WAC 296-20-03010 What are the general principles the department uses to determine drug coverage? In general, the department evaluates data on safety, health outcomes and cost-effectiveness for coverage. The department or self-insurer considers payment for drugs, including biologics and controlled substances, when:

• The drug is used to treat the industrial injury or occupational disease accepted under the claim; and

• The drug is prescribed consistent with the department's rules, guidelines and coverage decisions, and either:

- The drug is approved by the Food and Drug Administration (FDA) for that condition and prescribed in accordance with labeling, or is licensed by a regulatory entity similar to the FDA for workers who reside outside the United States; or

- If the drug is prescribed off-label, the use is supported by published scientific evidence of safety and effectiveness from high quality randomized trials (see WAC 296-20-02704). Off-label is defined as use of a FDA-approved drug for an indication which has not received FDA approval or is otherwise not consistent with the drug labeling.

[Statutory Authority: RCW 51.04.020 and 51.04.030. WSR 13-12-024, § 296-20-03010, filed 5/28/13, effective 7/1/13; WSR 00-01-040, § 296-20-03010, filed 12/7/99, effective 1/20/00.]