Washington State Health Care Authority

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

**Topic:** Peripheral nerve ablation for limb pain
**Meeting date:** January 18, 2019
**Final adoption:** May 17, 2019

**Meeting materials and transcript are available on the HTA website.**

**Number and coverage topic:**

**20190118B** – Peripheral nerve ablation for limb pain

**HTCC coverage determination:**

Peripheral nerve ablation, using any technique, to treat limb pain including for knee, hip, foot, or shoulder due to osteoarthritis or other conditions, is **not a covered benefit** for adults and children.

**HTCC reimbursement determination:**

**Limitations of coverage:** N/A

**Non-covered indicators:** N/A

**Agency contact information:**

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

**HTCC coverage vote and formal action:**

***Committee decision***

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

Based on these findings, the committee voted to not cover peripheral nerve ablation, using any technique, for limb pain due to osteoarthritis or other conditions for adults and children

| | Not Covered | Covered under certain conditions | Covered unconditionally |
|---|---|---|---|
| Peripheral nerve ablation, using any technique, for chronic limb pain due to osteoarthritis or other conditions for adults and children. | | | |
| Foot, Shoulder, Hip | 10 | 0 | 0 |
| Knee | 6 | 4 | 0 |

***Discussion***

The committee reviewed and discussed the available studies for use of peripheral nerve ablation for limb pain. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of peripheral nerve ablation for the foot, shoulder or hip, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer, more effective, or more cost-effective than comparators. The committee found that peripheral nerve ablation of the knee, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer or more cost-effective than comparators. The committee did find that in some cases, peripheral knee ablation of the knee, using any technique, for limb pain due to osteoarthritis or other conditions is more efficient.

***Additional Considerations***

The Committee recognizes, from information provided in the review process, that ongoing studies could impact the evidence-based determination: they will re-review this topic following publications of new research findings that could change the determination.

***Limitations***

N/A

***Action***

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Medicare does not have a NCD for peripheral nerve ablation for limb pain.

The committee discussed clinical guidelines, however, none of identified clinical practice guidelines made a recommendation for the use of nerve ablation procedures for limb pain. Organizational guidelines:

- Association of Extremity Nerve Surgeons (2014)
- American College of Occupational and Environmental Medicine (2013)
- American College of Foot and Ankle Surgeons (ACFAS) (2018)
- American Academy of Orthopaedic Surgeons (2013)
- National Institute for Health and Care Excellence (NICE) (2014)
- Veterans Administration/Department of Defense (2014)

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of peripheral nerve ablation for limb pain for public comment to be followed by consideration for final approval at the next public meeting.

**Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

## Key questions and background

### Peripheral nerve ablation for the treatment of limb pain

## Background

### Clinical need and target population

Severe limb pain can markedly limit quality of life if it is not effectively managed. Chronic Limb pain can occur in a joint, such as the hip, shoulder or knee and is most often due to osteoarthritis.[1] Other causes of chronic limb pain include traumatic injury, rheumatoid arthritis, postoperative pain syndromes, or soft tissue (e.g., muscles, tendons, ligaments) dysfunction.[2] Standard treatments for chronic limb pain include physical activity, weight loss, medications (prescription drugs and over-the-counter pain relievers), physical therapy, complementary and alternative therapies (e.g., massage, acupuncture), and surgery.[3] Treatments for osteoarthritis aim to reduce symptoms and improve function, although most treatments do not modify the natural history or progression of the disease.[2]

### Technology of interest

Nerve ablation can be accomplished in several ways, including radiofrequency ablation, chemical ablation, and surgical ablation. There are three different types of radiofrequency ablation that have been developed. Standard thermal radiofrequency nerve ablation is a minimally invasive procedure that uses heat and coagulation necrosis to damage or destroy nerve tissue.[2] A high frequency electrical current is applied to the target tissue, using a needle electrode that is inserted through the skin.[2] The electrode generates heat (80 to 90°C) which coagulates a small volume of tissue.[2] The goal is to destroy peripheral sensory nerve endings, resulting in alleviation of pain.[2] However, the affected nerves may regenerate, causing the pain to return.[4]

Cooled radiofrequency is a newer technology that uses a water cooled radiofrequency probe to create a larger lesion size and therefore treat a larger area than standard thermal radiofrequency ablation.[5] Cooled radiofrequency devices apply more energy at the desired location, but use water cooling to prevent as much heat diffusing beyond the target area.[5] COOLIEF, produced by Haylard Health, Inc., is a cooled radiofrequency treatment that was cleared for marketing by the FDA in 2017.[6] It is used to treat hip and knee osteoarthritis pain and is performed as an outpatient procedure.[5]

Pulsed radiofrequency treatment uses short bursts of radiofrequency current, rather than continuous current of standard radiofrequency ablation.[2] The heat from pulsed radiofrequency ablation (not exceeding 45°C) may cause less damage than standard thermal radiofrequency ablation.[2] Pulsed radiofrequency has been proposed as a possibly safer alternative to continuous radiofrequency ablation in the treatment of variety pain syndromes.[2]

## Policy context

Peripheral nerve ablation is one of many available treatments for patients with limb pain. This topic was selected for a health technology assessment because of high concerns for the safety and efficacy of the procedure and medium/high concern for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding peripheral nerve ablation for patients with limb pain.

## Key questions

1. What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
2. What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
3. Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:
    a. Indication
    b. Patient characteristics
4. What are the cost-effectiveness and other economic outcomes of peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?

## Scope

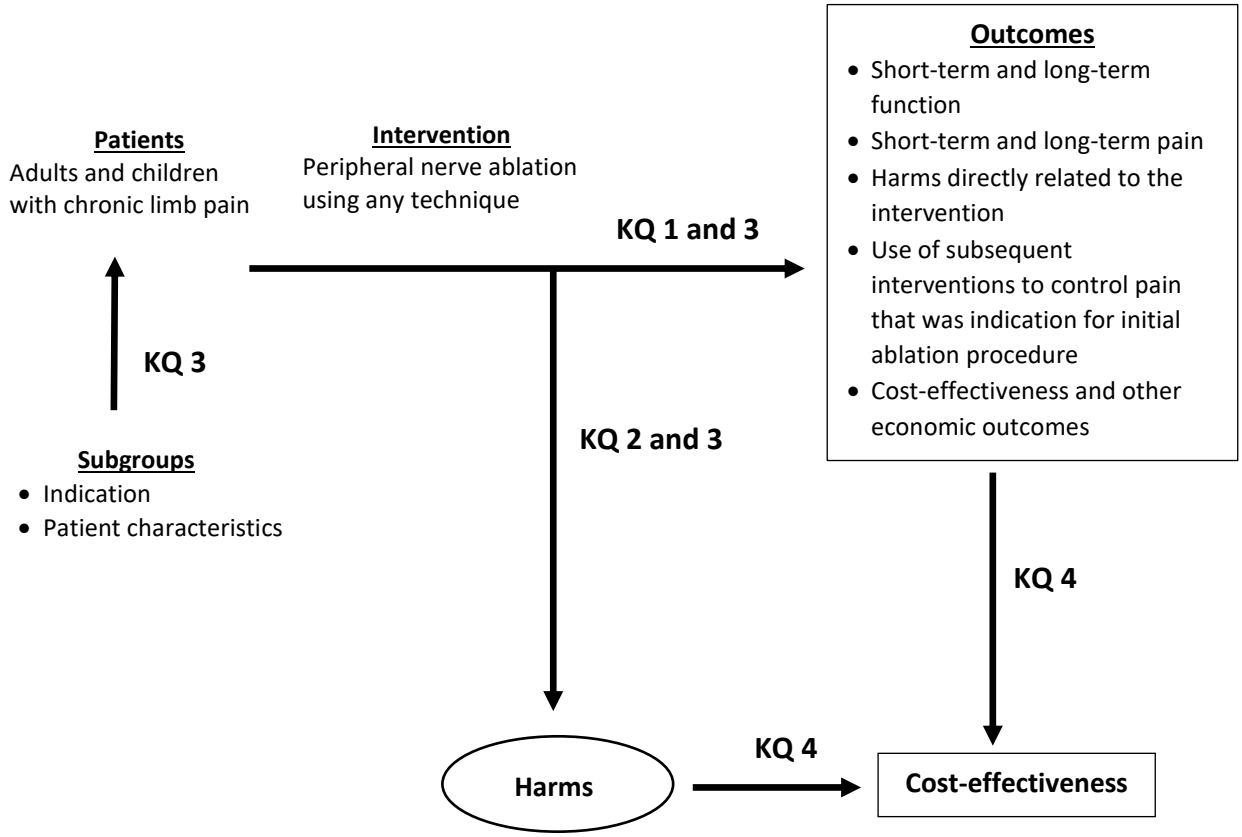
| Study component | Inclusion | Exclusion |
|---|---|---|
| Populations | Adults and children with chronic limb pain due to osteoarthritis or other conditions | Pain that does not arise from an extremity joint or soft tissue |
| Interventions | Peripheral nerve ablation using any technique | Ablation as part of another surgical intervention<br>Procedures involving the central nervous system |
| Comparators | Other treatments for limb pain, including:<br>• Medication<br>• Surgery<br>• Behavioral or psychological interventions | Studies without a comparator intervention<br>Studies with indirect comparisons<br>Studies with an outdated comparator or a comparator |

| Study component | Inclusion | Exclusion |
|---|---|---|
| | • Physical therapy or other non-invasive non-medication therapies<br>• Placebo<br>• Sham procedures<br>• No treatment | intervention that is not available in the U.S. |
| Outcomes | • Primary outcomes: short-term and long-term function measured by a validated method<br>• Secondary outcomes: short-term and long-term pain measured by a validated method<br>• Safety: harms directly related to the intervention<br>• Indirect outcomes: use of subsequent interventions to control pain that was the original indication for the initial peripheral nerve ablation procedure<br>• Economic: cost-effectiveness outcomes (e.g., cost per improved outcome) or cost-utility outcomes (e.g., cost per quality adjusted life year [QALY], incremental cost effectiveness ratio [ICER]) | Other outcomes |
| Study design | • KQ 1–4<br>○ Randomized controlled trials<br>○ Systematic reviews of randomized controlled trials<br>• Additional studies/data for KQ 2–3 (harms)<br>○ Non-randomized comparative studies<br>○ Non-randomized studies without a comparator will be assessed for harms only, if evidence for the intervention is included in KQ1<br>○ Governmental or other registries and databases containing reports of procedure-related harms or device recalls (e.g., FDA MAUDE database, FDA Medical Device Recall database)<br>• Additional studies/data for KQ 4<br>○ Cost-effectiveness studies and other formal comparative economic evaluations | Abstracts, conference proceedings, posters, editorials, letters, case reports and case series with fewer than 10 subjects (for harms only), studies with harms outcomes for an intervention that is not included in KQ1 |

| Study component | Inclusion | Exclusion |
|---|---|---|
| | ○ Systematic reviews of cost-effectiveness studies and other formal comparative economic evaluations | |
| Publication | • Studies in peer reviewed journals, technology assessments or publically available FDA or other federal government reports<br>• Published in English<br>• Published from database inception through September 2018 | Studies whose abstracts do not allow study characteristics to be determined<br>Studies that cannot be located<br>Duplicate publications of the same study that do not report different outcomes or follow-up times, or single site reports from multicenter studies<br>• Studies in languages other than English |

## Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.




## References

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3. National Institute of Arthritis and Musculoskeletal and Skin Disease. What is osteoarthritis? 2014; https://www.niams.nih.gov/sites/default/files/catalog/files/osteoarthritis_ff.pdf. Accessed 7/9/2018.

4. Choi EJ, Choi YM, Jang EJ, Kim JY, Kim TK, Kim KH. Neural ablation and regeneration in pain practice. *Korean J Pain.* 2016;29(1):3-11.

5. Halyard Health Inc. COOLIEF cooled radiofrequency treatment. 2018; https://www.mycoolief.com/. Accessed 7/9/2018.

6. Halyard Health Inc. FDA clears Halyard Health's COOLIEF* for the management of osteoarthritis knee pain. 2017; https://www.halyardhealth.com/about-us/halyard-

news/2017/april/fda-clears-halyard-healths-coolief-for-the-management-of-osteoarthritis-knee-pain.aspx. Accessed 7/9/2018.

## Public comment and response

See **Draft Key Questions: Comment and response** document published separately.