Health Technology Clinical Committee
Findings and Decision

Topic: Treatment of chronic migraine and chronic tension-type headache
Meeting date: May 19, 2017
Final adoption: July 14, 2017

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

Number and coverage topic:
20170519B - Treatment of chronic migraine and chronic tension-type headache

HTCC coverage determination:
Treatment of chronic migraine with OnabotulinumtoxinA is a covered benefit with conditions. Treatment of chronic tension-type headache with OnabotulinumtoxinA is not a covered benefit. Treatment of chronic migraine or chronic tension-type headache with acupuncture, massage, trigger point injections, transcranial magnetic stimulation, or manipulation/manual therapy is not a covered benefit.

HTCC reimbursement determination:
Limitations of coverage:
For treatment of chronic migraine (as defined by the International Headache Society), OnabotulinumtoxinA is covered when the following criteria are met:
1) Has not responded to at least three prior pharmacological prophylaxis therapies from two different classes of drugs AND
2) Condition is appropriately managed for medication overuse
OnabotulinumtoxinA injections must be discontinued when the condition:
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. Additional treatment cycles may be considered at agency discretion.
Non-covered indicators:
NA
### Agency contact information:

<table>
<thead>
<tr>
<th>Agency</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor and Industries</td>
<td>1-800-547-8367</td>
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<tr>
<td>Public Employees Health Plan</td>
<td>1-800-200-1004</td>
</tr>
<tr>
<td>Washington State Medicaid</td>
<td>1-800-562-3022</td>
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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 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.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Not covered</th>
<th>Covered under certain conditions</th>
<th>Covered unconditionally</th>
</tr>
</thead>
<tbody>
<tr>
<td>OnabotulinumtoxinA injections for chronic migraine</td>
<td>1</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>OnabotulinumtoxinA injections for chronic tension headaches</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Massage, trigger point injections, manipulation, and transcranial magnetic stimulation for chronic migraine</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Massage, trigger point injections, manipulation, and transcranial magnetic stimulation for chronic tension headaches</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acupuncture for chronic migraine and chronic tension headache</td>
<td>7</td>
<td>2</td>
<td>0</td>
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</tbody>
</table>

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:

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.
- 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.

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 Administrator.
Comments:
--Use the definition of chronic migraine that follows the IHS definition---HA: Headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month.

--Confusion on intent of #2 discontinuation criteria. Currently the way #2 reads it implies if the injection worked and reduced the HAs to <15 per month client would have to stop treatment?

--Clarify: maximum of five treatment cycles. Where did the maximum number come from? Specialist noted often needed to treat client for 1-2 years prior to wean off?

--Top of decision Manipulation is not listed

--should it be >50% reduction in HA days per month?

OnabotulinumtoxinA injections must be discontinued when the condition:
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.