

Stakeholder draft

Name of rule: Prescription drug substitution processes

Rule number: 2016-22

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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 covered prescribed therapy, drug or medication.

(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) 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 72 hours following receipt of the request. A carrier that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(c) 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 non-formulary 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 24 hours following receipt of the request.

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

~~_(b) A carrier's substitution process must not result in delay in treating an enrollee's emergency fill or urgent care needs, or expedited requests for authorization.~~

(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) 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) An 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 72 hours following its receipt of the request, if the original request was a standard exception request, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request.

(b) If an carrier grants a request for an external review of a standard exception request, the carrier must provide coverage of the non-formulary drug for the duration of the prescription. If a carrier

grants a request for an external review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

(7) In the event a carrier grants an external exception review and the external review process results in a denial, the enrollee or their designee still has the ability to request a review of an adverse benefit determination pursuant to RCW 48.43.530 and 48.43.535.

[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.]

WAC 284-43-5110 Cost-sharing for prescription drugs. (1) A carrier and health plan unreasonably restrict the treatment of patients if an ancillary charge, in addition to the plan's normal copayment or coinsurance requirements, is imposed for a drug that is covered because of one of the circumstances set forth in either WAC 284-43-5080 or 284-43-5100. An ancillary charge means any payment required by a carrier that is in addition to or excess of cost-sharing explained in the policy or

contract form as approved by the commissioner. Cost-sharing means amounts paid directly to a provider or pharmacy by an enrollee for services received under the health benefit plan, and includes copayment, coinsurance, or deductible amounts.

(2) When an enrollee requests a brand name drug from the formulary in lieu of a therapeutically equivalent generic drug or a drug from a higher tier within a tiered formulary, and there is not a documented clinical basis for the substitution, a carrier may require the enrollee to pay for the difference in price between the drug that the formulary would have required, and the covered drug, in addition to the copayment. This charge must reflect the actual cost difference.

(3) When a carrier approves a substitution drug, whether or not the drug is in the carrier's formulary, the enrollee's cost-sharing for the substitution drug must be adjusted to reflect any discount agreements or other pricing adjustments for the drug that are available to a carrier. Any charge to the enrollee for a substitution drug must not increase the carrier's underwriting gain for the plan beyond the gain contribution calculated for the original formulary drug that is replaced by the substitution.

(4) If a carrier uses a tiered formulary in its prescription drug benefit design, and a substitute drug that is in the formulary is required based on one of the circumstances in either WAC 284-43-5080 or 284-43-5100, the enrollee's cost sharing may be based on the tier in which the carrier has placed the substitute drug.

(5) In the event that a substitution is granted, the carrier must treat the drug as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing and towards any deductible.

[Statutory Authority: RCW 48.02.060. WSR 16-14-106 (Matter No. R 2016-11), § 284-43-5110, filed 7/6/16, effective 8/6/16. WSR 16-01-081, re-codified as § 284-43-5110, 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), § 284-43-819, filed 10/8/12, effective 11/8/12.]