WAC 296-20-02704 What criteria does the director or director's designee use to make medical coverage decisions? (1) In making medical coverage decisions, the director or the director's designee considers information from a variety of sources. These sources include, but are not limited to:

- Scientific evidence;
- National and community-based opinions;
- Informal syntheses of provider opinion;
- Experience of the department and other entities;
- Regulatory status.

Because of the unique nature of each health care service, the type, quantity and quality of the information available for review may vary. The director or director's designee weighs the quality of the available evidence in making medical coverage decisions.

(2) Scientific evidence.

(a) "Scientific evidence" includes reports and studies published in peer-reviewed scientific and clinical literature. The director or the director's designee will consider the nature and quality of the study, its methodology and rigorousness of design, as well as the quality of the journal in which the study was published.

- For treatment services, studies addressing safety, efficacy, and effectiveness of the treatment or procedure for its intended use will be considered.
- For diagnostic devices or procedures, studies addressing safety, technical capacity, accuracy or utility of the device or procedure for its intended use will be considered.

(b) The greatest weight will be given to the most rigorously designed studies and on those well-designed studies that are reproducible. The strength of the design will depend on such scientifically accepted methodological principles as randomization, blinding, appropriateness of outcomes, spectrum of cases and controls, appropriate power to detect differences, magnitude and significance of effect. Additional consideration will be given to those studies that focus on sustained health and functional outcomes of workers with occupational conditions rather than unsustained clinical improvements.

(3) National and community-based opinion.

(a) "National opinion" includes, but is not limited to, syntheses of clinical issues that may take the form of published reports in the scientific literature, national consensus documents, formalized documents addressing standards of practice, practice parameters from professional societies or commissions, and technology assessments produced by independent evidence-based practice centers.

The director or the director's designee will consider the nature and quality of the process used to reach consensus or produce the synthesis of expert opinion. This consideration will include, but may not be limited to, the qualifications of participants, potential biases of sponsoring organizations, the inclusion of graded scientific information in the deliberations, the explicit nature of the document, and the processes used for broader review.

(b) "Community-based opinion" refers to advice and recommendations of formal committees made up of clinical providers within the state of Washington. As appropriate to the subject matter, this may include recommendations from the department's formal advisory committees:

- The industrial insurance medical advisory committee;
- The industrial insurance chiropractic advisory committee.
- The Washington state pharmacy and therapeutics committee.

• The Washington state health technology assessment clinical committee.

(4) "Informal syntheses of provider opinion" includes, but is not limited to, professional opinion surveys.

(5) Experience of the department and other entities.

The director or director's designee may consider data from a variety of sources including the department, other state agencies, federal agencies and other insurers regarding studies, experience and practice with past coverage. Examples of these include, but are not limited to, formal outcome studies, cost-benefit analyses, and adverse event, morbidity or mortality data.

(6) Regulatory status.

The director or director's designee will consider related licensing and approval processes of other state and federal regulatory agencies. This includes, but is not limited to:

• The federal food and drug administration's (FDA) regulation of drugs and medical devices (21 U.S.C. 301 et seq. and 21 C.F.R. Chapter 1, Subchapters C, D, & H consistent with the purposes of this chapter, and as now or hereafter amended); and

• The Washington state department of health's regulation of scope of practice and standards of practice for licensed health care professionals regulated under Title 18 RCW.

[Statutory Authority: 2007 c 282, RCW 51.04.02 [51.04.020], 51.04.030. WSR 08-02-020, § 296-20-02704, filed 12/21/07, effective 1/21/08. Statutory Authority: RCW 51.04.020, 70.14.050. WSR 04-08-040, § 296-20-02704, filed 3/30/04, effective 5/1/04. Statutory Authority: RCW 51.04.020 and 51.04.030. WSR 00-01-037, § 296-20-02704, filed 12/7/99, effective 1/8/00.]