



August 18, 2006

(From March 18, 2005 Meeting Decision, revised at the July 21, 2006 meeting)

Criteria for Reviewing Medical Treatment Issues and Studies per ORS 656.245(3):

On March 18, 2005, and again on July 21, 2006, the Medical Advisory Committee considered how best to review treatments and consider studies related to medical treatment under review per ORS 656.245(3) in order to make recommendations to the Administrator of the Workers' Compensation Division and the Director of the Department of Consumer and Business Services.

1- Federal Drug Administration approval is necessary but not determinative. For a new device, "501(k) approval" is not sufficient. (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- The committee is using the following guidelines to weigh scientific literature when reviewing treatment per ORS 656.245(3).

a) All studies need to be reviewed on a case-by-case basis. To be most persuasive (as determined by the committee) a study should be:

- valid and acceptable in design and analysis,
- peer reviewed,
- well done considering materials and methods used,
- impartial, unbiased, and
- of sufficient size.

b) A double-blind, randomized prospective study is the "gold standard" and preferred. However, a retrospective study and case series can be persuasive if they meet the above criteria.

c) All study subjects do not need to be patients in workers' compensation. However, study outcomes must give confidence to the committee by demonstrating (in a significant percentage of study participants) that the treatment will overcome the "injured-worker effect".