WAC 284-43-5080 Prescription drug benefit design. (1) A carrier may design its prescription drug benefit to include cost control measures, including requiring preferred drug substitution in a given therapeutic class, if the restriction is for a less expensive, equally therapeutic alternative product available to treat the condition.

(2) A carrier may include elements in its prescription drug benefit design that, where clinically feasible, create incentives for the use of generic drugs. Examples of permitted incentives include, but are not limited to, refusal to pay for higher cost drugs until it can be shown that a lower cost drug or medication is not effective (also known as step therapy protocols or fail-first policies), establishing a preferred brand and nonpreferred brand formulary, or otherwise limiting the benefit to the use of a generic drug in lieu of brand name drugs, subject to a substitution process as set forth in subsection (3) of this section.

(3) A carrier must establish a process that a provider and enrollee (or their designee) may use to request a substitution for a prescribed therapy, drug or medication that is not on the formulary.

(a) The process must not unreasonably restrict an enrollee's access to nonformulary or alternate medications for refractory conditions. Used in this context, "refractory" means "not responsive to treatment."

(b) For an individual or small group plan, a carrier must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) of its coverage determination no later than seventy-two hours following receipt of the request. A carrier that grants a standard exception request must provide coverage of the nonformulary drug for the duration of the prescription, including refills.

(c) For an individual or small group plan, a carrier must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing provider (or other prescriber) to request an expedited review based on exigent circumstances. For purposes of this section, "exigent circumstances" exist when an enrollee is experiencing a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

(i) A carrier must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designees and the prescribing provider (or other prescriber) of its coverage determination no later than twenty-four hours following receipt of the request.

(ii) A carrier that grants an exception based on exigent circumstances must provide coverage of the nonformulary drug for the duration of the exigency.

(d) Subject to the terms and conditions of the policy that otherwise limit or exclude coverage, the carrier must permit substitution of a covered generic drug or formulary drug if:

(i) An enrollee does not tolerate the covered generic or formulary drug; or

(ii) An enrollee's provider determines that the covered generic or formulary drug is not therapeutically efficacious for an enrollee. A carrier may require the provider to submit specific clinical documentation as part of the substitution request; or

(iii) The provider determines that a dosage is required for clinically efficacious treatment that differs from a carrier's formulary

dosage limitation for the covered drug. A carrier may require the provider to submit specific clinical documentation as part of the substitution request and must review that documentation prior to making a decision.

(4) A carrier may include a preauthorization requirement for its prescription drug benefit and its substitution process, based on accepted peer reviewed clinical studies, Federal Drug Administration black box warnings, the fact that the drug is available over-the-counter, objective and relevant clinical information about the enrollee's condition, specific medical necessity criteria, patient safety, or other criteria that meet an accepted, medically applicable standard of care.

(a) Neither the substitution process criteria nor the type or volume of documentation required to support a substitution request may be unreasonably burdensome to the enrollee or their provider.

(b) The substitution process must be administered consistently, and include a documented consultation with the prescribing provider prior to denial of a substitution request.

(5) Use of a carrier's substitution process is not a grievance or appeal pursuant to RCW 48.43.530 and 48.43.535. Denial of a substitution request is an adverse benefit determination, and an enrollee, their representative provider or facility, or representative may request review of that decision using the carrier's appeal or adverse benefit determination review process.

(6) In an individual or small group plan, if the carrier denies a request for a standard exception or for an expedited exception, the carrier must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing provider (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(a) A carrier must determine whether or not to grant an external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) of its decision no later than seventy-two hours following its receipt of the request, if the original request was a standard exception request, and no later than twenty-four hours following its receipt of the request, if the original request was an expedited exception request.

(b) If a standard exception request is granted after an external review, the health plan must provide coverage of the nonformulary drug for the duration of the prescription. If an expedited exception request is granted after an external review, the health plan must provide coverage of the nonformulary drug for the duration of the exigency. If such an exigency ceases, any drug previously covered under such exigency may only be reauthorized through the standard exception request process.

[Statutory Authority: RCW 48.02.060, 48.18.140, and 48.43.510. WSR 17-03-087 (Matter No. R 2016-22), § 284-43-5080, filed 1/12/17, effective 2/12/17. WSR 16-01-081, recodified as § 284-43-5080, filed 12/14/15, effective 12/14/15. 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), § 284-43-817, filed 10/8/12, effective 11/8/12.]