**WAC 284-43-2021 Prescription drug utilization management exception and substitution process.** (1) For purposes of this section and WAC 284-43-2022:

(a) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of prescription drug utilization management.

(b) "Medically appropriate" means prescription drugs that under the applicable standard of care are appropriate:

(i) To improve or preserve an enrollee's health, life, or function;

(ii) To slow the deterioration of an enrollee's health, life, or function; or

(iii) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

(2) Beginning January 1, 2021, a carrier must establish an exception request program so that enrollees and providers may request substitution of a preferred drug, therapy or medication, and exceptions to prescription drug benefit limitations and procedures under a carrier's drug utilization management program. The process must include both nonurgent and urgent exception request procedures.

(3) A carrier must treat an exception request as urgent 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 the enrollee is undergoing a current course of treatment using a nonformulary drug.

(4) A carrier's exception request standards, procedures and the process description must be available to the commissioner for review upon request. A carrier must require any entity the carrier uses to administer its prescription drug benefit or to make coverage decisions for prescription drug, therapy, or medication coverage, to comply with the carrier's exception process requirements. Neither the exception request process criteria nor the type or volume of documentation required to support an exception request may be unreasonably burdensome to the enrollee or their provider.

(5) The exception request procedures must:

(a) Clearly explain the process a provider and enrollee may use to request approval from the carrier, or any entity providing benefit administration, to substitute one drug, therapy or medication for another drug, therapy or medication on both an urgent and nonurgent basis.

(b) Explain how the exception process provides an enrollee with access to drugs, therapies, or medication that are both on and off the carrier's formulary.

(c) Permit an enrollee and their provider to use the exception request process when a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(d) Permit a request for an exception to utilization management restrictions applied by the carrier or any entity providing benefit administration, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(e) Permit substitution coverage for nonspecialty and specialty drugs, biologics, self-administered medication, and off-label prescriptions of medications, which means a prescription of a medication, drug, or therapy for an indication that deviates significantly from the approved U.S. Food and Drug Administration labeling. An indication is defined as a diagnosis, illness, injury, syndrome, condition or

other clinical parameter for which a drug may be given. A carrier is not required to permit substitution coverage for vaccines.

(6) A carrier must not establish a special formulary tier or copayment or other cost-sharing requirement that is only applicable to prescription drugs approved for coverage under an exception request. When an enrollee or their provider requests a formulary or tiering exception to obtain a nonpreferred drug that is in a higher cost-sharing tier, a carrier may apply the cost-share for the substituted drug based on the substituted drug's placement on the formulary. For a drug that is not on the formulary, the carrier must apply the enrollee's share of cost to their out-of-pocket maximum calculations. A carrier's prescription drug benefit must include a description of the enrollee's cost-share obligation for off-formulary coverage of substituted drugs, therapies, or medications accessed through the exception process.

(7) A carrier must not require the enrollee to submit a new exception request for a refill if the enrollee's prescribing physician or other prescriber continues to prescribe the drug and the drug continues to be approved by the U.S. Food and Drug Administration for treating the enrollee's disease or medical condition, or if the drug was prescribed as part of the enrollee's participation in a clinical trial.

(a) If the substituted drug is for an off-label drug use, a carrier may require the enrollee to submit a new exception request when a prescription fill and renewal cycle ends.

(b) A carrier may require an enrollee to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug.

(c) A carrier must consider exception requests for a U.S. Food and Drug Administration approved drug used for purposes other than what is indicated on the official label if the use is medically acceptable. A carrier must take into consideration major drug compendia, authoritative medical literature, and accepted standards of practice when making its decision.

(8) Subject to the terms and conditions of the policy that otherwise limit or exclude coverage, the carrier must grant the exception request if it can determine at least one of the following from the information submitted by a provider or enrollee in support of the exception request:

(a) The enrollee does not tolerate the covered generic or formulary drug or such drug is contraindicated;

(b) The enrollee's provider has determined 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 exception request;

(c) The enrollee's provider has determined clinically efficacious treatment requires a dosage 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 exception request and must review that documentation prior to making a decision;

(d) The enrollee has tried the required prescription drug or another prescription drug in the same pharmacologic class or a drug with the same mechanism of action and, based on the enrollee's documented history, establishes to their provider's satisfaction that they discontinued use of that drug because it was not therapeutically efficacious, effective, had a diminished effect or caused the enrollee an

adverse event. A carrier may not deny an exception request solely on the basis that the enrollee's prior use of the required or preferred drug was not within a specific time frame;

(e) The provider has determined that changing from a currently prescribed drug to a drug required by the carrier's formulary management protocols may cause clinically predictable adverse reactions, or physical or mental harm to the enrollee. A carrier's exception program must include uniform standards for the type of clinical documentation required to establish that an adverse reaction, or physical or mental harm is clinically predictable; or

(f) The drug required by the carrier's formulary management protocols is not in the best interest of the enrollee. To grant an exception request under this standard, a carrier must require submission of documentation of medical appropriateness, including an explanation of why the provider expects the enrollee's use of the required drug to either create a barrier to the enrollee's adherence to or compliance with their plan of care, to negatively impact a comorbid condition of the enrollee, to cause a clinically predictable negative drug interaction or to decrease the enrollee's ability to achieve or maintain reasonable functional ability in performing daily activities.

(9) A carrier must include specific direction in its process explaining how an enrollee may request coverage for an emergency fill of a substitute drug, therapy or medication. A carrier must cover an emergency fill if the treating health care provider determines that the emergency fill is necessary to keep the enrollee stable while the exception request is being processed.

(a) A carrier is not required to grant an exception request for a substitute drug on the basis that an emergency fill was requested.

(b) The emergency fill exception request process in subchapter D of this chapter provides an exception to the carrier's emergency fill policy as required by WAC 284-170-470(8).

[Statutory Authority: RCW 48.02.060, 48.43.400, 48.43.410, and 48.43.420. WSR 20-24-105, § 284-43-2021, filed 12/1/20, effective 1/1/21.]