald Girard, M.D., Moderator, October 1998.


“Managing Chronic Pain,” Department of Family Medicine, Oregon Health Sciences University, February 2000.

“Chronic Pain and When to Refer to a Pain Specialist,” Gastroenterology Grand Rounds, Oregon Health Sciences University, 12 September 2000.

“Current Options for Pain Management,” Orthopedics Department, Oregon Health Sciences University, Portland, Oregon, October 3, 2000.


“Epidural Analgesia: Myths and Realities,” Department of Surgery Grand Rounds, Oregon Health & Science University, February 4, 2002.

“New/alternative pharmacologic agents for inpatient acute pain management,” lecture to inpatient nurse practitioners, Oregon Health & Science University, October 16, 2002.

“Pain Control and Palliative Care,” Hematology/Oncology Friday Conference, Oregon Health & Science University, November 8, 2002.


“Neuropathic Pain,” lecture for Pain Awareness Week, Oregon Health & Science University, February 6, 2003.


“Pain Treatment Update,” Internal Medicine faculty, Oregon Health & Science University, October 2007.

“Pain Management,” Department of Psychiatry “Expert Hour” lecture, Oregon Health & Science University, February 26, 2008.

“Preventing Chronic Postop Pain and CRPS Update,” Hand Conference, Plastic Surgery, Oregon Health & Science University, December 12, 2008; April 29, 2010.


Community Service Presentations:

“Pain Overview”  OHSU Housestaff Orientation June 18, 2013.
“State of Pain” Department of Anesthesiology and Pain Medicine, University of Washington, May 19, 2015.

“Community Service Presentations:

“What you can do about chronic pain,” Montefiore Hospital Senior Citizens Center, November, 1990
“Interstitial cystitis pain management,” Pittsburgh IC support Group November, 1990
“Our Healthy Community – Chronic Pain,” WCXJ Radio, Pittsburgh, February 1995
“Fibromyalgia and chronic fatigue syndrome,” Montefiore Public Lecture, Pittsburgh, May, 1995
“Chronic pain management”  UPMC, Pittsburgh, June, 1995
“UW doctors pioneering advanced opioid-free pain treatments,” KIRO Radio, Seattle, WA, November 2016
Peripheral Nerve Ablation (PNA) for the Treatment of Chronic Limb Pain

Gary Franklin, MD, MPH
Medical Director, Department of Labor and Industries
Research Professor, University of Washington
Co-chair, WA Agency Medical Director’s Group
January 18, 2019

Background

- Chemical, surgical, low temperature, thermal ablation techniques
- Theory: destroy sensory nerves that may be transmitting pain signals
- Types of technology reviewed in this report:
  - Pulsed radiofrequency ablation (pulsed RFA)
  - Continuous current (or conventional) RFA
  - Cooled RFA
  - Cryoablation
- How well defined is the nerve anatomy?
  - Franco et al Reg Anesth Pain Med 2015; 40: 363-8
  - Six nerves innervate the anterior knee capsule with variable proximal trajectories
  - Lack of consensus on number and origin of nerves to knee
The four ablation technologies are different

<table>
<thead>
<tr>
<th></th>
<th>Conventional RFA (cRFA)</th>
<th>Pulsed RFA</th>
<th>Cooled RFA</th>
<th>Cryoablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical design</td>
<td>Continuous high-freq AC</td>
<td>Short and high-voltage bursts with long pulses</td>
<td>Water running through the probe tip, which keeps the tip cool.</td>
<td>Nitrous oxide is used as the cryogen to create temperatures as cold as -88°C at the end of tip.</td>
</tr>
<tr>
<td>Probe temperature</td>
<td>60°C - 90°C</td>
<td>42°C</td>
<td>60°C</td>
<td>-88°C</td>
</tr>
<tr>
<td>Proposed mechanism of action</td>
<td>Thermal coagulation</td>
<td>Unclear. Transient endoneurial edema was observed</td>
<td>Thermal coagulation with a greater local lesion</td>
<td>Axonotmesis – The axons and their myelin sheath are damaged, but the endoneurium, perineurium and epineurium remain intact – a reversible damage.</td>
</tr>
</tbody>
</table>

Background

- Limited number of published studies - 13 RCTs included Re effectiveness; 8 observational studies included Re safety
- RCTs: 7 knee pain; 4 shoulder pain; 2 plantar fasciitis
- No cost-benefit studies
- Very low quality evidence, largely funded by device manufacturers
- FDA marketing approval only achieved via 510K equivalence with pre-1976 devices
- All payers consider this treatment investigational
Agency medical director concern level

- Safety = High
- Efficacy = High
- Cost = Medium-High

Current State Agency Policy

PEBB – Covered, but no explicit policy

HCA Medicaid – Covered, but no explicit policy

Labor and Industries – Covered, but no explicit policy

Note: none of the agencies covers cryoablation.
### Utilization – public employee benefit board (PEBB)

#### PEBB/UMP

<table>
<thead>
<tr>
<th>Year</th>
<th>Unique Patients</th>
<th>Procedures</th>
<th>Average Procedures/ Patient</th>
<th>Average Paid/ Ablation</th>
<th>Total Paid All Services Ablations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>23</td>
<td>39</td>
<td>1.7</td>
<td>$292</td>
<td>$30,801</td>
</tr>
<tr>
<td>2016</td>
<td>21</td>
<td>32</td>
<td>1.5</td>
<td>$288</td>
<td>$24,582</td>
</tr>
<tr>
<td>2017</td>
<td>27</td>
<td>29</td>
<td>1.0</td>
<td>$361</td>
<td>$29,769</td>
</tr>
</tbody>
</table>

71 unique patients over three years

#### PEBB Medicare

<table>
<thead>
<tr>
<th>Year</th>
<th>Unique Patients</th>
<th>Procedures</th>
<th>Average Procedures/ Patient</th>
<th>Average Paid/ Ablation</th>
<th>Total Paid All Services Ablations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>21</td>
<td>26</td>
<td>1.2</td>
<td>$107</td>
<td>$3,778</td>
</tr>
<tr>
<td>2016</td>
<td>39</td>
<td>50</td>
<td>1.3</td>
<td>$105</td>
<td>$7,654</td>
</tr>
<tr>
<td>2017</td>
<td>34</td>
<td>48</td>
<td>1.4</td>
<td>$80</td>
<td>$6,293</td>
</tr>
</tbody>
</table>

94 unique patients over three years. *PEBB pays secondary to Medicare*

### Utilization - Medicaid

#### Medicaid: MCO and FFS

<table>
<thead>
<tr>
<th>Year</th>
<th>Unique Patients</th>
<th>Procedures</th>
<th>Average procedures/patient</th>
<th>Average paid ablation</th>
<th>Total paid all services ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>30</td>
<td>43</td>
<td>1.4</td>
<td>$81</td>
<td>$20,629</td>
</tr>
<tr>
<td>2016</td>
<td>27</td>
<td>42</td>
<td>1.5</td>
<td>$155</td>
<td>$32,569</td>
</tr>
<tr>
<td>2017</td>
<td>28</td>
<td>40</td>
<td>1.4</td>
<td>$120</td>
<td>$22,515</td>
</tr>
</tbody>
</table>

*MCO and FFS patients are not mutually exclusive over the three year period. Dual eligibility claims were excluded. 85 unique patients over three years.*
Utilization - L&I

<table>
<thead>
<tr>
<th>Year</th>
<th>Unique patients</th>
<th>Procedures</th>
<th>Average procedures/patient</th>
<th>Average paid ablation</th>
<th>Total paid all service ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-2017</td>
<td>19</td>
<td>74</td>
<td>3.9</td>
<td>$743</td>
<td>$98,255</td>
</tr>
</tbody>
</table>

19 unique patients over three years. Utilization displayed in aggregate due to small numbers.

Key questions

- What is the evidence of efficacy and effectiveness for PNA for limb pain compared to other active interventions, placebos, sham procedures, or no treatment?
- What direct harms are associated with PNA for limb pain?
- Do important patient efficacy/effectiveness outcomes or direct harms from PNA for limb pain vary by:
  - Indication,
  - Patient characteristics
- What are the cost-effectiveness and other economic outcomes of PNA for limb pain?
Effectiveness

- Grade generally moderate to high risk of bias
  - Small study sample sizes
  - Short follow-up
  - Large or differential loss to f/u
  - No RCT had adequate description of allocation concealment
  - Insufficient detail about co-interventions

- Plus
  - Statistical uncertainty b/c no adjustment for multiple testing
  - No control for confounders

The strength of evidence (SOE) is very low for RFA used for plantar fasciitis

- Only one very small study for each technology (conventional and pulsed RFA)

<table>
<thead>
<tr>
<th>Study/Year/n</th>
<th>Technology</th>
<th>Comparator</th>
<th>Outcome</th>
<th>Results</th>
<th>N and k</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landsman/2013</td>
<td>Conventional RF</td>
<td>Sham</td>
<td>Pain at 4 wk</td>
<td>statistically significant improvement</td>
<td>N=17</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NA</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wu/2017</td>
<td>Pulsed RF</td>
<td>Sham</td>
<td>Pain at 12 wk</td>
<td>statistically significant improvement</td>
<td>N=36</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Function/pain (AOFAS) at 12 wk</td>
<td>statistically significant improvement</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### The strength of evidence (SOE) is very low for all three technologies used for chronic knee pain

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Technology</th>
<th>Comparator</th>
<th>N and k</th>
<th>SOE</th>
</tr>
</thead>
</table>
| Choi /2011  
/ n=35       | Conventional RF | Sham       | N=220   | Very low |
| Li-Houck /2018 
/ n=60       | Medication   |            | K=5     |       |
| Qudsi-Sinclear /2016 
/ n=28      | Genicular nerve blocks |            |         |       |
| Sar /2016  
/ n=73       | IAS         |            |         |       |
| Kay /2016  
/ n=24       | Hyaluronic acid injection |         |         |       |
| Davis /2018  
/ n=151      | Cooled RF    | IAS        | N=151   | Very low |
| Radnorich /2017 
N=180       | Cryoablation | sham       | N=180   | Very low |

IAS: intra-articular steroid injection

### Pulsed RFA is not better than the comparators or sham on shoulder pain

- The quality of evidence for RFA on shoulder pain is very low

<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Technology</th>
<th>comparator</th>
<th>Outcome</th>
<th>Effect</th>
<th>N and k</th>
<th>SOE</th>
</tr>
</thead>
</table>
| Eyigor/2010  
/ n=50       | Pulsed RF  | IAS        | Pain     | In favor of IAS |         |       |
|            |            |            | Function | In favor of IAS |         |       |
| Okmen/2017  
/ n=59       | Photobio-Modulation | Pain     | In favor of Photobio-Modulation | N=171  | K=4   | Very low |
|            |            |            | Function | In favor of Photobio-Modulation |         |       |
| Gofeld/2012  
/ n=22       | Sham       | Pain       | No difference |         |       |
|            |            | Function   | No difference |         |       |
| Korkmas/2016 
/ n=40       | TENS       | Pain       | No difference |         |       |
|            |            | Function   | No difference |         |       |

IAS: intra-articular steroid injection
Safety

- Evidence
  little evidence of serious harms in randomized and nonrandomized studies. There were few reports of serious adverse events and device malfunctions in U.S. government databases.

Cost-effectiveness

- No evidence found
The CMS does not have a coverage determination on peripheral nerve ablation.

Selected payers' coverage policy

<table>
<thead>
<tr>
<th>Payer</th>
<th>Policy</th>
<th>Effective time</th>
</tr>
</thead>
<tbody>
<tr>
<td>BlueCross BlueShield NC</td>
<td>Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered investigational.</td>
<td>2017-2018</td>
</tr>
<tr>
<td>Aetna</td>
<td>Aetna considers pulsed radiofrequency experimental and investigational for all indications, including osteoarthritis of the knee and plantar fasciitis</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Cigna</td>
<td>Peripheral nerve destruction using cryoablation or laser, electrical, chemical or radiofrequency ablation is considered experimental, investigational, or unproven for treatment of ANY of the following conditions</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Regence</td>
<td>Regence considers cryoablation (CPT 0440T and 0441T) investigational, including imaging guidance, for upper and lower distal peripheral nerve</td>
<td>2018</td>
</tr>
</tbody>
</table>
Agency Medical Director Recommendations

- Peripheral nerve ablation is not a covered benefit for the treatment of chronic limb pain
  
  Rationale
  - Paucity of very low quality evidence, mostly funded by manufacturers
  - No endorsement by professional society guidelines
  - Commercial payers all deem technology investigational

- Future
  - There are 12 ongoing RCTs of various modalities for peripheral nerve ablation to treat pain in the knee (9 studies), foot (1 study), hip (1 study), and post-amputation phantom lower limb pain (1 study) that are expected to be completed between 2018-2021
  - Perhaps timely re-review in 3 years

Questions?

More information:
www.hca.wa.gov/about-hca/health-technology-assessment
Order of scheduled presentations:

Peripheral nerve ablation for limb pain

<table>
<thead>
<tr>
<th></th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Michael Dana</td>
</tr>
<tr>
<td>2</td>
<td>John DiMuro, DO, MBA</td>
</tr>
<tr>
<td>3</td>
<td>Anne Stefurak</td>
</tr>
</tbody>
</table>
## Disclosure

Any unmarked topic will be considered a "Yes"

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<td>5. Research funding.</td>
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<td>6. Any other relationship, including travel arrangements.</td>
<td></td>
<td>X</td>
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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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<td>7. Representation: if representing a person or organization, include the name and</td>
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<td>funding sources (e.g. member dues, governmental/taxes, commercial products or services,</td>
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<tr>
<td>grants from industry or government).</td>
<td></td>
<td>X</td>
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If yes to #7, provide name and funding Sources:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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

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

X [Signature] 12/6/2018 [Date] Michael Dana [Print Name]

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

Email Address: Michael.Dana@Avanox.com

Phone Number: (253) 229-8909
Testimony for January 18th, 2019 – Michael Dana

Hello my name is Michael Dana and I am a long time employee of Baylis, Halyard and currently Avanos Medical. The strength of my testimony comes from the 20+ years of experience in supporting cases with patients right here in the Washington State area with local patients suffering with pain.

Cooled Thermal Radiofrequency technology has experienced technological advancements over time and one such improvement has been the probe.

Both conventional and cooled RF produce a lesion with over 80° C however, the characteristics differ in the following ways:

- Cooled Thermal RF pain relief lasts longer than conventional RF in fact studies show up to 24 months [hip and knee] (Menzies 2015)
- Different proteins denervate at different temperatures and cooled is equivalent to cutting the nerve (Prolong Study – to be published in 2019)
- More energy can be deposited due to the greater efficiency – in fact, the heat sink delivers approx.. 3.5 times more energy (Ball 2014)
- Eliminates and reduces use of opioid narcotics in the management of chronic musculoskeletal pain (Stelzer 2013, Davis 2018)

Cooled Thermal RF is an alternative to costly and invasive surgery that may be medically contraindicated or marginally effective. (Mirza 2013)

I want to thank the Washington State Health Care Authority Committee members and the Oregon Health & Science University at the Center for Evidence-based Policy for your time and consideration.

Thank you,
Michael Dana
Disclosure

Any unmarked topic will be considered a "Yes"

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AVANOS

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


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

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

[Signature]

Dr. John DiMuro

Date: 12/20/2018

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

Email Address: johnDimuro@gmail.com

Phone Number: (775) 842-5742
Dear Washington State Health Care Authority;

Please accept the testimony from Dr. John DiMuro as he would like to present at the January 18th, 2019 meeting.

Thank you for your consideration.

As one of the original researchers for Coolief back in 2005, I have used the Coolief product longer than anyone in the world. It is amazing to see that our original research on this product has developed into a global standard for not only spine pain but for even more common pain syndromes in the peripheral joints including the hip joint and knee joint.

Avanos has made it a priority to educate medical providers about best protocols and the ease of use for its product line. I have served as lead proctor for cadaver courses for more than a decade demonstrating the simplicity and rationale for this innovative modality. While I will not wander down a rabbit hole explaining the details of these protocols, I will apprise you that the ease of use for the Avanos Coolief system will make a good doctor a great doctor.

Published studies and cadaver dissections have clearly demonstrated the superiority of Coolief radiofrequency ablation over conventional radiofrequency ablation. As the former Chief Medical Officer for the state of Nevada, I am intimately familiar with State revised statutes, rules and regulations. I will tell you that the state of Washington will actually save money by approving coverage of this modality. The use of Coolief will help to decrease payments to providers for repeat pain procedures and in turn decrease analgesic and opioid consumption. As the co-write of Nevada’s opioid bill in the 2017 legislature, a Bill which was sponsored by Governor Sandoval and approved unanimously by the Legislature, I can tell you that inadequately treated pain syndromes account for a significant number of cases of opioid dependence and subsequent increases in mental health and substance abuse funding.

I hope this committee will do its homework to allow the medical community here in Washington state to utilize a product with a long history of success to treat very common pain syndromes. In conclusion I would ask that if you had knee or hip pain requiring medical treatment, would your request treatment using conventional radiofrequency ablation or the Coolief system?

Thank you for your time.

John DiMuro, DO, MBA
Board Certified in Anesthesiology & Pain Medicine
Disclosure

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<td></td>
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<tr>
<td>6. Any other relationship, including travel arrangements.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

I am an Employee of Avanos Medical Inc.
VP, Health Economics & Reimbursement for the Coolief® Cool Select Radiofrequency Technology.

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

I am an Employee of Avanos Medical.
VP, Health Economics & Reimbursement.

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

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

X 

Signature  14/10/19  ANNE STEFURAK

Date  Print Name

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

Email Address: anne.stefurak@avanos.com

Phone Number: 470-448-5181 (ofc)
Peripheral Nerve Ablation for the Treatment of Limb Pain

Washington State Health Care Authority
Health Technology Clinical Committee
January 18, 2019

Valerie J. King, MD, MPH

Outline

- Background
- Methods and search results
- Included studies
- Evidence review
- GRADE summary of evidence tables
- Clinical practice guidelines
- Payer policies
- Summary and conclusions
Background

- Common causes of chronic limb pain:
  - Arthritis
  - Traumatic injury and postoperative pain syndromes
  - Soft tissue-related conditions

- Treatments for chronic limb pain aim to reduce symptoms and improve function:
  - Lifestyle interventions: physical activity, weight loss
  - Medications (e.g., acetaminophen, NSAIDs, opioids)
  - Physical therapy
  - Complementary and alternative therapies (e.g., massage, acupuncture)
  - Surgery

Peripheral Nerve Ablation

- Peripheral nerve ablation (PNA) destroys sensory nerve tissues that transmit pain signals from the affected area to the brain

- Different types of PNA:
  - Conventional radiofrequency ablation (RFA)
  - Pulsed radiofrequency (pRF)
  - Cooled RF
  - Cryoablation
  - Chemical neurolysis
Anatomical Location for Nerve Ablation–Knee

Nerve ablation for the knee targets three genicular nerves
Source: Kidd et al., 2018

Anatomical Location for Nerve Ablation–Shoulder

Nerve ablation in the shoulder targets the SSN at the suprascapular notch
Source: Liliang et al., 2009
Peripheral Nerve Ablation Procedure

PNA procedures are often conducted with fluoroscopic guidance. Picture shows RF cannula at genicular nerves. 

Source: Sari et al., 2016

Peripheral Nerve Ablation Techniques

- **Radiofrequency techniques**
  - Conventional RFA: high-frequency electrical current generates heat (80°C to 90°C) at the target tissue
  - Pulsed RF: short bursts of RF current, rather than the continuous current of conventional RFA, generating less heat (not exceeding 45°C)
  - Cooled RF: similar to conventional RFA with water cooling of tissues beyond the target area

- **Cryoablation**
  - Uses a cryogen to deliver very cold temperatures that damage the nerves
FDA Regulation

- As a medical procedure, PNA not regulated by U.S. Food and Drug Administration (FDA)
- Devices used in nerve ablation procedures are regulated by the FDA
- Device manufacturers all received Section 501(k) premarket approval from the FDA
- Devices produced by NeuroTherm, Boston Scientific (formerly Cosman, Radionics), Avanos (formerly Halyard Health and Baylis), and Myoscience

Methods
Scope: PICO

- **Population**: Adults and children with chronic limb pain caused by osteoarthritis or other conditions
- **Interventions**: Peripheral nerve ablation (any technique)
- **Comparators**: Other active interventions, placebos, sham procedures, no treatment
- **Outcomes**
  - Primary outcomes: function
  - Secondary outcomes: pain, use of subsequent interventions
  - Safety: harms
  - Economic outcomes (e.g., cost-effectiveness)

Scope: Key Questions

1. What is the evidence of efficacy and effectiveness for PNA for limb pain?
2. What direct harms are associated with PNA for limb pain?
3. Do important patient efficacy/effectiveness outcomes vary by indication or patient characteristics?
4. What are the cost-effectiveness and other economic outcomes of PNA for limb pain?
Eligible Studies

- Key Questions 1 to 4
  - Randomized controlled trials (RCTs)
- Additional studies/data for Key Questions 2 and 3 (safety)
  - Nonrandomized comparative and noncomparative studies, if evidence for the intervention or device is included in KQ1
  - Governmental registries and databases containing reports of procedure-related harms or device recalls
- Additional studies/data for Key Question 4
  - Cost-effectiveness studies and other formal comparative economic evaluations and systematic review of such studies

Evidence Sources

- Ovid MEDLINE (search strategies in Appendix A)
- Cochrane Library
  - Database of Systematic Reviews
  - Cochrane Central Register of Controlled Trials
- Additional evidence sources:
  - Agency for Healthcare Research and Quality (AHRQ)
  - UK National Institute for Health and Care Excellence (NICE)
  - Veterans Administration Evidence-based Synthesis Program
  - Reference lists of included studies
- Dual independent review of studies for inclusion at the title/abstract and then full-text level
Other Sources

- ClinicalTrials.gov database for ongoing and recently completed registered trials
- FDA's Manufacturer and User Facility Device Experience (MAUDE) and Medical Device Recall databases for adverse events
- For clinical practice guidelines:
  - Evidence sources (e.g., MEDLINE)
  - AHRQ National Guideline Clearinghouse (as of July 2018)
- For payer policies:
  - Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database for National and Local Coverage Determinations applicable to Washington State
  - Private payers: Aetna, Cigna, and Regence websites

### PRISMA Study Flow Diagram

- **Database searching**
  - n = 2,369

- **Other sources**
  - n = 9

- **Total records**
  - n = 2,376

- **After duplicates removed**
  - n = 1,890

- **Excluded by title/abstract**
  - n = 1,631

- **Full-text articles assessed**
  - n = 259

- **Full-text articles excluded**
  - n = 238

- **Studies included**
  - n = 21
  - 13 randomized controlled trials
  - 8 nonrandomized studies (safety only)
Risk of Bias for Studies

- Two independent Center researchers evaluated studies for methodological risk of bias
- Each study assessed using Center instruments adapted from international standards and assessments
- A rating of high, moderate, or low risk of bias was assigned to each study based on adherence to recommended methods and potential for bias
- Risk-of-bias criteria are listed in Appendix B

Overall Quality of Evidence

- Center researchers assigned a summary judgment for the overall quality of evidence for each key outcome

<table>
<thead>
<tr>
<th>Quality</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td><strong>Very confident</strong> that the estimate of the effect of the intervention on the outcome lies close to the true effect</td>
</tr>
<tr>
<td>Moderate</td>
<td>True effect is likely to be close to the estimate of the effect, but there is a possibility that it is different</td>
</tr>
<tr>
<td>Low</td>
<td>Little confidence in the estimate of the effect of the intervention on the outcome and the true effect may be substantially different from the estimate of the effect</td>
</tr>
<tr>
<td>Very Low</td>
<td>No confidence in the estimate of the effect of the intervention on the outcome and the true effect is likely to be substantially different from the estimate of effect</td>
</tr>
</tbody>
</table>

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
Common Outcome Measures: Knee Function

- Minimal Clinically Important Difference (MCID) thresholds vary by population, condition, time interval, and baseline score
  - Generally, 10–20% change
- Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
  - MCID 10–15 points
- Oxford Knee Score (OKS)
  - MCID 6–14 points

Common Outcome Measures: Function

- Shoulder Pain and Disability Index (SPADI)
  - MCID 8–13 points
- American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score
  - MCID 10–20 points
Common Outcome Measures: Pain

- Visual analog scale (VAS)
  - MCID 10–15 points (for 100-point scale)
- The numerical rating scale (NRS)
  - MCID 2 points

Evidence Review
Key Question 1: Effectiveness

- 13 RCTs included in this evidence review for knee pain, shoulder pain, or plantar fasciitis

Number of Studies by Indication and Technology

<table>
<thead>
<tr>
<th>Technology</th>
<th>Knee</th>
<th>Shoulder</th>
<th>Plantar Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional RFA</td>
<td>5</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Pulsed RF</td>
<td>-</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Cooled RF</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cryoneurolysis</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

- Assessment of risk of bias:
  - 11 RCTs rated as having high risk of bias
  - 2 RCTs rated as having moderate risk of bias
  - Detailed risk-of-bias assessments in Appendix D

RCTs: Knee Pain–Conventional RFA

<table>
<thead>
<tr>
<th>Citation</th>
<th>Total N Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choi et al., 2011 South Korea</td>
<td>Total N = 35</td>
<td>Sham procedure</td>
</tr>
<tr>
<td></td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>El-Hakeim et al., 2018 Egypt</td>
<td>Total N = 60</td>
<td>Oral paracetamol, diclofenac, and PT</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Ray et al., 2018 India</td>
<td>N = 24</td>
<td>IA hyaluronic acid</td>
</tr>
<tr>
<td></td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Sari et al., 2016 Turkey</td>
<td>Total N = 73</td>
<td>IA betamethasone</td>
</tr>
<tr>
<td></td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>Post-TKA subjects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qudsi-Sinclair et al., 2016 Spain</td>
<td>Total N = 28</td>
<td>IA triamcinolone</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td></td>
</tr>
</tbody>
</table>
**RCTs: Knee Pain—Conventional RFA**

**Study Population Characteristics**

- Mean age range: 53–69 years
- % female range: 65%–86%
- 3 RCTs reported BMI
  - BMI range 23–31
- 4 RCTs reported mean symptom duration
  - Range: 7 months–7 years
- 2 RCTs reported radiologic osteoarthritis grade
  - Grade 3: 43%–58%
  - Grade 4: 37%–42%

**Results: Knee Pain—Conventional RFA**

- Change in OKS from baseline
  - Statistically significant benefit in treatment group vs. control at month 1 ($P < .001$) and month 3 ($P < .01$), but not at month 6 ($P = .11$) or month 12 ($P = .32$) (Choi et al.)
- WOMAC total, treatment vs. control, at end of study
  - Week 12: 12.06 ± 4.03 vs. 59.93 ± 15.99; $P < .0001$ (Ray et al.)
  - Month 3: 39.70 ± 8.89 vs. 42.33 ± 10.95; $P = .26$ (Sari et al.)
  - Month 6: 33.1 ± 4.1 vs. 43.0 ± 2.0; $P < .001$ (El-Hakeim et al.)
- 4 studies measured VAS pain at 3 months and all showed statistically significantly lower scores in treatment vs. control
- Patient satisfaction statistically significantly greater in treatment group vs. control at months 1 to 6
### GRADE Table: Knee Pain—Conventional RFA

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.)</th>
<th>k (studies)</th>
<th>Findings</th>
<th>Quality of Evidence</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Function—WOMAC total or OKS at 3 months</strong></td>
<td>N = 223</td>
<td>k = 5</td>
<td>4 RCTs found statistically significant and clinically meaningful improvement with RFA. 1 RCT found no statistically significant difference between groups.</td>
<td>Very low ●○○○</td>
<td>QoE downgraded: 2 levels for serious ROB • 1 level for indirectness (study locations, suboptimal comparator intervention, lack of longer-term outcomes)</td>
</tr>
<tr>
<td><strong>Pain—VAS or NRS at 3 months</strong></td>
<td>N = 150</td>
<td>k = 4</td>
<td>3 RCTs found statistically significant and clinically meaningful improvement favoring RFA. 1 RCT did not find any statistically significant difference.</td>
<td>Very low ●○○○</td>
<td>QoE downgraded: 2 levels for serious ROB • 1 level for indirectness (study location, suboptimal comparator intervention, lack of longer-term outcomes)</td>
</tr>
</tbody>
</table>

Detailed GRADE quality of evidence tables in Appendix E

---

### RCTs: Knee Pain—Cooled RF

<table>
<thead>
<tr>
<th>Citation Country</th>
<th>Total N</th>
<th>Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis et al., 2018 U.S.</td>
<td>Total N = 151</td>
<td>6 months</td>
<td>IA methylprednisolone, triamcinolone, or betamethasone</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Citation</th>
<th>Participant Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis et al., 2018</td>
<td>• Mean age: 64 years  • Gender: 66% female  • Race: 79% White, 18% Black, 1% Asian/Pacific Islander  • Mean BMI: 30.5  • Mean duration of knee pain: 115 months  • Radiologic osteoarthritis grade:  • 35% Grade 2; 44% Grade 3; 21% Grade 4</td>
</tr>
</tbody>
</table>
Results: Knee Pain–Cooled RF

- Difference in OKS group means, treatment vs. control
  - Baseline: −0.2 (95% CI, −1.8 to 1.3; \( P = .83 \))
  - Month 1: 4 (95% CI, 0.98 to 7.0; \( P = .004 \))
  - Month 3: 10 (95% CI, 7.28 to 12.7; \( P < .0001 \))
  - Month 6: 13.3 (95% CI, 10.28 to 16.4; \( P < .0001 \))
- Change in difference in group means for NRS from baseline
  - Month 1: -4.2 ± 2.5 vs. -3.3 ± 2.3 (\( P = .02 \))
  - Month 3: -4.4 ± 2.3 vs. -1.9 ± 2.1 (\( P < .0001 \))
  - Month 6: -4.9 ± 2.4 vs. -1.3 ± 2.2 (\( P < .0001 \))

GRADE Table: Knee Pain–Cooled RF

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.) k (studies)</th>
<th>Findings</th>
<th>Quality of Evidence Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function—OKS at 3 months</td>
<td>N = 151 k = 1</td>
<td>1 RCT found statistically significant and clinically meaningful improvement favoring cooled RF</td>
<td>Very low ●●●● QoE downgraded: • 1 level for moderate ROB • 1 level for imprecision (single study) • 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention)</td>
</tr>
<tr>
<td>Pain—NRS at 3 months</td>
<td>N = 151 k = 1</td>
<td>1 RCT found statistically significant and clinically meaningful improvement favoring cooled RF</td>
<td>Very low ●●●● QoE downgraded: • 1 level for moderate ROB • 1 level for imprecision (single study) • 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention)</td>
</tr>
</tbody>
</table>
RCTs: Knee Pain–Cryoneurolysis

<table>
<thead>
<tr>
<th>Citation Country</th>
<th>Total N Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radnovich et al., 2017 U.S.</td>
<td>Total N = 180 120 days</td>
<td>Sham procedure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Citation</th>
<th>Participant Characteristics</th>
</tr>
</thead>
</table>
| Radnovich et al., 2017 | • Median age: 61 years (range 36-75)  
• Gender: 66% female  
• Race: 89% White, 9% Black, 2% Asian/Pacific Islander  
• Mean BMI: 29  
• Mean time since diagnosis: 73 months  
• Radiologic osteoarthritis grade:  
  • 52% Grade 2, 48% Grade 3 |

Results: Knee Pain–Cryoneurolysis

- Least squares mean differences in WOMAC function from baseline, treatment vs. control groups
  - Day 30: -21.30 (95% CI, -34.02 to -8.57; \( P = .0012 \))  
  - Day 60: -13.14 (95% CI, -26.43 to -0.39; \( P = .044 \))  
  - Day 90: -15.89 (95% CI, -28.93 to -2.86; \( P = .017 \))  
  - Day 120: -9.16; (95% CI, -22.04 to 3.72; \( P = .16 \))

- Mean change in WOMAC pain from baseline, treatment vs. control
  - Day 30: -7.12 (95% CI, -11.01 to -3.22; \( P = .0004 \))  
  - Day 60: -4.65 (95% CI, -8.48 to -0.82; \( P = .02 \))  
  - Day 90: -5.67 (95% CI, -9.69 to -1.64; \( P = .006 \))  
  - Day 120: -2.82 (95% CI, -6.77 to 1.13; \( P = .16 \))

- No statistically significant difference between groups at any time point using SF-36 instrument
### GRADE Table: Knee Pain–Cryoneurolysis

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.) k (studies)</th>
<th>Findings</th>
<th>Quality of Evidence</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function—WOMAC total at 3 months</td>
<td>N = 180 k = 1</td>
<td>1 RCT found statistically significant, clinically meaningful improvement favoring cryoablation</td>
<td>Very low ◆◆◆◆</td>
<td>QoE downgraded: • 2 levels for serious ROB • 1 level for imprecision (single study) • 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention)</td>
</tr>
<tr>
<td>Pain—WOMAC pain at 3 months</td>
<td>N = 180 k = 1</td>
<td>1 RCT found statistically significant, clinically meaningful improvement favoring cryoablation</td>
<td>Very low ◆◆◆◆</td>
<td>QoE downgraded: • 2 levels for serious ROB • 1 level for imprecision (single study) • 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention)</td>
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### RCTs: Shoulder Pain–Pulsed RF

<table>
<thead>
<tr>
<th>Citation Country</th>
<th>Total N Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyigor et al., 2010 Turkey</td>
<td>Total N = 50</td>
<td>IA triamcinolone at glenohumeral and acromioclavicular joints and subacromial space</td>
</tr>
<tr>
<td></td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Gofeld et al., 2012 Canada</td>
<td>Total N = 22</td>
<td>Sham procedure</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Korkmaz et al., 2010 Turkey</td>
<td>Total N = 40</td>
<td>TENS</td>
</tr>
<tr>
<td></td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Ökmen et al., 2017 Turkey</td>
<td>Total N = 59</td>
<td>Photobiomodulation therapy (high-intensity laser)</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td></td>
</tr>
</tbody>
</table>
RCTs: Shoulder Pain–Pulsed RF
Study Population Characteristics

- Mean age: 52–69 years
- % female: 58%–77%
- 3 RCTs reported mean symptom duration
  - 10 months–34 months
- 2 RCTs reported underlying pathology:
  - Supraspinatus tendinopathy, 42% and 52%
  - Partial tear of the supraspinatus tendon, 48% and 45%
  - Acromioclavicular osteoarthritis, 8% and 3%

Results: Shoulder Pain–Pulsed RF

- SPADI total at month 3, treatment vs. control
  - 26.7 ± 14.5 vs. 22.9 ± 19.8; *P* < .05 (Eyigor et al.)
  - 35.2 vs. 45.5; *P* ≥ .05 (Gofeld et al.)
  - 25.5 ± 10.1 vs. 32.4 ± 20.5; *P* ≥ .05 (Korkmaz et al.)
  - 26.5 (6 to 86) vs. 20.0 (5 to 86); *P* = .347 (Ökmen et al.)
- VAS night pain statistically better in IAS group at week 12
  - Week 12: 1.65 ± 0.5 vs. 1.2 ± 0.9; *P* < .05 (Eyigor et al.)
  - No other VAS measures (night, rest, movement, overall) were significantly different between groups
Other Results: Shoulder Pain—Pulsed RF

- No statistically significant differences between groups at 12 weeks in SF-36 total or subscales, or Beck Depression Inventory (Eyigoret et al.)
- Patient satisfaction statistically significantly higher in treatment group at 1 and 3 months, but not at 6 months (Gofeld et al.)

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**GRADE Table: Shoulder Pain—Pulsed RF**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.)</th>
<th>Findings</th>
<th>Quality of Evidence Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function—SPADI total at 3 months</td>
<td>N = 171 k = 4</td>
<td>1 RCT had statistically significant difference in favor of IAS comparator. 3 RCTs did not have statistically significant differences between groups</td>
<td>Very low ●●●● QoE downgraded: • 2 levels for serious ROB • 1 level for inconsistency (2 studies favored control group and 2 studies favored intervention group) • 1 level for indirectness</td>
</tr>
<tr>
<td>Pain—VAS pain at 3 months</td>
<td>N = 149 k = 3</td>
<td>1 RCT found statistically significant, but likely not clinically meaningful, difference favoring IAS group. No other study found a statistically significant difference.</td>
<td>Very low ●●●● QoE downgraded: • 2 levels for serious ROB • 1 level for indirectness (study location, suboptimal or uncommonly used comparator, lack of long-term outcomes)</td>
</tr>
</tbody>
</table>
RCTs: Plantar Fasciitis—Conventional RFA

<table>
<thead>
<tr>
<th>Citation</th>
<th>Total N Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landsman et al.,</td>
<td>Total N = 17</td>
<td>Sham procedure</td>
</tr>
<tr>
<td>2013 U.S.</td>
<td>4 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean VAS first-step pain: 8.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean VAS initial average pain: 7.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean VAS initial peak pain: 9.2</td>
<td></td>
</tr>
</tbody>
</table>

Findings: Plantar Fasciitis—Conventional RFA

- No functional outcomes reported (Landsman et al.)
- Change in VAS from baseline to week 4, treatment vs. control (Landsman et al.)
  - Average pain: $4.06 \pm 2.10$ vs. $0.8 \pm 1.81$ ($P = .04$)
  - First-step pain: $5.00 \pm 3.90$ vs. $1.33 \pm 2.30$ ($P = .30$)
  - Peak pain: $5.33 \pm 4.31$ vs. $1.80 \pm 2.08$ ($P = .048$)
### GRADE Table: Plantar Fasciitis—Conventional RFA

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.)</th>
<th>Findings</th>
<th>Quality of Evidence</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function—no measure identified</td>
<td>N = 0</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pain—VAS overall at 3 months</td>
<td>N = 0</td>
<td>Reported VAS only at 1 month</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### RCTs: Plantar Fasciitis—Pulsed RF

<table>
<thead>
<tr>
<th>Citation Country</th>
<th>Total N</th>
<th>Duration</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu et al., 2017</td>
<td>Total N = 36</td>
<td>12 weeks</td>
<td>Sham procedure and lidocaine injected to posterior tibial nerve</td>
</tr>
<tr>
<td>Taiwan</td>
<td>• Mean age: 47 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Gender: 53% female</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean body weight: 68 kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Duration of symptoms: 9.8 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean VAS first-step: 6.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean VAS overall pain: 6.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean AOFAS ankle-hindfoot score: 58.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results: Plantar Fasciitis–Pulsed RF

- Change in AOFAS ankle-hindfoot from baseline, treatment vs. control (Wu et al.)
  - Week 1: 19.65 ± 13.93 vs. 3.60 ± 5.56 (P < .001)
  - Week 4: 27.10 ± 16.67 vs. 3.05 ± 6.53 (P < .001)
  - Week 8: 27.85 ± 17.55 vs. 1.00 ± 8.93 (P < .001)
  - Week 12: 32.10 ± 16.84 vs. -0.50 ± 8.59 (P < .001)

Results: Plantar Fasciitis–Pulsed RF cont.

- Change in VAS overall pain from baseline, treatment vs. control (Wu et al.)
  - Week 1: -2.73 ± 1.46 vs. -0.52 ± 0.30 (P < .001)
  - Week 4: -3.65 ± 1.66 vs. -0.20 ± 0.20 (P < .001)
  - Week 8: -3.91 ± 1.85 vs. -0.13 ± 0.21 (P < .001)
  - Week 12: -4.49 ± 2.10 vs. 0.02 ± 0.31 (P < .001)
GRADE Table: Plantar Fasciitis–Pulsed RF

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (partic.)</th>
<th>k (studies)</th>
<th>Findings</th>
<th>Quality of Evidence</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function—AOFAS ankle-hindfoot score at 3 months</td>
<td>N = 36</td>
<td>k = 1</td>
<td>1 RCT found statistically significant and clinically meaningful improvement after pulsed RF compared to sham treatment</td>
<td>Very low ★★★☆☆</td>
<td>QoE downgraded: • 1 level for moderate ROB • 1 level for imprecision (single study) • 1 level for indirectness (study location, lack of longer-term functional outcomes, composite outcome, suboptimal comparator intervention)</td>
</tr>
<tr>
<td>Pain—VAS overall at 3 months</td>
<td>N = 36</td>
<td>k = 1</td>
<td>1 RCT found statistically significant and clinically meaningful improvements in overall VAS pain score</td>
<td>Very low ★★★☆☆</td>
<td>QoE downgraded: • 1 level for moderate ROB • 1 level for imprecision (single study) • 1 level for indirectness (study location, lack of longer-term outcomes, suboptimal comparator intervention)</td>
</tr>
</tbody>
</table>

Limitations

- Common limitations for RCTs in this evidence review:
  - Small sample sizes
  - Inadequate description of allocation concealment
  - Use of suboptimal or inappropriate comparators
  - Inadequate length of follow-up to assess the durability of benefits or the development of harms
  - Large or differential losses to follow-up
Limitations

- Other limitations in some studies:
  - Use of last observation carried forward when data were missing (e.g., lost to follow-up)
  - Lack of controlling for known confounders such as smoking, age, sex, and weight
  - Substantial placebo effect in the control group
  - Several RCTs were funded by device manufacturers or had authors with financial relationships with those companies
  - Other RCTs did not report either study funding or author disclosures

Key Question 2: Safety – Included Studies

- Findings from the 13 RCTs
  - Little evidence of serious harms (many studies did not have robust method for assessing harms)
  - Most harms were procedure-related side effects such as bruising or procedural pain
- 8 additional nonrandomized studies included for safety, all rated as having high risk of bias
  - Limited harms reported, related to expected procedural effects
Key Question 2: Safety – Other Data

- All reports from MAUDE and Medical Device Recall databases in Appendix G
- FDA MAUDE database
  - Few reports of serious adverse events
  - Patient burns were most common reported harm
- FDA Medical Device Recall database
  - No recalls related to serious adverse events

Key Question 3: Specific Populations

- No RCT reported procedural outcomes stratified by age, sex, race, or other demographic factors
- Only 1 RCT (Qudsi-Sinclair et al., 2017) was conducted in a clinically distinct subpopulation:
  - Participants with at least 6 months of persistent pain after total knee arthroplasty
  - OKS function outcomes: statistically significant improvement in conventional RFA group compared to corticosteroid group at 1 and 3 months, but not at 6 or 12 months
  - Knee Society Score function outcomes: statistically significant improvement in conventional RFA group compared to corticosteroid group at 1, 3, and 6 months, but not at 12 months
Key Question 4: Economic Outcomes

- No studies reported economic outcomes

RCTs Registered at ClinicalTrials.gov

- 12 ongoing RCTs expected to be completed between 2018 and 2021

<table>
<thead>
<tr>
<th>Area of Body</th>
<th>RFA</th>
<th>Pulsed RF</th>
<th>Cooled RF</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee pain</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>MRgFUS</td>
</tr>
<tr>
<td>Foot pain</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>Cryoablation</td>
</tr>
<tr>
<td>Hip pain</td>
<td>--</td>
<td>--</td>
<td>1</td>
<td>--</td>
</tr>
<tr>
<td>Phantom limb pain</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>Cryoanalgesia</td>
</tr>
<tr>
<td>Shoulder pain</td>
<td>--</td>
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<td>--</td>
</tr>
<tr>
<td>Plantar fasciitis</td>
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</tr>
</tbody>
</table>

- List of all studies found on ClinicalTrials.gov in Appendix F
Guidelines and Policies

Clinical Practice Guidelines

- We included guidelines that met basic eligibility criteria and discussed management of limb pain, whether or not the guideline specifically mentioned PNA
- 3 of 8 included guidelines discussed PNA
- None of the 8 included guidelines recommend PNA
### Guidelines—No Mention of Peripheral Nerve Ablation

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>American Academy of Orthopaedic Surgeons</strong> guideline on hip osteoarthritis (2017)</td>
<td>Fair quality</td>
</tr>
<tr>
<td><strong>American Academy of Orthopaedic Surgeons</strong> guideline on knee osteoarthritis (2013) — updated guideline expected in 2019 to include discussion of peripheral nerve ablation</td>
<td>Fair quality</td>
</tr>
<tr>
<td><strong>National Institute for Health and Care Excellence</strong> guideline on osteoarthritis (2014)</td>
<td>Good quality</td>
</tr>
<tr>
<td><strong>Veterans Administration/Department of Defense</strong> guideline on hip and knee osteoarthritis (2014)</td>
<td>Fair quality</td>
</tr>
<tr>
<td><strong>American Physical Therapy Association</strong> guideline on plantar fasciitis (2014)</td>
<td>Fair quality</td>
</tr>
</tbody>
</table>

### Guidelines—Includes Discussion of Peripheral Nerve Ablation

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Quality</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>American College of Occupational and Environmental Medicine</strong> guideline on elbow disorders (2013)</td>
<td>Poor quality</td>
<td>No recommendation for or against the use of diathermy for the treatment of acute, subacute, or chronic lateral epicondylalgia</td>
</tr>
<tr>
<td><strong>American College of Foot and Ankle Surgeons</strong> guideline on adult-acquired infracalcaneal heel pain (2018)</td>
<td>Poor quality</td>
<td>Evidence on bipolar RF treatment for chronic, refractory plantar fasciitis is uncertain</td>
</tr>
<tr>
<td><strong>Association of Extremity Nerve Surgeons</strong> guideline (2014)</td>
<td>Poor quality</td>
<td>Does not recommend ablation for the primary treatment of Morton’s Neuroma</td>
</tr>
</tbody>
</table>
### Payer Policies

- **Medicare**
  - No Medicare National Coverage Determination related to peripheral nerve ablation for limb pain
  - Medicare Local Coverage Determination on nerve blockades for treatment of chronic pain and neuropathy
    - Thermal (not pulsed) radiofrequency is covered for a variety of pain diagnoses, including knee, hip, and shoulder pain

- **Private Payers**
  - Aetna, Cigna, and Regence do not provide coverage for peripheral nerve ablation

### Private Payers: Experimental or Investigational Procedures

- **Aetna does not cover:**
  - Pulsed RF for any indication
  - Cryotherapy or patellar denervation for knee osteoarthritis

- **Cigna does not cover:**
  - Peripheral nerve destruction using cryoablation; radiofrequency ablation; or electrical, chemical, or laser ablation
  - RF lesioning for pain resulting from plantar fasciitis

- **Regence does not cover:**
  - Nerve ablation (including cryoablation) of the upper or lower extremity peripheral nerves, nerve plexus, or other truncal nerves
  - Ablation using magnetic resonance-guided focused ultrasound and high-intensity focused ultrasound procedures for pain
Summary and Conclusions

Overall Summary

- Very low quality of evidence favoring PNA to improve some short-term functional and pain measures in studies of knee pain, shoulder pain, and plantar fasciitis
  - All studies have methodological limitations
  - 7 of the 13 RCTs reported improvements in short-term function and pain measures that were both statistically significant and likely clinically meaningful
  - Improvements small in magnitude and not consistent
  - Positive outcomes often reported in only 1 RCT, on 1 scale or subscale, or at 1 time period
  - The evidence is nearly exclusively limited to outcomes that occurred within 3 to 6 months
Overall Summary

- No studies involved head-to-head comparisons of nerve ablation techniques
- We found no RCTs of PNA to treat pain at other anatomic sites, including wrist, elbow, hip, ankle, or digits
- Potential harms of these procedures appear to be uncommon, but are poorly reported in published studies
- No studies reported economic outcomes
- 12 ongoing RCTs of PNA for various forms of lower limb pain
  - Completion dates from 2018 to 2021

Overall Summary

- No identified clinical practice guideline makes a recommendation for use of PNA for limb pain
- Medicare NCD and 3 private payers do not cover PNA for limb pain
- Conventional RFA is covered in Medicare LCD
- The current paucity of evidence to support these procedures is reflected in the lack of recommendations in clinical practice guidelines and lack of inclusion in payer coverage policies
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.

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\(^1\) 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](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](http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm)
In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

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

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

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

**Clinical committee findings and decisions**

**Efficacy considerations**

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

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

Cost impact

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

Overall

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

Next step: Cover or no cover

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

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

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

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

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

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

<table>
<thead>
<tr>
<th>Safety outcomes</th>
<th>Importance of outcome</th>
<th>Safety evidence/ confidence in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td></td>
<td></td>
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<tr>
<td>Procedure related pain</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy – effectiveness outcomes</th>
<th>Importance of outcome</th>
<th>Efficacy / Effectiveness evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)</td>
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<td></td>
</tr>
<tr>
<td>OKS (Oxford Knee Score)</td>
<td></td>
<td></td>
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<tr>
<td>SPADI (Shoulder Pain and Disability Index)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AOFAS ankle-hindfoot score (American Orthopedic Foot and Ankle Society)</td>
<td></td>
<td></td>
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<tr>
<td>VAS (Visual Analog Scale)</td>
<td></td>
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<tr>
<td>NRS (Numerical Rating Scale)</td>
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</table>

<table>
<thead>
<tr>
<th>Cost outcomes</th>
<th>Importance of outcome</th>
<th>Cost evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td></td>
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</tr>
<tr>
<td>Special population / Considerations outcomes</td>
<td>Importance of outcome</td>
<td>Special populations/ Considerations evidence</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>----------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Age</td>
<td></td>
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<tr>
<td>Race</td>
<td></td>
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</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
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<tr>
<td>Ethnicity</td>
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</tbody>
</table>

**For safety:**
Is there sufficient evidence that the technology is safe for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**For efficacy/ effectiveness:**
Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**For cost outcomes/ cost-effectiveness:**
Is there sufficient evidence that the technology is cost-effective for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
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</table>
Health Technology Evidence Identification

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

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

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

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

_____ Not covered _____ Covered unconditionally _____ Covered under certain conditions

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

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

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination
Following review of the proposed findings and decision document and public comments:

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

If yes, the process is concluded.
If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.
Medicare Coverage and Guidelines

From page 57 of final evidence report:
No Medicare National Coverage Determinations or Local Coverage Determinations were found that related to peripheral nerve ablation for limb pain.

Guidelines

From page 49 of final evidence report:

Clinical Practice Guidelines

A search for clinical practice guidelines related to the treatment of limb pain identified 8 eligible guidelines, although the majority of these guidelines do not include discussion of or recommendations regarding peripheral nerve ablation. We included any guideline that met basic eligibility criteria and discussed management of limb pain, whether or not it specifically mentioned peripheral nerve ablation.

The 2013 clinical practice guideline on elbow disorders from the American College of Occupational and Environmental Medicine states that there is no recommendation for or against the use of diathermy for the treatment of acute, subacute, or chronic lateral epicondylalgia. We rated this guideline as having fair methodological quality because of limitations in the rigor of development of the evidence and recommendations, as well as lack of detail about the role of the funder and how panelist conflicts were managed.

The 2014 guideline from the Association of Extremity Nerve Surgeons does not recommend ablation, including cryoablation and RFA, in the primary treatment of Morton’s Neuroma. We rated this guideline as having poor methodological quality because there were no explanations of how evidence was synthesized for the review, how recommendations were determined, and how editorial independence was assured.

The 2018 American College of Foot and Ankle Surgeons (ACFAS) guideline on adult-acquired infracalcaneal heel pain does not make a recommendation on bipolar RF treatment for chronic, refractory plantar fasciitis, concluding that the evidence on this treatment is uncertain—neither appropriate nor inappropriate. We rated this guideline as having poor methodological quality because there were no explanations of how evidence was synthesized for the review or how recommendations were determined, and there was a lack of detail about how conflicts of interest among panelists were managed.

Four guidelines on osteoarthritis pain management do not include recommendations or discussion of peripheral nerve ablation. Two of these are fair methodological quality guidelines from the American Academy of Orthopaedic Surgeons, including guidelines for osteoarthritis of the hip, and knee. The good methodological quality 2014 guideline from National Institute for Health and Care Excellence do not mention peripheral nerve ablation as a treatment for persistent pain attributable to osteoarthritis. The American Physical Therapy Association has a fair methodological quality guideline on the treatment of plantar fasciitis that does not mention peripheral nerve ablation. Details about methodological assessments of all guidelines are located in Appendix D, Table 19.