Washington State Health Care Authority
Health Technology Assessment

Health Technology Clinical Committee

Date: January 15, 2016
Time: 8:00 am – 5:00 pm
Location: SeaTac Conference Center, SeaTac, WA
Adopted: March 18, 2016

Meeting materials and transcript are available on the HTA website at:

www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

HTCC MINUTES

Members Present: Gregory Brown, MD, PhD; Joann Elmore, MD MPH; Louise Kaplan, PhD, ARNP; David K. McCulloch, MD, FRCP; Carson Odegard DC, MPH; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA , Christopher Standaert, MD; Kevin Walsh, MD; Tony Yen, MD

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Standaert, chair called the meeting to order. Sufficient members were present to constitute a quorum.
2. **November 20, 2015 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve was seconded. Minutes adopted by the committee with corrections noted.

   Action: Ten committee members approved the November 20, 2015 meeting minutes. One member abstained.
3. **Lumbar Fusion for Degenerative Disc Disease – Re-review Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. Four comments were received on the draft decision. The committee reviewed and discussed the comments. No changes were made to the draft based on the comments. A typographical error was noted in the draft and staff were directed to correct this.

   Action: Ten committee members voted to approve the Lumbar Fusion – Re-review Findings and Decision document with correction to footer; One member abstained.
4. **Tympanostomy Tubes in Children Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. One comment was received on the draft decision. Committee members reviewed the comment and modified the draft. Staff were directed to modify the final determination per the committee's changes.

   Action: Ten members voted to approve the Tympanostomy Tubes in Children Draft Findings and Decision document;One member abstained.

5. Novocure (Tumor Treating Fields):

Agency Utilization and Outcomes:

Daniel Lessler, MD, MHA, Chief Medical Director, Washington Health Care Authority presented the state agency perspective for Novocure to the committee. The full presentation is published with January 15, meeting materials.

Scheduled and Open Public Comments:

The chair called for public comments. No comments were provided.

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for Novocure, Lynne P. Taylor, MD, FAAN, FANA, neuro-oncologist, Virginia Mason Medical Center, Seattle, WA.

Natalie Slezack, PhD, Hayes, Inc. presented the evidence review of **Novocure (Tumor Treating Fields)**. The full presentation is published with January 15, 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 concluded that the current evidence on Novocure is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of Novocure compared to current alternative chemotherapeutic strategies for 1) newly diagnosed and untreated glioblastoma multiform, recurrent and previously treated glioblastoma multiforme (GBM), and 3) tumors other than glioblastoma. 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 Novocure (Tumor Treating Fields) for GBM, recurrent GBM or other tumors.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Novocure for newly diagnosed and untreated glioblastoma multiforme (GBM)	9	2	0
Novocure for recurrent and previously treated GBM	9	2	0
Novocure for other tumors (Non-GBM)	11	0	0

Discussion

The committee discussed the meaning quality of and methodology of the available studies of Novocure. In considering the evidence the committee cited concerns related to the limited number of trials, limited reporting of quality of life outcomes, and potential biases present in the available literature.

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for Novocure or tumor treating fields.

The committee discussed clinical guidelines identified for treatment of GBM and non-small cell lung cancer from the following organizations:

American Association of Neuroscience Nurses (AANN),

American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS),

European Association of Neuro-Oncology (EANO),

European Society for Medical Oncology (ESMO),

National Comprehensive Cancer Network (NCCN)

The Chair noted consistency with existing guidelines that include mention of tumor treating fields as some consider this an investigational treatment. Also noted is the fact that the most recent trial published was not considered in existing guidelines due as it was published 30 days prior to this committee's review?

The committee Chair directed HTA staff to prepare a Findings and Decision document on Novocure (Tumor Treating Fields) reflective of the majority vote for final approval at the next public meeting.

6. Charissa Fotinos MD, MSc, presented the state agency utilization rates for cardiac stents to the committee. The full presentation is published with January 15, meeting materials.

Scheduled and Open Public Comments:

The chair called for public comments. Comments were provided by:

Gary Weeks MD speaking for Wayne Powell and representing the Society for Cardiovascular Angiography and Intervention, University of Washington, Seattle, WA.

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for cardiac stents, Mike Ring MD, Providence Spokane Cardiology.

Andrea Skelly, PhD, Spectrum Research Incorporated, presented the evidence review addressing cardiac stents. The full presentation is published with January 15, 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 concluded that the current evidence for newer generation cardiac stents is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of cardiac stents compared to current medical management strategies for stable angina. The committee then considered the evidence of newer generation drug eluting stents versus bare metal stents for stable or unstable angina. 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 cardiac stents for unstable angina. The committee voted separately to cover with no conditions the use of drug eluting stents or bare metal stents when appropriate for stable or unstable angina.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Cardiac stents for stable angina	0	10	1
Cardiac stents, drug eluting vs bare metal	1	0	10

Discussion

The committee reviewed and discussed the evidence for use of cardiac stents compared to medical management for stable angina and discussed the meaning, quality and methodology of the available studies for stents vs medical management. The committee determined that coverage with conditions for the question of stable angina when compared to medical management. Limitations are for this condition and question only. For the question of drug eluting stents versus bare metal stents when stents are indicated the committee determined to cover without conditions. Therefore there are no limitations on the use of drug eluting or bare metal stents when intervention with cardiac stents is appropriate.

Limitations

For patients with **stable angina** cardiac stents are covered for the following:

1. Angina refractory to optimal medical therapy, and
2. Objective evidence of myocardial ischemia.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is a NCD (National Coverage Determination Manual: 20.7 (2014)) for percutaneous transluminal angioplasty with and without stent. The HTCC coverage determination is similar to the CMS decision.

The committee discussed and reviewed treatment criteria from clinical guidelines identified for treatment of stable angina and revascularization from the following organizations:

American College of Cardiology and American Heart Association;
American Association for Thoracic Surgery;
American College of Cardiology Foundation;
American College of Physicians;
American Diabetes Association;
Council on Clinical Cardiology;
Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure;
National Cholesterol Education Program (NCEP);
Preventive Cardiovascular Nurses Association;
Society for Cardiovascular Angiography and Interventions;
Society of Thoracic Surgeons

The chair noted consistency with existing guidelines that include risk identification, risk reduction, medical and revascularization treatment criteria.

The committee chair directed HTA staff to prepare a findings and decision document on Cardiac Stents reflective of the majority vote for final approval at the next public meeting.

7. Josh Morse, HTA program director presented a status update on HTA technology assessments now in process and those scheduled for 2016.

8. Meeting adjourned.