

WAC 296-20-02850 When may the department cover controversial, obsolete, investigational or experimental treatment? (1) The department or self-insurer will not authorize nor pay for treatment measures of a controversial, obsolete, investigational or experimental nature. (See WAC 296-20-03002.) Under certain conditions, the director or the director's designee may determine that such treatment is appropriate. In making such a decision, the director or director's designee will consider factors including, but not limited to, the following:

(a) Scientific studies investigating the safety and efficacy of the treatment are incomplete, or if completed, have conflicting conclusions, and:

- Preliminary data indicate the treatment or diagnostic procedure or device has improved net health and functional outcomes; and

- No alternative treatment or diagnostic is available; or

(b) The treatment or diagnostic procedure or device is prescribed as part of:

- A controlled, clinical trial that has been reviewed and approved by an institutional review board that was established in accordance with the federal Department of Health and Human Services (DHHS) regulations (45 C.F.R. Part 46 consistent with the purposes of this chapter, and as now or hereafter amended); and

- For medical devices not yet cleared for marketing, the clinical evaluation has an approved investigational device exemption (IDE) in accordance with the federal Food and Drug Administration (FDA) regulations (21 C.F.R. Parts 50, 56, and 812 consistent with the purposes of this chapter, and as now or hereafter amended); and

- For drugs not yet cleared for marketing, the clinical evaluation has been approved in accordance with the federal Food and Drug Administration (FDA) regulations (21 C.F.R. Part 312 consistent with the purposes of this chapter, and as now or hereafter amended); or

(c) The usually indicated procedure or diagnostic test would likely be harmful for the patient because of other unrelated conditions.

(2) The health care provider must submit a written request and obtain approval from the department or self-insurer, prior to using a controversial, obsolete, investigational, or experimental treatment. The written requests must contain a description of the treatment, the reason for the request, potential risks and expected benefits, length of care and estimated cost of treatment.

[Statutory Authority: RCW 51.04.020 and 51.04.030. WSR 00-01-037, § 296-20-02850, filed 12/7/99, effective 1/8/00.]