Washington State Health Care Authority

# 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

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| Applicant Name | Brett R. Stacey, MD |
| Address | UW Center for Pain Relief |
| | 4225 Roosevelt Way NE |
| | Seattle, WA 98105 |

## 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:

| Title | Business Name & Address | Business Type |
|---|---|---|
| | | |
| | | |
| | | |

(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:

| Business Name | Business Address | Business Type |
|---|---|---|
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## 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:

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

## 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.

| Source Name & Address | Received By | Source Type |
|---|---|---|
| University of Washington/<br>Association University Physicians | Me | Salary |
| | | |
| | | |
| | | |

(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.)

| Lobbyist Name | Business Name | Type Business Shared |
|---|---|---|
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**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:

| Income Source | Address | Description of Income Source |
|---|---|---|
| US Dept Justice | 1000 SW 3rd Ave, Suite 600 Portland, OR 97204 | Consulting work, legal case |
| MCE Conferences | 7220 Trade St. #201, San Diego, CA 92121 | Preparing, delivering CME content |
| Kineta | 307 Westlake Ave. N, Seattle, WA 98109 | Consulting innovative pharmaceuticals |
| Consulting Medical Associates | 360 3rd St, Suite 425, San Francisco, CA 94107 | Medical records/opinion review |
| Australian Victorian Govt | PO Box 4356 Melbourne, VIC 3001 AU | Consulting on Australian Medical Board Case |

## 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:

| Business Name | Business Address | Description of Business |
|---|---|---|
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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.

| Name | Description of Service |
|---|---|
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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

[redacted]

Signature

12/6/2018

Date

07/23/2018

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:**

| | | | |
|---|---|---|---|
| 1978-1982 | The Colorado College, Colorado Springs, Colorado | B.A. | magna cum laude |
| 1982-1986 | University of Michigan School of Medicine, Ann Arbor, Michigan | M.D. | |

**Postgraduate Training:**

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|---|---|---|---|
| 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:**

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|---|---|
| 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 |

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| 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:**

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|---|---|
| 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:**

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|---|---|
| 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:**

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| 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:**

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| 2007 | The Pain Clinic |
| 2018- | Clinical Journal of Pain, Associate Editor |

**Ad Hoc Editorial Review Activities:**

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|---|---|
| 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 |

**Commitees:**

**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 |
| 2008-2009 | Member, 2008, 2009 American Academy of Pain Management/Pfizer Visiting Professorships in Pain Medicine Advisory Board |
| 2016-2017 | Nominating Committee Member, American Pain Society |

**Regional**

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

**Institutional**

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|---|---|
| 1996 | Committee Member, Medical Ethics Committee, University of Pittsburgh Medical Center |
| 2000-2001 | OHSU Pain QI Committee member. Presentation to ambulatory care May 2001. Setting guidelines, standards for pain assessment at OHSU. |
| 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**

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|---|---|
| 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 |

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| 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**

National Institute of Arthritis and Musculoskeletal and Skin Diseases Grant 2R01 AR38698. CBP: A Biobehavioral Model of Functional Capacity. Thomas E. Rudy, Ph.D., Principal Investigator; Dennis C. Turk, Ph.D., Co-Principal Investigator; J. Robert Boston, Ph.D., Brett R. Stacey, M.D., William L. Hirsch, M.D., Carol C. Brewer, M.S., OTR/L, Susan R. Mercer, P.T., M.S., Co-Investigators. Direct Costs: $890,105, 1990–1994.

Fibromyalgia Workshop: The Next Advances. David V. Nelson, Ph.D., Principal Investigator; Brett Stacey, M.D, Co-Investigator. NIH/NIAMS 1-U13-AR050279-01.
$50,000, Sept 2003–Sept 2004.

Back pain Outcomes Longitudinal Data (BOLD)/ Lumbar Epidural Steroid Injection for Spinal Stenosis (LESS): Randomized Controlled Trial. 1R01HS019222 9/30/10 – 9/29/13. Agency for Healthcare Research and Quality (AHRQ), ARRA. David M. Sibell, MD, Principal Investigator; Hans Carlson, MD, Nels Carlson, MD, Brett Stacey, MD, Grace Chen, MD, Kimberly Mauer, MD, Lynn Marshall, ScD, Co-Investigators. July 2012–2013

**Other Support**

Double-Blind Randomized General Use Study of the Transdermal Fentanyl Delivery System. MC Brody, M.D., Principal Investigator; BR Stacey, M.D., Co-Investigator. Anaquest, $67,756, 1991

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, Randomized, Placebo-Controlled, Multi-Center Trial to Determine the Efficacy and Safety of Neurontin (gabapentin) in Migraine Prophylaxis. BR Stacey, M.D., Principal Investigator; J Goodwin, M.D. & C Roberts, M.D., Co-Investigators. Parke-Davis/Warner-Lambert Company, $53,958, 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.

Pregabalin Open-Label, Follow-On Trial in Patients with 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, $112,000, 1998.

Double-Blind, Randomized, Placebo-Controlled, Multi-Center Trial of Pregabalin for Treatment of Postherpetic Neuralgia. BR Stacey M.D., Principal Investigator; DM Sibell, M.D., Co-Investigator; JR Laidler, M.D., CD Hord, M.D., K. Chung, M.D., Sub-Investigators. Parke-Davis/Warner-Lambert Company, $76,000, 1998.

Pregabalin Open-Label, Extension Safety Trial in Patients With Chronic Pain. BR Stacey M.D., Principal Investigator; DM Sibell, M.D., Co-Investigator; JR Laidler, M.D., CD Hord, M.D., K. Chung, M.D., Sub-Investigators. Parke-Davis/Warner-Lambert Company, $72,000, 1998.

Assessment of Safety and Tolerability of Oral Sustained Release Tramadol vs. Oral Immediate Release Tramadol in Patients with Chronic Non-Malignant Pain. DM Sibell, M.D., Principal Investigator; BR Stacey M.D., Co-Investigator; AA Chiu M.D., G Holguin M.D., CD Hord M.D., JR Laidler M.D., J Vookles M.D., Sub-Investigators. Asta-Medica, Inc., $32,000, 1998.

An Open-Label, Long-Term Safety and Tolerability Study of Ziconotide Administered Intrathecally to Patients Suffering from Chronic Pain Using a Programmable Infusion System. BR Stacey M.D., Principal Investigator. Elan Pharmaceuticals, Inc., $202,200, April 1999.

Double-Blind, Placebo-Controlled Trial of Pregabalin (300mg/day) for Relief of Pain in Patients with Painful Diabetic Peripheral Neuropathic Pain (Protocol 1008-131-106); Pregabalin Open-Label Extension Safety Trial with Neuropathic Pain (Protocol 1008-134-106). BR Stacey M.D., Principal Investigator. Parke-Davis, $131,200, February 2000.

Double-Blind, Placebo-Controlled, Parallel Group Study of Pregabalin in Patients with Postherpetic Neuralgia (Protocol 1008-127-025); Pregabalin Open-Label Extension Safety Trial with Neuropathic Pain (Protocol 1008-134-025). BR Stacey M.D., Principal Investigator. Parke-Davis, $131,200, February 2000.

A 4-week, Randomized, Double-Blind, Multicenter, Placebo and Positive-Controlled, Parallel-Group Study of Pregabalin BID on Sleep Quality and Architecture in Patients With Disturbed Sleep Concurrent with Neuropathic Pain (Protocol 1008-160-215). BR Stacey, M.D., Principal Investigator. Pfizer Inc. $34,800, September 2000.

A 12-Week, Randomized, Double-Blind, Multicenter, Placebo-Controlled Study of Pregabalin Twice a Day (BID) in the Treatment of Postherpetic Neuralgia (Protocol 1008-132-123). DM Sibell, M.D., Principal Investigator; BR Stacey, M.D., Co-Investigator. Pfizer, Inc. $58,000, September 2000.

Pregabalin (BID) Long-Term, Open-Label Extension, Safety Trial in Patients With Neuropathic Pain (Protocol 1008-174-123). DM Sibell, M.D., Principal Investigator; BR Stacey, M.D., Co-Investigator. Pfizer, Inc. $28,128, September 2000.

Pregabalin Open-Label Trial in Chronic Pain Patients Meeting Treatment Refractory Criteria (Protocol 1008-197). BR Stacey, M.D., Principal Investigator. Pfizer, Inc. September 2001.

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.

Development of a Chronic Pain Screening Tool for Use in a Primary Care Setting (Protocol NRA9450004). BR Stacey, M.D., Principal Investigator. Pfizer, Inc. October 2002.

A Double-Blind, Vehicle-Controlled, Single Dose Study to Assess the Safety, Tolerability, and Efficacy of Topical KDS-2000 (anandamide) in the Treatment of Pain Associated with Postherpetic Neuralgia. BR Stacey, M.D., Principal Investigator. Kadmus Pharmaceuticals. July 2003, $29,960.

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.

A Randomized Placebo-Controlled Trial of the Efficacy and Safety of Pregabalin in the Treatment of Subjects with Neuropathic Pain Associated with Lumbosacral Radiculopathy (Protocol A0081007-1020). M Diaz-Ramirez, M.D., Principal Investigator; BR Stacey, M.D. Sub-Investigator. Pfizer, Inc. March 2005.

Multicenter, Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of Lenalidomide in the Treatment of Complex Regional Pain Syndrome Type 1. BR Stacey, M.D, Principal Investigator. Jau-Shin, Lou, M.D., Julio Gonzalez-Sotomayor, M.D., Kimberly Kaplan, M.D., Jennifer Vookles, M.D., Co-Investigators. Celgene Corporation. $150,000, August 2005–August 2008.

A Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of ABT-894, Duloxetine and Placebo in Subjects with Diabetic Neuropathic Pain (Protocol M06-850). BR Stacey, M.D, Principal Investigator. Julio Gonzalez-Sotomayor, M.D., Kimberly Kaplan, M.D., Kathryn Snyder, P.A., Co-Investigators. Abbott Laboratories. $82,215, September 2007–October 2008.

A Phase III, Multi-Center, Open-Label, Prospective, Repeated Dose, Randomized, Controlled, Multi-Day Study of the Safety and Efficacy of Intravenous Acetaminophen in Adult Inpatients (Protocol CPI-APA-351). Julio Gonzalez-Sotomayor, M.D., Principal Investigator; Kimberly Kaplan, M.D., Kathryn Snyder, P.A., Brett Stacey, M.D., Co-Investigators. Cadence Pharmaceuticals. February 2008–October 2008.

A Phase IIa, Double-Blind, Randomized, Parallel-Group, Multi-Centre Study to Evaluate the Analgesic Efficacy of 28 Days Oral Administration of AZD2066 with One-Dose Escalation Compared to Placebo in Peripheral Neuropathic Pain Patients with Mechanical Hypersensitivity (Protocol AZDO475C00016). BR Stacey, M.D., Coordinating Investigator. AstraZeneca. April 2009 – 20112.

A Phase 3b Multicenter, Double-Blind, Efficacy and Safety Study of Pregabalin in the Treatment of Patients with Inadequately Treated Painful Diabetic Peripheral Neuropathy (Protocol A0081242). BR Stacey, M.D., Principal Investigator; Grace Chen, M.D., Kimberly Kaplan, M.D., Co-Investigators. Pfizer, Inc. August 2010 – April 2011.

A Multicenter Randomized, Double-blind, Controlled Study to Evaluate Safety, Tolerability and Preliminary Efficacy of Two Capsaicin Concentration Variations of NGX-1998 (10% or 20% w/w) in Subjects with Postherpetic Neuralgia (PHN) (Protocol C204). BR Stacey, M.D., Principal Investigator; Grace Chen, M.D., Julio Gonzalez-Sotomayor, M.D., Kimberly Kaplan Mauer, M.D., Pamela Kirwin, M.D., Co-Investigators. NeurogesX, Inc. January 2011 – November 2011.

A Multicenter, Randomized, Double-Blind, Placebo and Active Controlled Study Comparing the Analgesic Efficacy and Safety of ABT-639 to Placebo in Subjects with Diabetic Neuropathic Pain (Protocol M11-891). BR Stacey, M.D., Principal Investigator; Grace Chen, M.D., Kimberly Kaplan Mauer, M.D., Pamela Kirwin, M.D., Co-Investigators. Abbott Laboratories. August 2011 – November 2011.

A Phase 3b Multicenter, Double-Blind, Randomized, Placebo-Controlled Cross-Over Efficacy and Safety Study of Pregabalin in the Treatment of Patients with Painful Diabetic Peripheral Neuropathy and Pain on Walking (Protocol

A0081269). BR Stacey, M.D., Principal Investigator; Grace Chen, M.D., Kimberly Mauer, M.D., Co-Investigators. Pfizer, Inc. April 2012 – December 2012.

A Phase 4, Multicenter, Open-label, Pilot Study of Pregabalin and Prediction of Treatment Response in Patients with Postherpetic Neuralgia (Protocol A9001464). BR Stacey, M.D., Principal Investigator; Grace Chen, M.D., Kimberly Mauer, M.D., Co-Investigators. Pfizer, Inc. December 2012 – July 2013.

Characterization of Neuropathic Pain and its Subtypes in the United Sates (Protocol: A0081342). BR Stacey, M.D., Principal Investigator; Pfizer, Inc. $8,717.50, December 2015 – 11/30/2016.

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 Study to Evaluate the Safety and Efficacy of Topically Applied TV-45070 (4% and 8% w/w Ointment) in Patients with Postherpetic Neuralgia (Protocol: TV-45070-CNS-20013). BR Stacey, M.D., Principal Investigator; TEVA Branded Pharmaceutical Products R&D, Inc. $90,005, 9/22/2016-5/4/2017.

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:**


1. Rudy TE, Stacey BR. The futility of neglecting physical aspects of disability. APS Journal. 1994; 3:200-03.
2. Stacey BR, Watkins WD. Mechanisms and modulators of opioid analgesia. Current Opinion in Anesthesiology. 1994 Jul; 7:343-46.
3. Boston JR, Rudy TE, Lieber SJ, Stacey BR. Measuring treatment effects on repetitive lifting for patients with chronic low back pain: speed, style, and coordination. Journal of Spinal Disorders. 1995;8(5):342-51.
4. Rosenberg SK, Stacey BR. Postoperative Guillain-Barre syndrome, arachnoiditis and epidural analgesia. Reg Anesth. 1996; 21(5):486-89.
5. Stacey BR. Effective management of chronic pain: the analgesic dilemma. Postgrad Med, 1996 Sep; 100(3):281-96.
6. Stacey BR, Rudy TE, Nelhaus D. Management of patient-controlled analgesia: a comparison of primary surgeons and a dedicated pain service. Anesth Analg. 1997 Jul; 85(1):130-4.
7. Roach JA, Stacey BR. Acetaminophen toxicity. Orthop Nurs. 1997 May-Jun;16(3):49-55.
8. McGraw T, Stacey BR. Gabapentin for treatment of neuropathic pain in a 12-year-old girl. Clinical Journal of Pain. 1998 Dec; 14(4):354-6.
9. Segal R, Stacey BR, Rudy T, Baser S,Markham J. Spinal cord stimulation revisited. Neurological Research. 1998 Jul; 20:391-96.
10. Rowbotham M, Harden N, Stacey B, Podolnick P, Magnus-Miller L. Gabapentin for the treatment of post-herpetic neuralgia: a multicenter, double-blind, placebo-controlled study. JAMA. 1998 Dec 2; 280(21):1837-42.
11. Mathew NT, Rapoport A, Saper J, Magnus L, Klapper J, Ramadan N, Stacey BR, Tepper S. Efficacy of gabapentin in migraine prophylaxis. Headache. 2001 Feb; 41(2):119-28.
12. Rudy TE, Boston JR, Lieber SJ, Kubinski JA, Stacey BR. Body motion during repetitive isodynamic lifting: a comparative study of normal subjects and low-back pain patients. Pain. 2003; 105:319-26.
13. Stacey, BR and Glanzman, RL. Use of gabapentin for postherpetic neuralgia: results of two randomized, placebo-controlled studies. Clin Ther. 2003 Oct; 25(10):2597-608.
14. Stacey B, Parsons B, Huang S, Peyser S, Dukes E. Gabapentin and improved health status in elderly patients with postherpetic neuralgia: a pooled analysis of three clinical studies. Pharmacy and Therapeutics: P&T. 2004 Oct; 29(10):646-51.
15. Backonja MM, Stacey B. Neuropathic pain symptoms relative to overall pain rating. Journal of Pain. 2004 Nov; 5(9):491-7.
16. Sibell, DM, Colantonio AJ, Stacey BR. Successful use of spinal cord stimulation in the treatment of severe Raynaud's disease of the hands. Anesthesiology. 2005 Jan; 102(1):225-7.
17. Gore M, Brandenburg NA, Dukes E, Hoffman DL, Tai K, Stacey B. Pain severity in diabetic peripheral neuropathy (DPN) is associated with patient functioning, symptom levels of anxiety and depression, and sleep. J Pain Symptom Manage. 2005 Oct; 30(4):374-85.
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28. Stacey B, Feeman R, Emir B, D'Urso de Cruz E, Griesing T. Pregabalin significantly reduces the pain associated with diabetic peripheral neuropathy by day one of treatment. Poster presented at the 65th Scientific Sessions of the American Diabetes Association; 2005 Jun 10-14; San Diego, CA.
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**International and National Invitational Lectures:**

1. "Developing Guidelines for Program Education and Quality Improvement," American Pain Society, Annual Meeting, Orlando, FL, November 1993.
2. "Does Regional Anesthesia Improve Outcome?" and "Thoracic Epidural, Hands-On Workshop," American Society of Regional Anesthesia Refresher Course, Pittsburgh, PA, September 1996.
3. "Reflex Sympathetic Dystrophy," American Orthopaedic Foot and Ankle Society, Annual Regional Refresher Course, Vancouver, WA, October 1996.
4. "Dilemmas in Pain Management Resident Education," Society for Education In Anesthesia Meeting, San Antonio, TX, May, 1997.
5. "Acute Pain Service - Is it Worthwhile?" Panel Chair, American Society of Anesthesiologists Annual Meeting, Orlando, FL, October 1998.
6. "Other Novel Therapies for Neuropathic Pain," The Pain Society (Britain and Ireland), Annual Scientific Meeting, University of Warwick, England, April 2000.
7. "Tailoring Treatments and Mixing Psychosocial and Invasive/Interventional Therapies for Chronic Pain: Can It Be Done Well," The American Pain Society's 20th Annual Scientific Meeting, Symposium, Phoenix, AZ, April, 2001.
8. B Stacey, H Benzon, C Criscuo, J Katz. "Noninjection Techniques for Pain Management," Panel Presentation, American Society of Anesthesiologists Annual Meeting, Orlando, FL, October, 2002.
9. BR Stacey. "Neural Blockade for Neuropathic Pain," Fifth International Conference on the Mechanisms and Treatment of Neuropathic Pain, Bermuda, November 2002.
10. BR Stacey. "Rationale Use of Polypharmacy for the Treatment of Low Back Pain," 6th International Conference on the Mechanisms and Treatment of Neuropathic Pain, San Francisco, CA, Sept 18-20, 2003.
11. BR Stacey. "Two Refractory Chronic Pain Patients," Dinner Workshop presentation, 7th International Conference on the Mechanisms and Treatment of Neuropathic Pain, Bermuda, , November 4-6, 2004.
12. BR Stacey. "An Update on Neural Blockade and Other Interventional Approaches," 7th International Conference on the Mechanisms and Treatment of Neuropathic Pain, Bermuda, , November 4-6, 2004.
13. "Central Pain, Sensitization, and Other Biobehavioral Disorders," Moderator and Session Chair, Fibromyalgia Workshop: The Next Advances, Washington DC, November 11-12, 2004.
14. "Chronic Back and Neck Pain," Essentials of Pain Management Course, American Pain Society Annual Meeting, Boston, MA, April 2005.
15. "Review of Newer Therapies in Neuropathic Pain Management," American Academy of Pain Medicine annual meeting, San Diego, CA, February 24, 2006.
16. "Medical Management of Facial Pain" and "A Pain Physician's Perspective on Facial Pain" Trigeminal Neuralgia Association 6th Annual Conference, Portland, OR, September 16, 2006.
17. "Spinal cord stimulators in neuropathic pain: the evidence," 9th International Conference of the Mechanisms and Treatment of Neuropathic Pain, Bermuda, November 4-6, 2006.
18. "Complex Regional Pain Syndrome" and "Chronic Opioid Analgesic Therapy," 5th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, August 10, 2007.
19. "Preventing and Treating Neuropathic Postoperative Pain," 10th International Conference on the Mechanisms and Treatment of Neuropathic Pain, November 1-3, 2007, Snowbird City, UT.
20. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society Annual Meeting, Tampa, FL, May 2008.
21. "Medical Perspective: How should breakthrough neuropathic pain be treated?" 11th International Conference on the Mechanisms and Treatment of Neuropathic Pain, Bermuda, November 7, 2008.
22. "Postherpetic Neuralgia" Satellite Symposium: Optimizing the Management of Disease–Specific Causes of Peripheral Neuropathic Pain. American Academy of Pain Medicine 2009 Annual Meeting. Honolulu, HI, January 29, 2009.
23. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society Annual Meeting, San Diego, CA, May 2009.
24. "Complex Regional Pain Syndrome" and "Chronic Opioid Analgesic Therapy," 7th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, August 6, 2009.
25. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society 29th Annual Meeting, Baltimore, MD, May 5, 2010
26. "Pain following Spinal Surgery," Symposium at the American Pain Society 29th Annual Meeting, Baltimore, MD, May 6, 2010
27. "Complex Regional Pain Syndrome," "Chronic Opioid Analgesic Therapy," "Spinal Cord Stimulation, " 8th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, July 29-30th, 2010

28. "What is Chronic Pain?" Official Satellite Symposium, 13th World Congress on Pain, Montreal, Quebec, August, 30, 2010.
29. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society 30th Annual Meeting, Austin, TX, May 18, 2011.
30. "Treating chronic pain: what is the role of opioids?," "Spinal Cord Stimulation Review," and "Complex Regional Pain Syndrome" 9th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, August 4-5th, 2011.
31. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society 31st Annual Meeting, Honolulu, HI, May 16, 2012.
32. "Treating chronic pain: what is the role of opioids?," "Spinal Cord Stimulation Review," and "Complex Regional Pain Syndrome" 10th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, August 9-10th, 2012.
33. "Neuropathic Pain," Essentials of Pain Management Course, American Pain Society 32nd Annual Meeting, New Orleans, LA, May 8, 2013.
34. "NeuPSIG Interventional Guidelines: Spinal Cord Stimulation," 4th International Conference on Neuropathic Pain, Toronto, ON, May 25, 2013.
35. "Treating chronic pain: what is the role of opioids?," "Spinal Cord Stimulation Review," and "Complex Regional Pain Syndrome" 11th Annual Comprehensive Pain Board Review Symposium, University of Wisconsin, Madison, WI, August 8-9th, 2013.
36. "Complex Regional Pain Syndrome," "The Role of Opioids In Chronic Pain," and "Review of Spinal Cord Stimulation" Comprehensive Review of Pain Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, August 21-22, 2014.
37. "Chronic Neuropathic Pain" and "Spinal Cord Stimulation", Fundamentals of Pain Management: An Interdisciplinary Primer, American Pain Society 34th Annual Meeting, Palm Springs, CA, May 13-16, 2015.
38. "Long-Term Opioids for Chronic Non-Cancer Pain: Efficacy and Adverse Effects, Including Addiction," "Complex Regional Pain Syndrome: Assessment and Treatment," and "Role of Spinal Cord Stimulation in Chronic Pain Treatment." Comprehensive Review of Pain Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, August 13-14, 2015.
39. American Society of Regional Anesthesia and Pain Medicine (ASRA), 14th Annual Pain Medicine Meeting: "Neuropathic Pain: Evidence-Based Approach to Pharmacological Management," "Neuropathic Cancer Pain and Cancer in Pediatrics: Neuropathic Cancer Pain: Optimizing Medical Management," "Neuropathic Cancer Pain and Cancer in Pediatrics: Panel Discussion and Open Forum," "Pharmacology and Indications of Pain Medications and Adjuvants: Pharmacology and Indications of Anticonvulsants and Antidepressants," and "Pharmacology and Indications of Pain Medications and Adjuvants: Panel Discussion and Open Forum." Miami, FL, Nov. 19-21, 2015.
40. "What Is Pain?" "Use of Opioids in Chronic Pain," "Headache Overview," "Neuropathic Pain," "The Role of Interventions in Pain Treatment." American Pain Society 2016 Fundamentals of Pain Management: An Interdisciplinary Primer. Austin, TX, May 10-11, 2016
41. "Interventional Pain Management in Patients of Neuropathic Pain; Considerations for Patient Selection and Outcome Measures." Canadian Pain Society, Vancouver, BC, May 24, 2016
42. "Opioids for Chronic Pain: Rationally Starting, Continuing, and Tapering." PAINWeek, Las Vegas, NV, September 9, 2016.
43. "I Need a Refill: 8,000 Patients Search for a New Pain Home in a Statewide Response to a Real Medical Crisis," "Mobilizing Societies, Healthcare Systems, and Pain Clinicians in Advocating for Quality Patient Care: Lessons Learned from Washington State." 33rd Annual American Academy of Pain Medicine, Orlando, FL, March 16, 2017.
44. "Neuropathic Pain: Still Unrecognized and Undertreated: Where Are We in 2017?." Moderator. "Neuropathic Pain: Overview of Epidemiology and Impact." Speaker. 33rd Annual American Academy of Pain Medicine, Orlando, FL, March 18, 2017.
45. "When to Get Invasive: Who is the right candidate for this treatment?," "You Can't Go It Alone: The Pragmatic Approach to Multidisciplinary Management of Pain." The Fundamentals of Translational Pain Medicine: Integrating Science with Clinical Care. American Pain Society Annual Meeting, Pittsburgh, PA. May 17, 2017.
46. "Neuropathic Guidelines: Wisdom or Waste of Time?" PAINWeek, Las Vegas, NV, September 7, 2017.
47. "Assessing opioid use and opioid outcomes (e.g., dosage, time to event, duration of use)." IMMPACT XXI, Washington, DC, July 26, 2018.

48. "Opioids: Rationally Starting Them, Rationally Stopping Them," "Spinal Cord Stimulation: 2018 Update," "Complex Regional Pain Syndrome." Comprehensive Review of Pain Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI, August 16, 2018.
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**Regional and Local Invitational Lectures:**

1. "Spinal Opioids," Annual Meeting Pennsylvania Cancer Pain Initiative, Pittsburgh, PA, April 1992.
2. "Chronic Pain Management," Rehabilitation Grand Rounds, St. Francis Medical Center, Pittsburgh, PA, September 1992.
3. "Basics of Pain," St. John's Medical Center, Steubenville, OH, November 1992.
4. "Pain Assessment in the I.C.U.," St. Francis Medical Center, Critical Care Meeting, Taos, NM, April 1993.
5. "Pharmacologic Management of Cancer Pain," Chartwell Home Therapies Seminar, Pittsburgh, PA, November 1993.
6. "Pharmacologic Management of Chronic Pain," Dubois Medical Society, Dubois, PA, November 1993.
7. "Pharmacologic Management of Chronic Pain," 21st Annual Refresher Course in Family Practice for University of Pittsburgh Medical Center, Pittsburgh, PA, June 1994.
8. "Pain Management," Advanced Clinical Principles Course, Laroche College, Pittsburgh, PA, March 1995.
9. "Conservative Management of Patients with Acute and Chronic Low Back Pain," Bradford Regional Medical Center, Bradford, PA, April 1995.
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.
13. "Medications for Chronic Pain," Southwest Washington Medical Center, Family Practice Residency lecture series, Vancouver, WA, May, 1997.
14. "Chronic Pain Overview," Mid-Columbia Medical Center, Nursing Grand Rounds, The Dalles, OR, January 1998.
15. "Principles of Chronic Pain Management," Mid-Columbia Medical Center, Medical Staff Meeting, The Dalles, OR, January 1998.
16. "Chronic Pain: Pharmacologic Management," 29th Annual Family Practice Review, Oregon Health & Science University, Portland, OR, February 1998.
17. "Advances in Cancer Pain management," Portland Oncologic Nursing Society, Portland, OR, February 1998.
18. "Update in Chronic Pain Management," Yale University, Department of Anesthesiology, New Haven, CT, May 1998.
19. "Approaches to the Treatment of Common Neuropathic Pain Problems," Yale University Pain Refresher Course, New Haven, CT, May 1998.
20. "Treatment of Neuropathic Pain," Physician Education Series, Norwalk Hospital, Norwalk, CT, September 1998.
21. "Money Matters: Poverty and Health Care Access," 18th Annual Gender Studies Symposium (Examining the Issues: Gender, Poverty and Health), Lewis and Clark College, Portland, OR, March 1999.
22. "Medical Approaches to Chronic Pain," Annual Sommers Memorial Lecture Series, Portland, OR, May 1999.
23. "Neuropathic Pain" and "Pain the Fifth Vital Sign," Oregon Society of Anesthesiologists, Spring Scientific Meeting, Salishan Lodge, Newport, OR, May 1999.
24. "Pain Management: Focus on Back Pain," Oregon Health & Science University 31st Annual Family Practice Review, Portland, OR, February 2000.
25. "Chronic Pain Management," Oregon Health & Science University Internal Medicine Review, Portland, OR, April 2000.

26. “Neuropathic Pain Assessment and Treatment,” University of Washington, Department of Neurology Grand Rounds, Seattle, WA, January 4, 2001.
27. "Epidural and Intrathecal Pain Treatment," OHSU Pain Awareness Week Educational Lecture, OHSU, February 5, 2001.
28. “Chronic Pain Assessment and Treatment,” Southwest Washington Medical Center, Family Medicine Case Conference, Vancouver, WA, March 5, 2001.
29. "Pain Management," Marquam Hill Lecture Series. Oregon Health & Science University. March 15, 2001.
30. “Pharmacological Therapies” and “Integrated Multidisciplinary Pain Programs,” Advances in Pain Therapy, 4th Biennial University of Wisconsin Pain Conference, Madison, WI, October 19, 2001.
31. “Managing Chronic Pain,” Providence Milwaukie Hospital Quarterly Medical Staff Meeting, Milwaukie, OR, November 6, 2001.
32. “Outpatient Pain Management,” Internal Medicine Residents Weekly Conference, Providence St. Vincent Medical Center, Portland, OR, February 4, 2002.
33. “Neuropathic Pain,” Oregon Health & Science University Annual Family Practice Review, Portland, OR, February 13, 2002.
34. “Acute Pain Management,” Oregon Health & Science University Annual Family Medicine Review, Portland, OR, February 10, 2003.
35. “Acute Pain Assessment and Treatment,” 14th Annual Northwest States Trauma Conference, Sunriver, OR, April 6-8, 2003.
36. “Multimodal Pain Management,” Anesthesiology and Surgery Combined Education Course, Southwest Washington Medical Center, Vancouver, WA, September 10, 2003.
37. “Chronic Pain,” Lecture at OHSU Complementary and Alternative Medicine (CAM) Grand Rounds, May 18, 2005
38. “Pre-emptive analgesic and use of opioids in chronic Pain” Western Neurosurgical Society Pain Symposium, Squaw Valley, NV, September 20, 2005
39. “Pain Management in Older Adults,” Oregon State University Gerontology Annual Conference, Corvallis, OR, April 7, 2006.
40. “Finding and Treating Neuropathic Pain,” Terrence M. Murphy Memorial Lecturer in the Department of Anesthesiology and Pain Center at the University of Washington, Seattle, WA, April 11, 2006.
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.
44. “Neuropathic Pain: Overview and Treatment Options,” 38th Annual Family Medicine Review, Oregon Health & Science University Division of Continuing Medical Education, February 13, 2007.
45. “Optimizing Chronic Pain Medication,” 14th Annual Internal Medicine Review, April 13, 2007.
46. “Postherpetic Neuralgia,” Oregon Health & Science University 39th Annual Family Medicine Review, Portland, OR, February 28, 2008.
47. “Neuropathic Pain,” Western Pain Society Annual Conference, Portland, OR, April, 2008.
48. “Neuropathic Pain” Brain Research Awareness and Information Network, Multnomah Athletic Club, Portland, OR, September 21, 2009.
49. “Complex Regional Pain Syndrome” OHSU hand conference, April 29, 2010.
50. “Diabetic Peripheral Neuropathy” OHSU Family Medicine Grand Rounds, August 18, 2010.
51. “Opioids and Chronic Pain” Opioid Prescription Summit, State of Oregon, Portland, OR, November 22, 2010.
52. “Opioids, Diversion, and Chronic Pain” Community Action To Reduce Substance Abuse quarterly meeting, Portland, OR, January 5, 2011
53. “The Mystery of Pain” Bing Pain Lounge: OHSU Medical Breakthroughs. Darnall BD & Stacey BR (co-presenters) Topic: Taped and internet broadcast. Portland, OR, February 9, 2011.
54. “Opioids: Use with Caution” 2011 Annual Musculoskeletal Update for Primary Care: Urgencies & Emergencies in Musculoskeletal Medicine; Sunriver, OR, March 26, 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
56. “Pain Control in Trauma: What’s New?” Annual Northwest States Trauma Conference, Sunriver, OR. April 14, 2011
57. “Treating Chronic Pain: Are Opioids Necessary?” Tuality Hospital & Palliative Care of Washington County symposium: “Everything you wanted to know about pain,” Hillsboro, OR, May 26, 2011

58. "Chronic Pain, Neuropathic Pain and Yoga" Yoga of Awareness for Chronic Pain Teacher Training Course, OHSU, June 6, 2011.
59. "The role of Opioids in Treating Chronic Pain" Tuality Hospital Medical Clinical Service, Hillsboro, OR, July 26, 2011.
60. "Multidisciplinary Management of Chronic Pain" Clinical Neuroscience at the Oregon Coast, OHSU Brain Institute, Gleneden Beach, OR, September 23, 2011.
61. "Complex Regional Pain Syndrome," Oregon Pain Society, Portland Chapter Monthly Meeting, Portland, OR, November 15, 2011.
62. "Opioids: The two ends of the spectrum" Workshop: Opioids for chronic pain management: should we take that path? OHSU Pain Day, February 28, 2012.
63. "Chronic Pain. Opioids" American Academy of Professional Coders, Portland Chapter, monthly meeting, April 18,2012.
64. "What is Chronic Pain? What to do about it?" VA Medical Center, Portland OR, NW Pain Lecture Series, April 26, 2012.
65. "Chronic Pain, Opioids, and Neuropathic Pain" Yoga of Awareness for Chronic Pain Teacher Training Course, OHSU, May 29, 2012.
66. "Treating chronic pain: are opioids necessary?" Salem Clinic Staff Conference, Salem, OR, September 24, 2012.
67. "Procedures: show me the evidence!" OHSU Pain Day, February 28, 2013.
68. "Painful Diabetic Peripheral Neuropathy" St. John Medical Center Grand Rounds, Longview, WA, April 2, 2013.
69. "Painful Diabetic Peripheral Neuropathy" 22nd Annual Ashland Endocrine Conference OHSU, Ashland, OR, July 27, 2013
70. "Diabetic Neuropathy Update" American Diabetes Association Annual Practice Update, Portland, OR, November 1, 2013
71. "Chronic Pain and Opioids" Columbia Memorial Medical Center Grand Rounds, Astoria, OR, November 12, 2013
72. "The Problem of Acute Pain" OHSU Pain Day, April 11, 2014
73. "Physiology of Spinal Cord Stimulation" and "Indications for Spinal Cord Stimulation" 11th Annual Mazama Spine Summit, Winthrop, WA, February 8, 2015
74. "Neuropathic Pain: Overview, Guidelines, Databases, and Procedures" University of Washington, Department of Neurology. Seattle, WA, April 16, 2015.
75. "Pharmacology and Indications of Pain Medications and Adjuvants: Panel Discussion and Open Forum," 8th Annual John D. Loeser Pain Conference – CME Lecture: Improving Care, Improving Outcomes in Primary Care, Shoreline, WA, October 23, 2015
76. "Spinal Cord Stimulation: 2016 Update" Yakima Low Back Pain Conference, Yakima, WA, March 19, 2016
77. "CRPS/Neuropathic Pain," University of Washington, Department of Orthopaedics and Sports Medicine, Hand Conference, Seattle, WA, May 27, 2016.
78. "Five New Things: Pain," University of Washington, Department of Neurology, Grand Rounds, Seattle, WA, July 14, 2016.
79. "What is Pain", "Opioids In Chronic Pain", "Opioid Overuse and Tapering", "Treating Chronic Pain Without Opioids" Sitka Community Hospital, Sitka, AK, July 29, 2016. Course Director.
80. "Pain Management Without Opioids," 9th Annual John D. Loeser Pain Conference, Moving Ahead with Pain Treatment in Primary Care, Shoreline, WA, November 4, 2016.
81. "Treating Pain: Not Just Opioids!", 10th Annual John D. Loeser Pain Conference, Updates on Essentiaol Issues. Shoreline, WA, October 27, 2017.
82. "Spinal Cord Stimulation: Trial," "SCS: Implant," "SCS Cadaver Learning and Life Demo" 4th Annual Interventional Pain Management Course. Seattle Science Foundation. Seattle, WA, November 17, 2017. https://www.youtube.com/watch?v=Yme7AxnIRWI
83. "Interventional Pain Techniques,"University of Washington, Department of Anesthesiology and Pain Medicine. Seattle, WA, December 6, 2017.
84. "Non-Opioid Pain Management," Women's Healthcare Update. University of Washington, School of Medicine, Department of Obstetrics and Gynecology. Seattle, WA, March 23, 2018.
85. "Multiple Sclerosis and Pain," National Multiple Sclerosis Society, Seattle, WA, June 9, 2018
86. "Spinal Cord Stimulation Procedure Trial Overview" and "Implant Techniques of Spinal Cord Stimulation & Dorsal Root Ganglion Systems." 5th Annual Interventional Pain Management Course. Seattle Science Foundation. Seattle, WA, November 18, 2018.

## 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:**

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| 1991-1996 | Established ACGME-accredited pain fellowship with first-time written curriculum, University of Pittsburgh Medical Center |
| 1996-1998 | Revamped curriculum for ACGME-accredited pain fellowship |
| 2002-2005 | Member, Complementary and Alternative Medicine (CAM) Science Curriculum Task Force, Oregon Health & Science University |
| 2003-2005 | Third Year Students' Continuity Curriculum Task Force, Oregon Health & Science University |

**Educational Publications:**

University of Pittsburgh Medical Center brochure: "House Officer's Guide to PCA," BR Stacey and C Dunwoody, July 1991, updated several times.

**Educational Conference Presentations:**

"Pharmacologic Management of Pain," Organized all-day 4th year medical student course, University of Pittsburgh Medical Center, April 1996.
"Dilemmas in Pain Management Resident Education," Society for Education in Anesthesia Meeting, San Antonio, TX, May, 1997.
"Chronic Pain", Course Director, Sitka Community Hospital, Sitka, AK, July 29th, 2016.

## EDUCATIONAL ACTIVITIES

**Medical Student Education:**

"Airway Management and Intravenous Skills," University of Pittsburgh medical students, 1988-89.
"Local Anesthetics and Regional Anesthesia," University of Pittsburgh medical students, 1989.
"Pain and Suffering," 3rd year medical student lecture, University of Pittsburgh Medical Center, July, September, November 1989; January, March, April 1991; September 1992; January & March 1993.
"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.
"Acute Pain Management," 3rd year medical student lecture, Anesthesiology Rotations, Oregon Health & Science University, September 2001, May & December 2002.
"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.
"Opiates and Post-Op Pain," medical student lecture, Oregon Health & Science University, April & September 2004.
Neuroscience and Behavior course, 2nd year medical students, Oregon Health & Science University, small group presentation and discussion on analgesic drugs, January 1997, 1998, 2006, 2007, 2011
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.
"Positioning and Complications," CA-1 Lecture Series, University of Pittsburgh Medical Center, February 1991, October 1992, October 1993.
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.
"Chronic Pain Management," Pediatric Anesthesiology Fellows, University of Pittsburgh Medical Center, May 1993.
"Principles of Interdisciplinary Pain Management," Fellowship Didactic Series, University of Pittsburgh Medical Center, August 1993
"Anatomy and Physiology," Fellowship Didactic Series, University of Pittsburgh Medical Center, July 1993, July 1994, July 1995.
"Principles of Pain Management," lecture to Internal Medicine Residents, University of Pittsburgh Medical Center, February 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.
"Post-Op Pain Management," Veterans Administration Medical Center, Orthopedic Resident Lecture, December 19, 2001.
"Mock Oral Exam for Oregon Health & Science University Anesthesia Resident," March 8, 2002.
"Medications for back pain," Fellowship Didactic Lecture, October 6, 2003.

"Postherpetic Neuralgia," Fellowship Didactic Lecture, December 1, 2003.
"Cancer Pain," Fellowship Didactic Lecture January 26, 2004.
"Atypical treatment for Neuropathic Pain," Fellowship Didactic Lecture, February 9, 2004.
"Chronic Pain Management," lecture to CA-3 residents, June 23, 2004.
"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.
"Spinal & Epidural Anesthesia," lecture to CA-1 residents, OHSU, July 2004.
"Neuropathic Pain 1," Fellowship Didactic Lecture, July 19, 2004.
"Medical Economics 1," Fellowship Didactic Lecture, August 30, 2004.
"Analgesic Pharmacotherapy 3 (NSAIDS & Steroids)," Fellowship Didactic Lecture, September 13, 2004.
"Epidural Injection Rationale & Techniques," Fellowship Didactic Lecture, September 20, 2004.
"Analgesic Pharmacotherapy 2 (Anticonvulsant Drugs)," Fellowship Didactic Lecture, October 4, 2004.
"Multidimensional Assessment of Pain," Fellowship Didactic Lecture, October 9, 2006.
"Peripheral Nerve Blocks in Chronic Pain," Fellowship Didactic Lecture, November 22, 2004.
"Cryotherapy & Neurolytic Procedures," Fellowship Didactic Lecture, November 29, 2004.
"Intrathecal Drug Administration Systems," Fellowship Didactic Lecture, January 10, 2005.
"Analgesic Pharmacology 4 (Antidepressants)," Fellowship Didactic Lecture, January 24, 2005.
"Neurological Testing (EMG/QSART,ETC)," Fellowship Didactic Lecture, February 7, 2005.
"Back Pain for Primary Care," Fellowship Didactic Lecture, March 21, 2005.
"Phantom pain," Fellowship Didactic Lecture, April 18, 2005.
"Abdominal & Pelvic pain conditions," Fellowship Didactic Lecture, May 16, 2005.
"Fibromyalgia and other Strange Things," Fellowship Didactic Lecture, May 23, 2005.
Incoming Residents and Fellow Hospital Orientation "Pain in the House," June 21 & 30, 2005, June 30, 2006, July 14, 2006, June/July 2007, July 2008, June 22, 2009.
"NMDA Antagonists," Fellowship Didactic Lecture, June 27, 2005.
"Neuropathic Pain 1," Fellowship Didactic Lecture, July 18, 2005.
"Acute Pain Management 1," Fellowship Didactic Lecture, August 1, 2005.
"Analgesic Pharm 2 (Anticonvulsants & Antidepressants)," Fellowship Didactic Lecture, August 29, 2005.
"Epidural Injection Rationale & Techniques," Fellowship Didactic Lecture, October 17, 2005.
"Medical Economics 1," Fellowship Didactic Lecture, October 31, 2005.
"Intrathecal Drug Administration Systems," Fellowship Didactic Lecture, November 7, 2005.
"Acute Pain Management 2 (Plexus Anesthesia in outpatients)," Fellowship Didactic Lecture, November 14, 2005.
"Preventive Analgesia," Fellowship Didactic Lecture. February 6, 2006, June 18, 2007.
"Spinal Cord Stimulation," Fellowship Didactic Lecture, March 3, 2006, January 29, 2007, August 13, 2007.
"Acute Pain," lecture to CA-3 residents, June 3, 2006.
"Fibromyalgia & other Mysteries," Fellowship Didactic Lecture, June 12, 2006
"Acute Post-Op Pain," lecture to CA-2 residents, June 14, 2006.
"Pain in Cancer 1," Fellowship Didactic Lecture, August 28, 2006.
"Multidimensional Assessment of Pain," Fellowship Didactic Lecture, October 9, 2006.
"Peripheral Nerve Blocks in Chronic Pain," Fellowship Didactic Lecture, November 20, 2006.
"Fibromyalgia Intercystal Cystitis, Loin Pain, Hematuria, Erythromelalgia," Fellowship Didactic Lecture. March 5, 2007
"Outpatient Treatment of Back Pain (and quick neuropathic overview)," lecture to Internal Medicine residents, Fellowship Didactic Lecture November 14, 2007.
"Spinal & Epidural Anesthesia," lecture to CA-2 residents, November 29, 2007.
"Trigeminal Neuralgia & Atypical Face Pain," Fellowship Didactic Lecture, December 10, 2007.
"CRPS," Fellowship Didactic Lecture, December 31, 2007.
"TENS and other less invasive Stimulation Modalities," Fellowship Didactic Lecture, September 15, 2008.
"Optimizing Chronic Pain Medications," Fellowship Didactic Lecture, October 27, 2008.
"Complex Regional Pain Syndrome and Prevention," Fellowship Didactic Lecture, November 17, 2008.
"Treating Pain without Opioids," Fellowship Didactic Lecture, 12/8/2008.
"Postherpetic Neuralgia," Fellowship Didactic Lecture, 3/9/2009.
"Management of Acute Postoperative Pain" CA-3 lecture, 6/9/2009.
"Neuropathic Pain Overview," Fellowship Didactic Lecture, 7/6/2009.
"Opioid Therapy," Fellowship Didactic Lecture, 7/27/2009.
"Postoperative Pain Management: Improving function and Outcomes," Fellowship Didactic Lecture, 1/4/2010.
"Cancer Pain," Fellowship Didactic Lecture, 3/1/2010.

"Opioid Management," OHSU Richmond Family Health Center resident lecture, 5/12/2010.
"Central Sensitization and Atypical Pain Syndromes," Fellowship Didactic Lecture, 5/17/2010.
"Opioid Therapy," Fellowship Didactic Lecture, 8/2/2010.
"What is Chronic Pain?" Family Medicine Resident Lecture, 8/15/2010.
"Neuropathic Pain," Fellowship Didactic Lecture, 11/8/2010.
"Diabetic Neuropathy," Fellowship Didactic Lecture, 12/6/2010.
"Central Sensitization and specific pain syndromes," Fellowship Didactic Lecture, 2/7/11.
"Trigeminal Neuralgia & Atypical Face Pain," Fellowship Didactic Lecture, 3/14/2011.
"Postoperative Pain Control: Improving Function and Outcomes, & Epidural Tips," Fellowship Didactic Lecture, 4/11/2011.
Mock Oral Examination, APOM, 4/11/2011.
"Opioids: clinical practice interactive discussion," Fellowship Didactic Lecture, 6/6/2011.
"Acute Pain," CA-1 Didactic Lecture, APOM, 6/13/2011.
"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.
"Pain Overview: Acute Pain" General Surgery Orientation, OHSU 7/30/2012.
"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:**

"Anesthesia Management and Acute Pain," senior nurse anesthesia students, University of Pittsburgh Medical Center, November 1991.
"Regional Anesthesia and Pain," senior nurse anesthesia students, University of Pittsburgh Medical Center, December 1992, November 1993.
"Diabetic Pain Management," diabetes nursing educators, University of Pittsburgh Medical Center, June 1993.
"Post-Op Pain Management," senior nurse anesthesia students, University of Pittsburgh Medical Center, November 1994.
"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 ACITVITIES**
**Departmental Lectures:**

"Anesthesia and Mediastinal Masses," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, March 1989.
"Complications of Regional Anesthesia," monthly morning lecture, Presbyterian University Hospital, October 1989.
"Anesthesia for Laser Surgery," Presbyterian University Hospital, November 1989.

"New Concepts in Acute Pain," Eye and Ear Morbidity and Mortality Conference, University of Pittsburgh Medical Center, July 1991.
"Continuous versus Bolus Epidural Narcotics," Pain Evaluation and Treatment Institute Journal Club, University of Pittsburgh Medical Center, January 1992.
"Epidural Steroids," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, January 1992.
"Peripheral Opioids," Department of Anesthesia Journal Club, University of Pittsburgh Medical Center, February 1993.
"Adjuvant Medication for Neuropathy," Pain Evaluation and Treatment Institute Journal Club, University of Pittsburgh Medical Center, August 1993.
"Acute Pain Management," Magee Women's Hospital – Anesthesia Department, November 1993.
"Regional Anesthesia," Presbyterian University Hospital Recovery Room, May 1994.
"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.
"Acute Pain Management," Eye and Ear Anesthesia, University of Pittsburgh Medical Center, Inservice, 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.
"Pre-Operative Pain Management Issues," Pre-Admission Testing Clinic Inservice, Oregon Health Sciences University, February 2000.
"Post-Operative Pain Management," Pre-Admission Testing Clinic Inservice, Oregon Health Sciences University, February 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.
"Short Stay Acute Pain Issues" Short Stay Nursing Inservice, 2004.
"Pre-Op Prevention of Post-Op Pain" Lecture at Oregon Health & Science University Department of Anesthesiology and Peri-Operative Medicine Journal Club, June 6, 2005.
"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.
"Preemptive and Preventive Analgesia," faculty moderator, Journal Club, Oregon Health & Science University, December 6, 2006.
"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:**

"Diabetic Pain Management," Diabetes Center, University of Pittsburgh Medical Center, January 1993.
"Chronic Pain and the Pain Institute," University of Pittsburgh Medical Center Social Work Department, February 1993.
"Nerve Blocks in Chronic Pain," Physical Medicine and Rehabilitation, Grand Rounds, University of Pittsburgh Medical Center, January 1995.
"Chronic Pain Research at the Pain Institute: Interdisciplinary Approaches"; Research Minisymposium; Montefiore University Hospital, Pittsburgh, PA, May 1995.
"Acute Pain Management," Orthopedic Grand Rounds, University of Pittsburgh Medical Center, September 1995.
"Neuropathic Pain," Vascular Surgery Lecture Series, Oregon Health Sciences University, January 1997.
"Anesthesia & Analgesia and Surgical Outcome," Department of Surgery Grand Rounds, Oregon Health Sciences University, April 1997.
"Outpatient Pain Management," Department of Dermatology Conference, Oregon Health Sciences University, May, 1997.
"Updates in Acute Pain Management," Surgery Grand Rounds, Oregon Health Sciences University, April 1998.
"Pharmacologic Management of Neuropathic Pain," Videotape Series, Oregon Health Sciences University, Donald Girard, M.D., Moderator, October 1998.
"Management of Chronic Pain," Orthopaedic Surgery Grand Rounds, Oregon Health Sciences University, November 1999.
"Postoperative Pain Management," Obstetrics and Gynecology Conference, Oregon Health Sciences University, March 2000.
"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.
"Ongoing Pain - What Can Be Done About It?" Saturday, May 5, 2001. OHSU "Healthy Talk." Symposium chair.
"Treating Cancer Pain," moderator and speaker, Healthy Talks Program on "Pain Management: Past Treatments and Present Alternatives," Oregon Health & Science University, February 2, 2002.
"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," Neurosurgery Grand Rounds, Oregon Health & Science University, February 3, 2003.
"Neuropathic Pain," lecture for Pain Awareness Week, Oregon Health & Science University, February 6, 2003.
"Complex Regional Pain Syndrome and Neuropathic Pain," Hand Conference, Plastic Surgery, Oregon Health & Science University, December 2004, December 9, 2005 and December 8, 2006, December 2007.
"Chronic Pain," lecture at Complementary and Alternative Medicine (CAM) Grand Rounds, Oregon Health & Science University, May 18, 2005.
"Screening for Pain Options for Developing a Clinically Relevant Management Plan" and case study presentation, Advances in Pain Management Seminar Series, Portland, Oregon, December 13, 2005.
"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.
"CRPS and Acute Pain Management," OHSU Hand Conference, April 21, 2011.
"CRPS and Neuropathic Pain," OHSU Hand Conference April 19, 2012.
"CRPS," OHSU Hand Conference, April 18, 2013.

"Pain Overview" OHSU Housestaff Orientation June 18, 2013.
"State of Pain" Department of Anesthesiology and Pain Medicine, University of Washington, May 19, 2015.
"Treating Pain Without/Beyond Opioids," Department of Family Medicine, Annual Advances in Family Medicine & Primary Care. Seattle, WA. September 11, 2018.

**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
"Pain Management," interview on KOTK "Smart Fitness" Radio Show, February 22, 2004.
"Treating Pain," Rotary Club of East Portland, September 6, 2007.
"Community Forum: Managing Chronic Pain" Sitka Alaska, July 29, 2016.
"UW doctors pioneering advanced opioid-free pain treatments," KIRO Radio, Seattle, WA, November 2016

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Agency medical director comments

# 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

Washington State Health Care Authority

## 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

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## The four ablation technologies are different

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

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## 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

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## Agency medical director concern level

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

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## 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.

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## Utilization – public employee benefit board (PEBB)

**PEBB/UMP**

| Year | Unique Patients | Procedures | Average Procedures/ Patient | Average Paid/ Ablation | Total Paid All Services Ablations |
|---|---|---|---|---|---|
| 2015 | 23 | 39 | 1.7 | $292 | $30,801 |
| 2016 | 21 | 32 | 1.5 | $288 | $24,582 |
| 2017 | 27 | 29 | 1.0 | $361 | $29,769 |

71 unique patients over three years

**PEBB Medicare**

| Year | Unique Patients | Procedures | Average Procedures/ Patient | Average Paid/ Ablation | Total Paid All Services Ablations |
|---|---|---|---|---|---|
| 2015 | 21 | 26 | 1.2 | $107 | $3,778 |
| 2016 | 39 | 50 | 1.3 | $105 | $7,654 |
| 2017 | 34 | 48 | 1.4 | $80 | $6,293 |

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

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## Utilization - Medicaid

**Medicaid: MCO and FFS**

| Year | Unique patients | Procedures | Average procedures/patient | Average paid ablation | Total paid all service ablation |
|---|---|---|---|---|---|
| 2015 | 30 | 43 | 1.4 | $81 | $20,629 |
| 2016 | 27 | 42 | 1.5 | $155 | $32,569 |
| 2017 | 28 | 40 | 1.4 | $120 | $22,515 |

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

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## Utilization - L&I

| Year | Unique patients | Procedures | Average procedures/patient | Average paid ablation | Total paid all service ablation |
|---|---|---|---|---|---|
| 2015–2017 | 19 | 74 | 3.9 | $743 | $98,255 |

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

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## 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, and
  - Patient characteristics
- What are the cost-effectiveness and other economic outcomes of PNA for limb pain?

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## 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

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## 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)

| Study/Year/n | Technology | Comparator | Outcome | Results | N and k | SOE |
|---|---|---|---|---|---|---|
| Landsman/2013 /n=17 | Conventional RF | Sham | Pain at 4 wk | statistically significant improvement | N=17 | Very low |
| | | | NA | NA | | |
| Wu/2017 /n=36 | Pulsed RF | Sham | Pain at 12 wk | statistically significant improvement | N=36 | Very low |
| | | | Function/pain (AOFAS) at 12 wk | statistically significant improvement | | |

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## The strength of evidence (SOE) is very low for all three technologies used for chronic knee pain

| Author/ Year/n | Technology | Comparator | N and k | SOE |
|---|---|---|---|---|
| Choi /2011 /n=35 | Conventional RF | Sham | N=220 K=5 | Very low |
| El-Hakein /2018 /n=60 | | Medication | | |
| Qudsi-Sinclear /2016 /n=28 | | Genicular nerve blocks | | |
| Sari /2016 /n=73 | | IAS | | |
| Ray/2016 /n=24 | | Hyaluronic acid injection | | |
| Davis /2018 /n=151 | Cooled RF | IAS | N=151 K=1 | Very low |
| Radnorich /2017 N=180 | Cryoablation | sham | N=180 k= 1 | Very low |

IAS: intra-articular steroid injection

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## 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

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

IAS: intra-articular steroid injection

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## 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.

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## Cost-effectiveness

- No evidence found

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## National Coverage Determination (NCD)

- The CMS dos not have a coverage determination on peripheral nerve ablation.

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## Selected payers' coverage policy

| Payer | Policy | Effective time |
|---|---|---|
| BlueCross BlueShield NC | Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered investigational. | 2017-2018 |
| Aetna | Aetna considers pulsed radiofrequency experimental and investigational for all indications, including osteoarthritis of the knee and plantar fasciitis | 2018-2019 |
| Cigna | 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 | 2018-2019 |
| Regence | Regence considers **cryoablation** (CPT 0440T and 0441T) investigational, including imaging guidance, for upper and lower distal/peripheral nerve | 2018 |

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## 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

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## Questions?

**More information:**
www.hca.wa.gov/about-hca/health-technology-assessment

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Washington State Health Care Authority

**Order of scheduled presentations:**

Peripheral nerve ablation for limb pain

| | Name |
|---|---|
| **1** | Michael Dana |
| **2** | John DiMuro, DO, MBA |
| **3** | Anne Stefurak |

## Disclosure

Any unmarked topic will be considered a "Yes"

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

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

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

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

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

I certify that I have read and understand this Conflict of Interest form and that the information I have pro[redacted] of this date.

X [redacted] 12/21/2018 Michael Dana

*Signature* *Date* *Print Name*

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

Email Address: Michael.Dana@Avanos.com

Phone Number: (253) 229-8909

[redacted]

**Subject:** Michael Dana Testimony & Participant Conflict Disclosure Form

**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"

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

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

ANANOS

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

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

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

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

X [redacted] 12/20/2018
Date

Dr. John DiMuro
Print Name

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

Email Address: JohnDiMuro@gmail.com

Phone Number: (775) 842-5742

[redacted]

**From:** Weaver, Diane <Diane.Weaver@avanos.com>
**Sent:** Friday, December 21, 2018 2:11 PM
**To:** HCA ST Health Tech Assessment Prog
**Cc:** Weaver, Diane; Dana, Michael; Browne, Craig
**Subject:** DiMuro testimony for Washington State

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.

**From:** DiMuro Pain Management <dimuropainmanagement@gmail.com>
**Sent:** Friday, December 21, 2018 1:37 PM
**To:** Weaver, Diane <Diane.Weaver@avanos.com>
**Cc:** John DiMuro <johndimuro@gmail.com>
**Subject:** [EXTERNAL] DiMuro testimony for Washington State

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. hile 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

**Dr. John DiMuro**
**Board-Certified Anesthesiology & Pain Medicine**

*DiMuro Pain Management*
*1000 Caughlin Crossing, Unit 55*
*Reno, NV 89519*
*DiMuroPainManagement@gmail.com*
*Phone: (775) 828-9665*
*Fax: (775) 622-4150*

## Disclosure

Any unmarked topic will be considered a "Yes"

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

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® cooled radiofrequency technology.

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

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 [redacted] 12/20/18 ANNE STEFURAK

*Signature* *Date* *Print Name*

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# Peripheral Nerve Ablation for the Treatment of Limb Pain

Washington State Health Care Authority
Health Technology Clinical Committee
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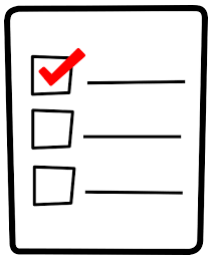
## Outline

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



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## 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

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## 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

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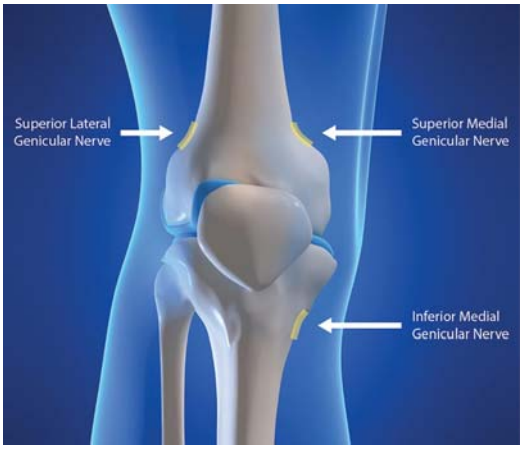
## Anatomical Location for Nerve Ablation–Knee




Nerve ablation for the knee targets three genicular nerves

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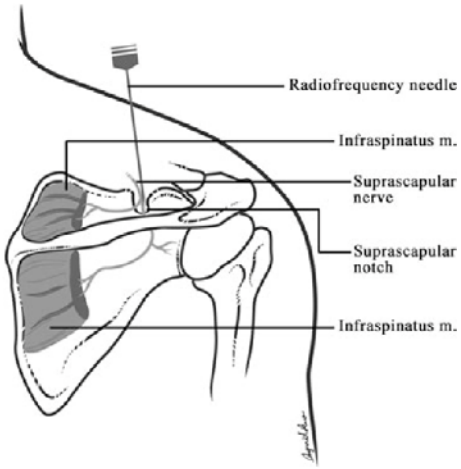
Source: Kidd et al., 2018

## Anatomical Location for Nerve Ablation–Shoulder




Nerve ablation in the shoulder targets the SSN at the suprascapular notch

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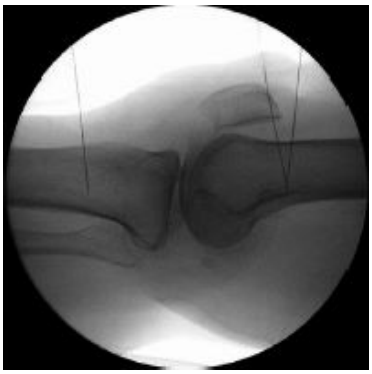
Source: Liliang et al., 2009

## Peripheral Nerve Ablation Procedure

PNA procedures conducted under sterile conditions. Picture shows RF cannulae inserted into the knee, attached to an RF generator.

Source: Qudsi-Sinclair et al., 2017



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

Source: Sari et al., 2016

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## 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

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## 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

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# 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)

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## 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?

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## 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

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## 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

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## 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

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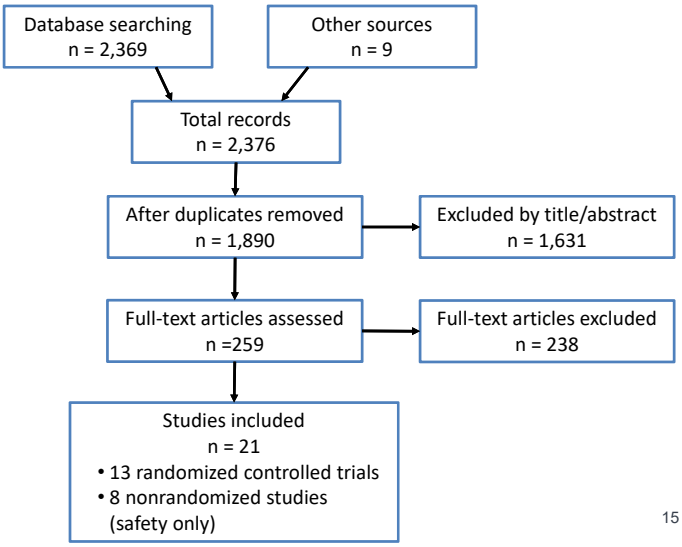
## PRISMA Study Flow Diagram

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## 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

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## Overall Quality of Evidence

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

| | |
|---|---|
| High | Very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect |
| Moderate | True effect is likely to be close to the estimate of the effect, but there is a possibility that it is different |
| Low | 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 |
| Very Low | 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 |

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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

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## 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

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## Common Outcome Measures: Pain

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

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# 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

| Technology | Knee | Shoulder | Plantar Foot |
|---|---|---|---|
| Conventional RFA | 5 | - | 1 |
| Pulsed RF | - | 4 | 1 |
| Cooled RF | 1 | - | - |
| Cryoneurolysis | 1 | - | - |

- 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

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## RCTs: Knee Pain–Conventional RFA

| Citation<br>Country | Total N<br>Duration | Comparator |
|---|---|---|
| Choi et al., 2011<br>South Korea | Total N = 35<br>12 weeks | Sham procedure |
| El-Hakeim et al., 2018<br>Egypt | Total N = 60<br>6 months | Oral paracetamol, diclofenac, and PT |
| Ray et al., 2018<br>India | N = 24<br>12 weeks | IA hyaluronic acid |
| Sari et al., 2016<br>Turkey | Total N = 73<br>3 months | IA betamethasone |
| Post-TKA subjects<br>Qudsi-Sinclair et al., 2016<br>Spain | Total N = 28<br>12 months | IA triamcinolone |

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## 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%

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## 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

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## GRADE Table: Knee Pain–Conventional RFA

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

Detailed GRADE quality of evidence tables in Appendix E

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## RCTs: Knee Pain–Cooled RF

| Citation Country | Total N Duration | Comparator |
|---|---|---|
| Davis et al., 2018<br>U.S. | Total N = 151<br>6 months | IA methylprednisolone, triamcinolone, or betamethasone |

| Citation | Participant Characteristics |
|---|---|
| Davis et al., 2018 | • Mean age: 64 years<br>• Gender: 66% female<br>• Race: 79% White, 18% Black, 1% Asian/Pacific Islander<br>• Mean BMI: 30.5<br>• Mean duration of knee pain: 115 months<br>• Radiologic osteoarthritis grade:<br>  • 35% Grade 2; 44% Grade 3; 21% Grade 4 |

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## 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)

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## GRADE Table: Knee Pain–Cooled RF

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

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## RCTs: Knee Pain–Cryoneurolysis

| Citation<br>Country | Total N<br>Duration | Comparator |
|---|---|---|
| Radnovich et al., 2017<br>U.S. | Total N = 180<br>120 days | Sham procedure |

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

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## 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 -01.82; *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

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## GRADE Table: Knee Pain–Cryoneurolysis

| Outcome | N (partic.) k (studies) | Findings | Quality of Evidence Rationale |
|---|---|---|---|
| **Function—WOMAC total at 3 months** | N = 180<br>k = 1 | 1 RCT found statistically significant, clinically meaningful improvement favoring cryoablation | Very low ●○○○<br>QoE downgraded:<br>• 2 levels for serious ROB<br>• 1 level for imprecision (single study)<br>• 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention) |
| **Pain—WOMAC pain at 3 months** | N = 180<br>k = 1 | 1 RCT found statistically significant, clinically meaningful improvement favoring cryoablation | Very low ●○○○<br>QoE downgraded:<br>• 2 levels for serious ROB<br>• 1 level for imprecision (single study)<br>• 1 level for indirectness (lack of longer-term outcomes, suboptimal comparator intervention) |

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## RCTs: Shoulder Pain–Pulsed RF

| Citation Country | Total N Duration | Comparator |
|---|---|---|
| Eyigor et al., 2010<br>Turkey | Total N = 50<br>12 weeks | IA triamcinolone at glenohumeral and acromioclavicular joints and subacromial space |
| Gofeld et al., 2012<br>Canada | Total N = 22<br>6 months | Sham procedure |
| Korkmaz et al., 2010<br>Turkey | Total N = 40<br>12 weeks | TENS |
| Ökmen et al., 2017<br>Turkey | Total N = 59<br>6 months | Photobiomodulation therapy (high-intensity laser) |

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## 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%

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## 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; $P \geq .05$ (Gofeld et al.)
  - 25.5 ± 10.1 vs. 32.4 ± 20.5; $P \geq .05$ (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

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## 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 (Eyigor 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

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

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## RCTs: Plantar Fasciitis–Conventional RFA

| Citation<br>Country | Total N<br>Duration<br>Participant Characteristics | Comparator |
|---|---|---|
| Landsman et al., 2013<br>U.S. | Total N = 17<br>4 weeks<br>• Mean VAS first-step pain: 8.5<br>• Mean VAS initial average pain: 7.3<br>• Mean VAS initial peak pain: 9.2 | Sham procedure |

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## 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 ± 2.10 vs. 0.8 ± 1.81 (*P* = .04)
  - First-step pain: 5.00 ± 3.90 vs. 1.33 ± 2.30 (*P* = .30)
  - Peak pain: 5.33 ± 4.31 vs. 1.80 ± 2.08 (*P* = .048)

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## GRADE Table: Plantar Fasciitis–Conventional RFA

| Outcome | N (partic.) k (studies) | Findings | Quality of Evidence Rationale |
|---|---|---|---|
| **Function—no measure identified** | N = 0<br>k = 0 | N/A | N/A |
| **Pain—VAS overall at 3 months** | N = 0<br>k = 0 | Reported VAS only at 1 month | N/A |

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## RCTs: Plantar Fasciitis–Pulsed RF

| Citation<br>Country | Total N<br>Duration<br>Participant Characteristics | Comparator |
|---|---|---|
| Wu et al., 2017<br>Taiwan | Total N = 36<br>12 weeks<br>• Mean age: 47 years<br>• Gender: 53% female<br>• Mean body weight: 68 kg<br>• Duration of symptoms: 9.8 months<br>• Mean VAS first-step: 6.3<br>• Mean VAS overall pain: 6.0<br>• Mean AOFAS ankle-hindfoot score: 58.0 | Sham procedure and lidocaine injected to posterior tibial nerve |

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## 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 ($P < .001$)

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## 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 ($P < .001$)

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## GRADE Table: Plantar Fasciitis–Pulsed RF

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

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## 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

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## 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

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## 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

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## 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

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## 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

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## Key Question 4: Economic Outcomes

- No studies reported economic outcomes

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## RCTs Registered at ClinicalTrials.gov

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

| Area of Body | RFA | Pulsed RF | Cooled RF | Other |
|---|---|---|---|---|
| Knee pain | 4 | 2 | 2 | MRgFUS |
| Foot pain | -- | -- | -- | Cryoablation |
| Hip pain | -- | -- | 1 | -- |
| Phantom limb pain | -- | -- | -- | Cryoanalgesia |
| Shoulder pain | -- | -- | -- | -- |
| Plantar fasciitis | -- | -- | -- | -- |

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

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# 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

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## Guidelines–No Mention of Peripheral Nerve Ablation

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

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## Guidelines–Includes Discussion of Peripheral Nerve Ablation

| Guideline | Quality | Summary |
|---|---|---|
| **American College of Occupational and Environmental Medicine** guideline on elbow disorders (2013) | Poor quality | No recommendation for or against the use of diathermy for the treatment of acute, subacute, or chronic lateral epicondylalgia |
| **American College of Foot and Ankle Surgeons** guideline on adult-acquired infracalcaneal heel pain (2018) | Poor quality | Evidence on bipolar RF treatment for chronic, refractory plantar fasciitis is uncertain |
| **Association of Extremity Nerve Surgeons** guideline (2014) | Poor quality | Does not recommend ablation for the primary treatment of Morton's Neuroma |

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## 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

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## 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

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# 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

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## 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

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## 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

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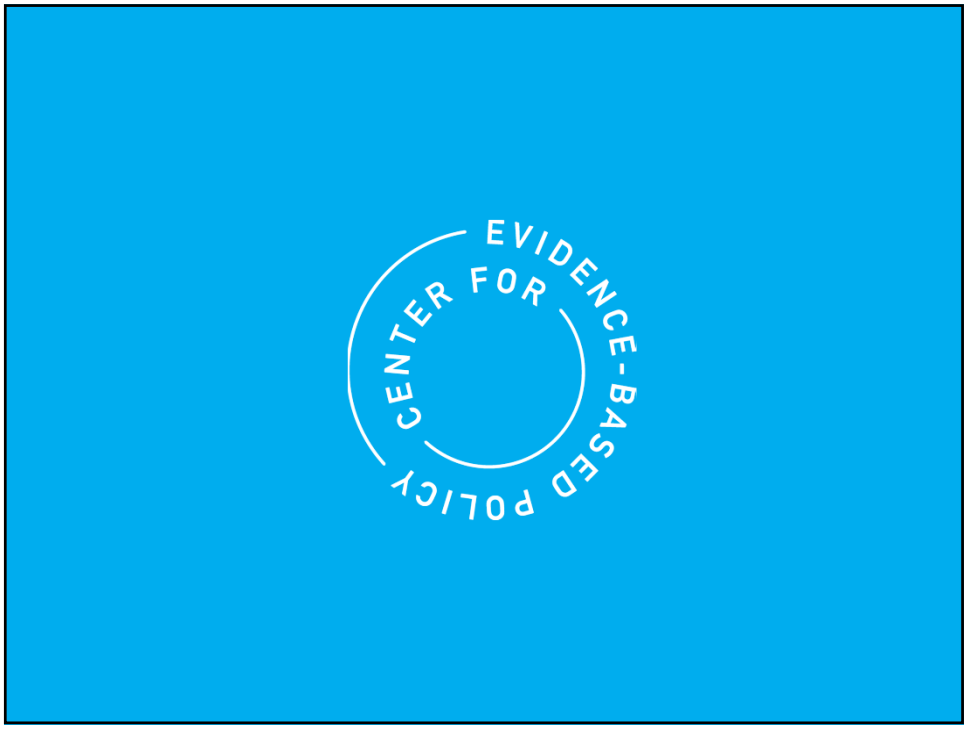
EVIDENCE-BASED POLICY
CENTER FOR

# 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.

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

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

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

- 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[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

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

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

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

### *3. Factors for Consideration - Importance*

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

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

## 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)

| Safety outcomes | Importance of outcome | Safety evidence/ confidence in evidence |
|---|---|---|
| Bruising | | |
| Procedure related pain | | |
| | | |
| | | |

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

| Cost outcomes | Importance of outcome | Cost evidence |
|---|---|---|
| Cost | | |
| Cost effectiveness | | |
| | | |

## Health Technology Evidence Identification

| Special population / Considerations outcomes | Importance of outcome | Special populations/ Considerations evidence |
|---|---|---|
| Age | | |
| Race | | |
| Gender | | |
| Ethnicity | | |
| | | |

### For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

| Unproven (no) | Less (yes) | Equivalent (yes) | More in some (yes) | More in all (yes) |
|---|---|---|---|---|
| | | | | |

### For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

| Unproven (no) | Less (yes) | Equivalent (yes) | More in some (yes) | More in all (yes) |
|---|---|---|---|---|
| | | | | |

### For cost outcomes/ cost-effectiveness:

Is there sufficient evidence that the technology is cost-effective for the indications considered?

| Unproven (no) | Less (yes) | Equivalent (yes) | More in some (yes) | More in all (yes) |
|---|---|---|---|---|
| | | | | |

**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.[40] 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.[44] 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.[46] 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,[43] and knee.[39] The good methodological quality 2014 guideline from National Institute for Health and Care Excellence[38] and the fair methodological quality 2014 guideline on hip and knee osteoarthritis from the Veterans Administration/Department of Defense[41] 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[42] that does not mention peripheral nerve ablation. Details about methodological assessments of all guidelines are located in Appendix D, Table 19.