WAC 284-30-450 Insurance policies and contracts—Coverage for drugs. (1) Authority and purpose.

(a) Some insurers deny payment for drugs that have been approved by the Federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labelling approved by the FDA (off-label use) while other insurers with similar coverage terms pay for off-label use. Denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness.

(b) Equity among insured residents of this state and fair claims settlement practices and fair competition among companies providing coverage to residents of this state require comparable reimbursement for prescribed drugs among insurers, health care service contractors, and health maintenance organizations.

(c) Use of off-label indications often provides efficacious drugs at a lower cost.

(d) To prevent unfair methods of claims settlements, unfair competition, and unfair or deceptive acts or practices of insurers and prohibited acts or practices of health care service contractors or health maintenance organizations, this rule is adopted.

(2) Scope.

This regulation affects all insurance and health benefit policies and contracts providing coverage for drugs to a resident of this state which are issued, amended, delivered or renewed on or after January 1, 1995.

(3) Definitions. The following definitions are used in this section:

(a) "Drug" or "drugs" means any substance prescribed by a physician taken by mouth, injected into a muscle, the skin, a blood vessel, or a cavity of the body, or applied to the skin to treat or prevent a disease, and specifically includes drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication or for the treatment of people with HIV or AIDS.

(b) "Off-label" means the prescribed use of a drug which is other than that stated in its FDA approved labelling.

(c) "Peer-reviewed medical literature" means scientific studies printed in journals or other publications in which original manuscripts are published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. Peer-reviewed medical literature does not include in-house publications of pharmaceutical manufacturing companies.

(d) "Physician" means a medical doctor or other health care provider acting within the scope of his or her professional license.

(e) "Policy" or "contract" means any individual, group or blanket policy of insurance or health benefit contract issued by a disability insurer, health care service contractor, or health maintenance organization which is issued, amended, delivered or renewed on or after January 1, 1995, and which provides coverage for drugs to a resident of this state.

(f) "Standard reference compendia" means:

(i) The American Hospital Formulary Service-Drug Information;

(ii) The American Medical Association Drug Evaluation;

(iii) The United States Pharmacopoeia-Drug Information; or

(iv) Other authoritative compendia as identified from time to time by the Federal Secretary of Health and Human Services or the insurance commissioner.

(4) Standards of coverage.

(a) No insurance policy or contract which provides coverage for prescription drugs to a resident of this state shall exclude coverage of any such drug for a particular indication on the grounds that the drug has not been approved by the Federal Food and Drug Administration for that indication, if such drug is recognized as effective for treatment of such indication:

(i) In one of the standard reference compendia;

(ii) In the majority of relevant peer-reviewed medical literature if not recognized in one of the standard reference compendia; or

(iii) By the Federal Secretary of Health and Human Services.

(b) Coverage of a prescription drug required by this section shall also include medically necessary services associated with the administration of the drug.

(c) This regulation shall not be construed to require coverage for any drug when the Federal Food and Drug Administration has determined its use to be contra-indicated.

(d) This regulation shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the Federal Food and Drug Administration.

[Statutory Authority: RCW 48.01.030, 48.02.060 and 48.30.010. WSR 94-18-038 (Order R 94-17), § 284-30-450, filed 8/30/94, effective 9/30/94.]