WAC 284-43-5100 Formulary changes. An issuer is not required to use a formulary as part of its prescription drug benefit design. If a formulary is used, an issuer must, at a minimum, comply with these requirements when a formulary change occurs.

(1) In addition to the requirements set forth in WAC 284-30-450, an issuer must not exclude or remove a medication from its formulary if the medication is the sole prescription medication option available to treat a disease or condition for which the health benefit plan, policy or agreement otherwise provides coverage, unless the medication or drug is removed because the drug or medication becomes available over-the-counter, is proven to be medically inefficacious, or for documented medical risk to patient health.

(2) If a drug is removed from an issuer's formulary for a reason other than withdrawal of the drug from the market, availability of the drug over-the-counter, or the issue of black box warnings by the Federal Drug Administration, an issuer must continue to cover a drug that is removed from the issuer's formulary for the time period required for an enrollee who is taking the medication at the time of the formulary change to use an issuer's exception request process to request continuation of coverage for the removed medication, and receive a decision through that process, unless patient safety requires swifter replacement.

(3) Formularies and related preauthorization information must be posted on an issuer or issuer's contracted pharmacy benefit manager website and must be current. Unless the removal is done on an immediate or emergency basis or because a generic equivalent becomes available without prior notice, formulary changes must be posted sixty days before the effective date of the change. In the case of an emergency removal, the change must be posted as soon as practicable, without unreasonable delay.

(4) An issuer must make current formulary information electronically available for loading into e-prescribing applications/electronic health records utilizing the National Council for Prescription Drug Programs (NCPDP) formulary and benefit standard transaction. Issuers must include all required data elements as well as the following information, to the extent supported by the transaction:

(a) Tier level;

(b) Contract exclusions;

(c) Quantity limits;

(d) Preauthorization required;

(e) Preferred/step therapy.

(5) The issuer's exception request process for any aspect of its prescription drug utilization management program must permit requests for off-formulary substitutions, as well as substitution of one drug on the formulary for another.

[Statutory Authority: RCW 48.02.060, 48.43.400, 48.43.410, and 48.43.420. WSR 20-24-105, § 284-43-5100, filed 12/1/20, effective 1/1/21. WSR 16-01-081, recodified as § 284-43-5100, filed 12/14/15, effective 12/14/15. Statutory Authority: RCW 48.02.060, 48.20.450, 48.20.460, 48.165.0301, 48.43.525, 48.43.530, 48.44.020, 48.44.050, 48.46.060(2), and 48.46.200. WSR 15-24-074 (Matter No. R 2014-13), § 284-43-818, filed 11/25/15, effective 7/1/16. 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), § 284-43-818, filed 10/8/12, effective 11/8/12.]