Process for Medical Issue Review and Study Analysis under ORS 656.245(3)
Approved by MAC on Feb. 16, 2018

The Medical Advisory Committee considered how best to review treatments and consider studies related to medical treatment under ORS 656.245(3) to make recommendations to the Administrator of the Workers' Compensation Division and the Director of the Department of Consumer and Business Services. This memo replaces prior committee agreements made in 2006 and 2007.

The committee will apply the following when reviewing medical issues:

1. Federal Drug Administration approval is necessary but not determinative. For a new device, "501(k) approval" is not sufficient.[1]

2. The committee will use Level I and II studies as classified by the "Levels of Evidence For Primary Research Questions," adopted by the North American Spine Society in January 2005 (see Appendix A).

3. When analyzing whether there is bias in a trial, the committee will consider[2]:

    a. **Selection Criteria/Bias**
        - Participants and those who recruit should remain unaware of next assignment in sequence. Empirical research has shown that lack of allocation concealment is associated with bias. Therefore, approaches such as below should be used.
            - Allocation by central office unaware of subject characteristics
            - Pre-numbered or coded identical containers which are administered serially to participants
            - On-site computer system combined with allocations kept in an unreadable until file that can be accessed only after the characteristics of enrolled participants have been entered.

[1] When the Medical Device Amendment to the Federal Food, Drug, and Cosmetics Act passed in 1976, Section 510(k) helped the Federal Food and Drug Administration handle the increase in requests for approval. By submitting a 501(k) application under Section 510(k), the manufacturer only needed to demonstrate that its product was "substantially equivalent" to a device already marketed. In other words, the application only needed to show minor improvements to an already marketed device, without substantial change from the comparison device. This did not require the device to go through the formal pre-market approval process.
[2] Adapted from Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.6 [updated September 2006]. http://www.cochrane.org

b. **Performance Criteria/Bias**
   - Refers to systematic differences in the care provided to the participants in the comparison groups other than the intervention under investigation.
   - To protect against unintended differences in care and placebo effects, those providing and receiving care can be *blinded* so that they did not know the group to which the recipients of care have been allocated.

c. Attrition Criteria/Bias
   - Refers to systematic differences between comparison groups in the loss of participants from the study.
   - How are losses of participants (withdrawals, dropouts, protocol deviations) handled?

d. Detection Criteria/Bias
   - Refers to systematic differences between the comparison groups in outcome assessment.

Appendix A

Levels of Evidence For Primary Research Question[1]

As Adopted by the North American Spine Society January 2005*

https://www.spine.org/Documents/ResearchClinicalCare/LevelsOfEvidence.pdf accessed Aug. 2017

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case Series[8]	Case Series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

[1] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
[2] A combination of results from two or more prior studies.
[3] Studies provided consistent results.
[4] Study was started before the first patient enrolled.
[5] Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
[6] The study was started after the first patient enrolled.
[7] Patients identified for the study based on their outcome, called "cases"; e.g. failed total arthroplasty, are compared to those who did not have outcome, called "controls"; e.g. successful total hip arthroplasty.
[8] Patients treated one way with no comparison group of patients treated in another way.

*These documents have also been adopted by the American Academy of Orthopaedic Surgeons, Pediatric Orthopaedic Society of North America, *Clinical Orthopaedics and Related Research, Journal of Bone & Joint Surgery and Spine*. September 28, 2004