

# **Health Technology Clinical Committee**

Date: May 18, 2018 Time: 8:00 am - 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted: July 13, 2018

Meeting materials and transcript are available on the HTA website

#### **HTCC Minutes**

<u>Members present:</u> John Bramhall, MD, PhD, Gregory Brown, MD, PhD; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Christoph Hofstetter, MD, PhD; Melinda Hull, PharmD

#### **HTCC Formal Action**

- **1. Call to order:** Dr. Brown, chair, called the meeting to order; members present constituted a quorum.
- **2. HTA program updates:** Josh Morse, program director, presented an overview of the development and purpose of the HTA program. He also provided information regarding the 2019 committee calendar.
- **3.** March **16, 2018 meeting minutes:** Draft minutes reviewed; a motion was made to revise the language indicating committee approval of the revised bylaws. New language was proposed to simply state the purposes of the changes. Motion made to approve amended minutes as proposed, seconded. Committee voted to accept the minutes.

Action: Eight committee members approved the July 14, 2017 meeting minutes.

4. Surgery for symptoms of lumbar radiculopathy/ sciatica:

**Clinical expert:** The chair introduced Christoph P. Hofstetter, MD, PhD, Assistant Professor, Department of Neurological Surgery, University of Washington; Director of Spine Surgery, University of Washington Medical Center; Neurosurgeon, Harborview Medical Center.

**Agency utilization and outcomes:** Gary Franklin, MD, Medical Director, Department of Labor and Industries; Research Professor, University of Washington; Co-chair, WA Agency Medical Director's Group, presented the state agency perspective on Surgery for symptoms of lumbar radiculopathy/sciatica. The full presentation is published with the May 18, meeting materials.

**Scheduled and open public comments:** The chair called for public comments. Comments were provided by:

- Jean Christophe Levegue, MD
- Trent Tredway, MD

Public presentation materials provided are published with the May 18, meeting materials.

# **Vendor report / HTCC question and answer:**

Leila Kahwati, MD, MPH presented the evidence review for Surgery for symptoms of lumbar radiculopathy/ sciatica. The full presentation is published with the <u>May 18, meeting materials</u>.

## 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 also determined that current evidence is sufficient to make a determination on this topic.

The committee concluded that the current evidence on surgery for lumbar radiculopathy/ sciatica should be considered and voted on by separate procedure type: open procedures, microdisectomy procedures and procedures that do not include laminectomy, laminotomy or foraminotomy. The committee discussed and voted separately on the evidence for use of these procedures by type. 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 cover with conditions open discectomy and microdiscectomy, with or without endoscopy. This includes lumbar laminectomy, laminotomy, discectomy, foraminotomy. Separately, the committee voted to not cover minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including, but not limited to, energy ablation techniques, Automated Percutaneous Lumbar Discectomy (APLD), percutaneous laser, and nucleoplasty.

	Not covered	Covered under certain conditions	Covered unconditionally
Open procedures	1	8	0
Microdiscectomy surgical procedures	1	8	0
Minimally invasive procedures	8	1	0

#### Discussion

The committee reviewed and discussed the available studies of surgical treatment for lumbar radiculopathy. Details of study design, inclusion criteria and other factors affecting study quality were discussed and considered. A majority of committee members found the evidence sufficient to determine that select open and micro-procedures for lumbar radiculopathy were equivalent for safety and equivalent for effectiveness compared to alternatives, and less than sufficient or unproven for cost-effectiveness. For minimally invasive techniques that do not include laminectomy, laminotomy or foraminotomy a majority found the evidence to be unproven for efficacy, safety and cost-effectiveness. Based on the information reviewed and

considered, the committee identified conditions for coverage. A majority of the committee voted to cover with conditions surgery for lumbar radiculopathy/ sciatica.

#### Limitations

Open discectomy and microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with conditions:

- Adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (CT scan, MRI or myelogram), AND
- Failure to improve with minimum of six weeks of non-surgical care unless progressive motor weakness is present.

Not covered - Minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including, but not limited to, energy ablation techniques, APLD, percutaneous laser, nucleoplasty, etc.

#### **Action**

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD for open standard or microsurgical decompressive procedures.

The committee discussed clinical guidelines identified for surgery for lumbar radiculopathy/ sciatica from the following organizations:

- Low back pain and sciatica in over 16s: assessment and management-Invasive treatments;
  National Institute for Health and Care Excellence (NICE) 2016.
- Clinical Guidelines for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy; North American Spine Society (2012).
- Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain; American Society of Interventional Pain Physicians (2013).
- Low back disorders. In occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers; American College of Occupational and Environmental Medicine (2016).
- Percutaneous transforaminal endoscopic lumbar discectomy for sciatica: Interventional procedures guidance (2016).
- Percutaneous interlaminar endoscopic lumbar discectomy for sciatica: Interventional procedures guidance (2016).
- Percutaneous coblation of the intervertebral disc for low back pain and sciatica: Interventional procedures guidance (2016).
- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica: Interventional procedures guidance (2016).
- Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain: Interventional procedures guidance (2016).
- Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica: Interventional procedures guidance (2016).

- Percutaneous intradiscal laser ablation in the lumbar spine: Interventional guidance (2010).
- Automated percutaneous mechanical lumbar discectomy: Interventional procedures guidance (2005).
- Endoscopic laser foraminoplasty: Interventional procedures guidance (2003).

The committee's determinations are consistent with these guidelines.

## 5. Pharmacogenetic testing for patients being treated with oral anticoagulants:

**Clinical expert:** The chair introduced Melinda Hull, CACP, Clinical Programs Coordinator, Kaiser Permanente.

**Agency utilization and outcomes:** Charissa Fotinos, MD, Deputy Chief Medical Officer, Washington Health Care Authority, presented the state agency perspective for Pharmacogenetic testing for patients being treated with oral anticoagulants. The full presentation is published with the <a href="May 18, meeting materials">May 18, meeting materials</a>.

**Scheduled and open public comments:** The chair called for public comments. No comments were provided.

**Vendor report/ HTCC question and answer:** Valerie J. King, MD, MPH presented the evidence review for Pharmacogenetic testing for patients being treated with oral anticoagulants. The full presentation is published with the May 18, meeting materials.

## **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 Pharmacogenetic testing for patients being treated with oral anticoagulants is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of Pharmacogenetic testing for patients being treated with oral anticoagulants compared to self-monitoring with conventional meters and other study methods (i.e. sham CGM). 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 cover Pharmacogenetic testing for patients being treated with oral anticoagulants with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Pharmacogenetic testing for patients being treated with oral anticoagulants	0	9	0

### Discussion

The committee reviewed and discussed the available studies of use of pharmacogenetic testing for patients being treated with oral anticoagulants. 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 select use of pharmacogenetic testing for patients being treated with oral anticoagulants was equivalent for safety and equivalent for effectiveness compared to not being tested. A majority of the committee voted to not cover, Pharmacogenetic testing for patients being treated with oral anticoagulants.

# Limitations N/A

#### Action

The committee checked for availability of a Medicare national coverage decision (NCD). The one Medicare NCD identified does not provide coverage for pharmacogenetic testing, unless the beneficiary is enrolled in an RCT of anticoagulation therapy with warfarin.

The committee discussed clinical guidelines identified for Pharmacogenetic testing for patients being treated with oral anticoagulants from the following organizations:

- American College of Chest Physicians 2012 guideline Evidence-Based Management of Anticoagulant Therapy
- Scottish Intercollegiate Guidelines Network (SIGN) 2013 guidelines on antithrombotics indications and management
- Australasian Society of Thrombosis and Haemostasis's 2013 guideline
- Clinical Pharmacogenetics Implementation Consortium (CPIC) 2017 updated guideline
- Canadian Pharmacogenomics Network for Drug Safety 2015 guideline
- Canadian Agency for Drugs and Technologies in Health (CADTH) 2013 guidelines on atrial fibrillation
- American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society 2014 guidelines on atrial fibrillation
- American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines 2017 guidelines on valvular heart disease

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on the use of Pharmacogenetic testing for patients being treated with oral anticoagulants for public comment; followed by consideration for final approval at the next public meeting.

### 6. Meeting adjourned.