

Health Technology Clinical Committee

Date: March 18, 2016

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted: May 20, 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. **January 15, 2016 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve was seconded. Minutes adopted by the committee with corrections noted.

Action: Eleven committee members approved the January 15, 2016 meeting minutes.

3. **Novocure 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. The committee reviewed and discussed the comment. No changes were made to the draft based on the comment.

Action: Eleven committee members voted to approve the Novocure findings and decision document

4. **Cardiac Stents - Re-review 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 after the comment period. Committee members reviewed the comment and modified the draft to correct a typographical error and reformat language for clarity based on staff suggestion. Staff was directed to modify the final determination per the committee's changes.

Action: Eleven members voted to approve the Cardiac Stents - Re-review findings and decision document.

Final

5. Extracorporeal Membrane Oxygenation Therapy (ECMO):

Agency Utilization and Outcomes:

G. Steve Hammond, PhD, MD, MHA, Chief Medical Officer, Washington Department of Corrections presented the state agency perspective for ECMO to the committee. The full presentation is published with [March 18, meeting materials](#).

Scheduled and Open Public Comments:

The chair called for public comments.

No scheduled or open public comments received.

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for ECMO, Eileen Bulger, MD, FACS, Chief of Trauma, Harborview Medical Center, Seattle, WA.

Elizabeth Russo, MD, Institute for Clinical and Economic Review presented the evidence review of extracorporeal membrane oxygenation therapy. The full presentation is published with [March 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 concluded that the current evidence on ECMO is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of ECMO compared to conventional intensive care management. 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 extracorporeal membrane oxygenation therapy.

| | Not Covered | Covered Under Certain Conditions | Covered Unconditionally |
|---|-------------|----------------------------------|-------------------------|
| Extracorporeal Membrane Oxygenation Therapy | 0 | 11 | 0 |

Discussion

The committee reviewed and discussed the evidence, and the quality and limitations of the evidence. Based on the available information and including contextual input from the clinical expert the committee developed conditions for coverage for ECMO to address use for patients with severe life threatening respiratory or cardiac dysfunction that is not responding to conventional management but is potentially reversible; as a bridging therapy for patients in pulmonary failure and

who are on a pulmonary transplant list; and as a bridging therapy for patient in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation. All procedures should only be provided at a facility participating in the Extracorporeal Life Support Organization (ELSO) registry to continue to collect valuable registry data for future use. With the above noted condition the committee voted to cover ECMO with conditions.

Limitations

In patients with severe life threatening, but potentially reversible, acute respiratory or cardiac dysfunction unresponsive to conventional management.

As a bridging therapy for patients in pulmonary failure who are on a pulmonary transplant list.

As a bridging therapy for patients in cardiac failure who are eligible for a ventricular assist device or cardiac transplantation.

All procedures only at a facility participating in the ELSO case registry.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for ECMO.

The committee discussed clinical guidelines identified for treatment addressing use of ECMO from the following organizations:

Extracorporeal Life Support Organization (ELSO)(2010)

American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (AHA)(2010)

International Society of Heart and Lung Transplantation (ISHLT)(2010)

American Thoracic Society (1997)

National Institute for Health and Care Excellence (NICE)(2014)

The chair noted consistency with existing guidelines and the fact that some of the guidelines preceded some of the available literature.

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

6. Shana Johnson, MD presented the state agency perspective and utilization rates for the spinal injections re-review topic to the committee. The full presentation is published with [March 18, meeting materials](#).

Scheduled and Open Public Comments:

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

- Steven Stanos, DO
- Janna Friedly, MD
- Paul Dreyfuss, MD & Brandon Messerli, DO (*Representing the following*)
 - William A. Anderson, MD
 - Jason G. Attaman, DO
 - Kevin Berry
 - Doug Burns, MD
 - Alan Chen, MD
 - Michele Curatolo, MD, PhD
 - Rebecca C. Dale, DO
 - Natalya Eykhvald
 - Kelvin Franke, DO
 - Zing Fu, MD
 - Jon Geffen, DO
 - Christopher Godbout, MD
 - William B. Gray, DO
 - Brandy Gump
 - Michael Hatzakis, MD
 - Xiang Jing, ARNP
 - Stephen Johnson, MD
 - Henry Kim, MD
 - Eric Kinder, MD
 - Hisashi Kobayashi, MD
 - Daniel Kwon, MD
 - Yung Lee, DO
 - Katrina Lewis, MD
 - Carolyn Marquardt, MD
 - Christopher Merifield, MD, MHA
 - Carlos E. Moravek, MD
 - Linda Nixon, PAC
 - Chan Saetern
 - Richard Seroussi, MD
 - Virtaj Singh, MD
 - Ben Snyder, MD
 - Brett Stacey, MD
 - Alison Stout, DO
 - Geoffery E. Sultana, MD
 - David J. Tauben, MD, FACP
 - Jessi Thao
 - Marco Wen, MD
 - Jiang Wu, MD
 - Irene Young, MD
 - Ryan Zhender, MD
- Kathy Kroening
- Diana Kusulos
- Carol Glenn
- Carol O'Connell
- Henry Sherwood
- Brett Stacey, MD
- Richard Seroussi, MD

Vendor Report and HTCC Q & A:

The chair introduced the clinical expert for spinal injections re-review, Kevin Vorenkamp, MD.

Joseph Dettori, PhD, Spectrum Research Incorporated, presented the evidence review addressing spinal injections re-review. The full presentation is published with [March 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 concluded that the current evidence for spinal injections is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of spinal injections compared to alternatives. 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 spinal injections with no change to the conditions from the original determination. The committee did add a clarifying statement to make clear that the determination does not apply to injections for “inflammatory arthropathy”.

| | Not Covered | Covered Under Certain Conditions | Covered Unconditionally |
|-------------------|--------------------|---|--------------------------------|
| Spinal Injections | 0 | 11 | 0 |

Discussion

The committee reviewed and discussed the evidence for use of spinal injections. The committee determined that new evidence did not support a change in the original determination of coverage with conditions and the original conditions were not changed.

Limitations*

- Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain;
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy;
 - No more than two without clinically meaningful improvement in pain and function; and
 - Maximum of three in six months.
- Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With fluoroscopic guidance or CT guidance;
 - After failure of conservative therapy; and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review.

*Limitations do not apply to injections for inflammatory arthropathy

Non-Covered Indicators:

- Therapeutic medial branch nerve block injections; intradiscal injections and facet injections are not a covered benefit.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no NCD for spinal injections.

The committee discussed and reviewed treatment criteria from clinical guidelines identified for spinal injections from the following organizations:

- American Society for Interventional Pain Management (2013)
- American Society of Anesthesiologists Task Force/American Society of Regional Anesthesia and Pain Management (2010)
- Colorado Division of Workers' Compensation (2012), (2014)
- Institute for Clinical Systems Improvement (2012)
- Toward Optimized Practice (2011)
- U.S. Food and Drug Administration Safe Use Initiative (2015)

The chair noted consistency with existing guidelines with some differences based on evidence analysis and interpretation.

The committee chair directed HTA staff to prepare a findings and decision document on spinal injections 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.**