Washington State Health Care Authority

Health Technology Clinical Committee

Date:May 19, 2017Time:8:00 am - 5:00 pmLocation:SeaTac Conference Center, SeaTac, WAAdopted:July 14, 2017

Meeting materials and transcript are available on the HTA website at: www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Final HTCC Minutes

<u>Members present</u>: Gregory Brown, MD, PhD; Joann Elmore, MD, MPH; Chris Hearne, RN, DNP, MPH; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, MPH; Seth Schwartz, MD, MPH; Christopher Standaert, MD; Kevin Walsh, MD; Sheila Rege, MD

Clinical experts: Mark H. Meissner, MD; Natalia Murinova, MD, MHA

HTCC Formal Action

- **1. Call to order:** Dr. Standaert, 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 2017 committee calendar.
- 3. March 17, 2017 meeting minutes: Draft minutes reviewed; no changes or updates suggested. Motion made to approve March 17, 2017 minutes as written, seconded. Committee voted to accept the minutes.

<u>Action:</u> Eight committee members approved, 1 abstained the March 17, 2017 meeting minutes.

4. Extracorporeal shockwave therapy – Draft findings and decision: Chair referred members to the draft findings and decision and called for further discussion. One comment was received on the draft decision. The committee reviewed and discussed the comment. No changes were made to the draft.

<u>Action</u>: Six committee members voted to approve the extracorporeal shockwave therapy findings and decision and three abstained.

5. Selected treatments for varicose veins

Clinical expert: The chair introduced Mark H. Meissner, MD, Vascular Surgery & Interventional Radiology, and University of Washington Medical Center, Seattle, WA.

Agency utilization and outcomes: Emily Transue, MD, Associate Medical Director, Health Care Authority, presented the state agency perspective for Selected Treatments for Varicose Veins. The full presentation is published with the <u>May 19, meeting materials</u>.

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Final

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

- Kathleen Gibson, MD, Lake Washington Vascular
- Monte Madsen, Medical Science Advisor Endovenous, Medtronic

Public presentation materials provided are published with the May 19, meeting materials.

Vendor report / HTCC question and answer:

Candi Wines, MPH, Hayes, Inc. presented the evidence review of *Selected Treatments for varicose veins*. The full presentation is published with the <u>May 19, 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 decided that the current evidence on selected treatments of varicose veins is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for treatment of varicose veins compared to the more invasive surgical intervention vein stripping. 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 varicose veins with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Selected treatments for varicose veins	0	9	0

Discussion

The committee reviewed and discussed the available studies of treatments for varicose veins. 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 treatment for varicose veins were equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, selected treatment for varicose veins.

Limitations

Exclusions include pregnancy, active infection, peripheral arterial disease, and deep vein thrombosis (DVT).

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for treatment of varicose veins.

Final

Page 2 of 5

The committee discussed clinical guidelines identified for varicose vein treatment from the following organizations:

- Society for Vascular Surgery (SVS) and the American Venous Forum (AVF): the care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines, 2011.
- Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF), 2014.
- Diagnosis and management of varicose veins in the legs: National Institute for Health and Care (NICE), 2013.
- Management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). 2015.

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on selected treatment of varicose veins for public comment; followed by consideration for final approval at the next public meeting.

6. Migraine and chronic tension-type headaches

Clinical expert: The chair introduced Natalia Murinova, MD, MHA, Director, University of Washington Medicine Headache Center, University of Washington Medical Center, Seattle, WA.

Agency utilization and outcomes: Shana Johnson, MD, Medical Officer, Health Care Authority, presented the state agency perspective for chronic migraines and chronic tension-type headaches. The full presentation is published with the <u>May 19</u>, meeting materials.

Scheduled and open public comments: The chair called for public comments. There were no comments.

Vendor report / HTCC question and answer: Andrea Skelly, MPH, PhD, Spectrum Research, Inc., presented the evidence review of *Chronic Migraines and Chronic Tension-type Headaches*. The full presentation is published with the <u>May 19 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 treatment of chronic migraine and chronic tension headaches should be considered and voted on separately. The committee discussed and voted separately on the evidence for use of OnabotulinumtoxinA injections; massage, trigger point injections, manipulation, and transcranial magnetic stimulation; and acupuncture treatment for chronic migraine and chronic tension headaches. The committee considered the evidence and

Final

Page 3 of 5

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 OnabotulinumtoxinA injections for chronic migraine.

Separately, the committee voted to Not Cover:

- OnabotulinumtoxinA injections for chronic tension headaches;
- Massage, trigger point injections, manipulation, and transcranial magnetic stimulation for chronic migraines and chronic tension headaches; and
- Acupuncture for chronic migraine and for chronic tension headaches.

	Not covered	Covered under certain conditions	Covered unconditionally
OnabotulinumtoxinA injections for chronic migraine	1	8	0
OnabotulinumtoxinA injections for chronic tension headaches	9	0	0
Massage, trigger point injections, manipulation, and transcranial magnetic stimulation for chronic migraine	9	0	0
Massage, trigger point injections, manipulation, and transcranial magnetic stimulation for chronic tension	0	0	0
headaches	9	0	0
Acupuncture for chronic migraine and chronic tension headache	7	2	0

Discussion

The committee reviewed and discussed the available studies of treatment of chronic migraines. Details of study design, inclusion criteria and other factors affecting study quality were examined. A majority of committee members found the evidence sufficient to determine that select treatment for chronic migraine were equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions, and more in some cases for cost-effectiveness. Based on the information reviewed and considered the committee identified conditions for coverage. A majority of the committee voted to cover OnabotulinumtoxinA injections for chronic migraine with conditions.

Limitations

OnabotulinumtoxinA injections are a covered benefit with conditions in adults with chronic migraine (defined as headaches on \geq 15 days per month of which \geq 8 days are with migraine) if:

- (1) They have not responded to at least three prior pharmacological prophylaxis therapies from two different classes of drugs AND
- (2) Their condition is appropriately managed for medication overuse

OnabotulinumtoxinA injections must be discontinued in people whose condition:

Final
Page 4 of 5

- (1) Has shown inadequate response to treatment (defined as <50% reduction in headache days per month after two treatment cycles) OR
- (2) Has changed to episodic migraine (defined as <15 headache days per month) for three consecutive months.

Maximum of five treatment cycles.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have a NCD for treatment of migraines and chronic tension headaches.

The committee discussed clinical guidelines identified for chronic migraine and chronic tension headaches treatment from the following organizations:

- Diagnosis and management of headaches in young people and adult; National Institute for Health and Care Excellence (NICE) 2012.
- Botulinum toxin type A for the prevention of headaches in adults with chronic migraine; National Institute for Health and Care Excellence (NICE) 2012.
- Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache, American Academy of Neurosurgeons (AAN) 2016.
- Guideline for Primary Care Management of Headache in Adults, Towards Optimized Practice (TOP) 2016.

The committee's determinations are consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on selected treatment of varicose veins for public comment; followed by consideration for final approval at the next public meeting.

6. Meeting adjourned.

Final