WAC 284-43-5420 Clinical trials. A carrier must not restrict coverage of routine patient costs for enrollees who participate in a clinical trial. "Routine costs" means items and services delivered to the enrollee that are consistent with and typically covered by the plan or coverage for an enrollee who is not enrolled in a clinical trial. A carrier may continue to apply its limitations and requirements related to use of network services.

(1) A carrier may require enrollees to meet the eligibility requirements of the clinical trial according to the trial protocol. While not required to impose such a condition, a carrier may refuse coverage under this section if the enrollee does not provide medical and scientific information establishing that the individual's participation in such trial would be appropriate based on the individual meeting the eligibility requirements for the clinical trial, unless the enrollee is referred to the clinical trial by a health care provider participating in the carrier's network.

(2) This includes the cost of prescription medication used for the direct clinical management of the enrollee, unless the trial is for the investigation of the prescription medication or the medication is typically provided by the research sponsors free of charge for any enrollee in the trial.

(3) The requirement does not apply to:

(a) A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;

(b) For items and services provided solely to satisfy data collection and analysis needs;

(c) Items and services that are not used in the direct clinical management of the enrollee; or

(d) The investigational item, device, or service itself.

(4) Clinical trial means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition, funded or approved by:

(a) One of the National Institutes of Health (NIH);

(b) An NIH cooperative group or center which is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group including, but not limited to, the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;

(c) The federal Departments of Veterans Affairs or Defense;

(d) An institutional review board of an institution in this state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH; or

(e) A qualified research entity that meets the criteria for NIH Center Support Grant eligibility.

"Life threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

[WSR 16-01-081, recodified as § 284-43-5420, filed 12/14/15, effective 12/14/15. Statutory Authority: RCW 48.02.060. WSR 13-03-038 (Matter No. R 2012-25), § 284-43-850, filed 1/9/13, effective 2/9/13. Statutory Authority: RCW 48.02.060, 48.02.062, 48.18.140, 48.43.525, 48.44.050, 48.44.440(2), 48.44.460(2), 48.46.200, and 48.46.510. WSR 12-21-019 (Matter No. R 2012-03), § 284-43-850, filed 10/8/12, effective 11/8/12.]