

AMENDATORY SECTION (Amending WSR 17-12-069, filed 6/5/17, effective 7/6/17)

WAC 284-43-0160 Definitions. Except as defined in other subchapters and unless the context requires otherwise, the following definitions shall apply throughout this chapter.

(1) "Adverse determination" has the same meaning as the definition of adverse benefit determination in RCW 48.43.005, and includes:

(a) The determination includes any decision by a health carrier's designee utilization review organization that a request for a benefit under the health carrier's health benefit plan does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested benefit is therefore denied, reduced, or terminated or payment is not provided or made, in whole or in part for the benefit;

(b) The denial, reduction, termination, or failure to provide or make payment, in whole or in part, for a benefit based on a determination by a health carrier or its designee utilization review

organization of a covered person's eligibility to participate in the health carrier's health benefit plan;

(c) Any prospective review or retrospective review determination that denies, reduces, or terminates or fails to provide or make payment in whole or in part for a benefit;

(d) A rescission of coverage determination; or

(e) A carrier's denial of an application for coverage.

(2) "Authorization" or "certification" means a determination by the carrier that an admission, extension of stay, or other health care service has been reviewed and, based on the information provided, meets the clinical requirements for medical necessity, appropriateness, level of care, or effectiveness in relation to the applicable health plan.

(3) "Clinical review criteria" means the written screens or screening, decision rules, medical protocols, or clinical practice guidelines used by the carrier as an element in the evaluation of medical necessity and appropriateness of requested admissions, procedures, and services, including prescription drug benefits, under the auspices of the applicable plan.

(4) "Covered health condition" means any disease, illness, injury or condition of health risk covered according to the terms of any health plan.

(5) "Covered person" or "enrollee" means an individual covered by a health plan including a subscriber, policyholder, or beneficiary of a group plan.

(6) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of a preauthorization request. Emergency fill only applies to those circumstances where a patient presents at a contracted pharmacy with an immediate therapeutic need for a prescribed medication that requires a prior authorization.

(7) "Emergency medical condition" means the emergent and acute onset of a symptom or symptoms, including severe pain, that would lead a prudent layperson acting reasonably to believe that a health condition exists that requires immediate medical attention, if failure to provide medical attention would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

(8) "Emergency services" has the meaning set forth in RCW 48.43.005.

(9) "Enrollee point-of-service cost-sharing" or "cost-sharing" means amounts paid to health carriers directly providing services, health care providers, or health care facilities by enrollees and may include copayments, coinsurance, or deductibles.

(10) "Expedited prior authorization request" means any request by a provider or facility for approval of a service where the passage of time could seriously jeopardize the life or health of the enrollee, seriously jeopardize the enrollee's ability to regain maximum function, or, in the opinion of a provider or facility with knowledge of the enrollee's medical condition, would subject the enrollee to severe pain that cannot be adequately managed without the service that is the subject of the request.

(11) "Facility" means an institution providing health care services((~~r~~)) including, but not limited to, hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory, and imaging centers, and rehabilitation and other therapeutic settings, and as defined in RCW 48.43.005.

(12) "Formulary" means a listing of drugs used within a health plan. A formulary must include drugs covered under an enrollee's medical benefit.

(13) "Grievance" has the meaning set forth in RCW 48.43.005.

(14) "Health care provider" or "provider" means:

(a) A person regulated under Title 18 RCW or chapter 70.127 RCW, to practice health or health-related services or otherwise practicing health care services in this state consistent with state law; or

(b) An employee or agent of a person described in (a) of this subsection, acting in the course and scope of his or her employment.

(15) "Health care service" or "health service" means that service offered or provided by health care facilities and health care providers relating to the prevention, cure, or treatment of illness, injury, or disease.

(16) "Health carrier" or "carrier" means a disability insurance company regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, and a health maintenance organization as defined in RCW 48.46.020, and includes "issuers" as that term is used in the Patient Protection and Affordable Care Act (P.L. 111-148, as amended (2010)).

(17) "Health plan" or "plan" means any individual or group policy, contract, or agreement offered by a health carrier to provide, arrange, reimburse, or pay for health care service except the following:

(a) Long-term care insurance governed by chapter 48.84 RCW;

(b) Medicare supplemental health insurance governed by chapter 48.66 RCW;

(c) Limited health care service offered by limited health care service contractors in accordance with RCW 48.44.035;

(d) Disability income;

(e) Coverage incidental to a property/casualty liability insurance policy such as automobile personal injury protection coverage and homeowner guest medical;

(f) Workers' compensation coverage;

(g) Accident only coverage;

(h) Specified disease and hospital confinement indemnity when marketed solely as a supplement to a health plan;

(i) Employer-sponsored self-funded health plans;

(j) Dental only and vision only coverage; and

(k) Plans deemed by the insurance commissioner to have a short-term limited purpose or duration, or to be a student-only plan that is guaranteed renewable while the covered person is enrolled as a regular full-time undergraduate or graduate student at an accredited higher education institution, after a written request for such classification

by the carrier and subsequent written approval by the insurance commissioner.

(18) "Immediate therapeutic needs" means those needs where passage of time without treatment would result in imminent emergency care, hospital admission or might seriously jeopardize the life or health of the patient or others in contact with the patient.

(19) "Indian health care provider" means:

(a) The Indian Health Service, an agency operated by the U.S. Department of Health and Human Services established by the Indian Health Care Improvement Act, Section 601, 25 U.S.C. §1661;

(b) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. §1603(14), that operates a health program under a contract or compact to carry out programs of the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. §450 et seq.;

(c) A tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. §1603(26), that operates a health program under a contract or compact to carry out programs of the Indian Health Service pursuant to the ISDEAA, 25 U.S.C. §450 et seq.;

(d) An Indian tribe, as defined in the Indian Health Care Improvement Act, Section 4(14), 25 U.S.C. §1603(14), or tribal organization, as defined in the Indian Health Care Improvement Act, Section 4(26), 25 U.S.C. §1603(26), that operates a health program with funding provided in whole or part pursuant to 25 U.S.C. §47 (commonly known as the Buy Indian Act); or

(e) An urban Indian organization that operates a health program with funds in whole or part provided by Indian Health Service under a grant or contract awarded pursuant to Title V of the Indian Health Care Improvement Act, Section 4(29), 25 U.S.C. §1603(29).

(20) "Managed care plan" means a health plan that coordinates the provision of covered health care services to a covered person through the use of a primary care provider and a network.

(21) "Medically necessary" or "medical necessity" in regard to mental health services and pharmacy services is a carrier determination as to whether a health service is a covered benefit because the service is consistent with generally recognized standards within a relevant health profession.

(22) "Mental health provider" means a health care provider or a health care facility authorized by state law to provide mental health services.

(23) "Mental health services" means in-patient or out-patient treatment, partial hospitalization or out-patient treatment to manage or ameliorate the effects of a mental disorder listed in the *Diagnostic and Statistical Manual (DSM) IV* published by the American Psychiatric Association, excluding diagnoses and treatments for substance abuse, 291.0 through 292.9 and 303.0 through 305.9.

(24) "Network" means the group of participating providers and facilities providing health care services to a particular health plan or line of business (individual, small, or large group). A health plan network for issuers offering more than one health plan may be smaller in number than the total number of participating providers and facilities for all plans offered by the carrier.

(25) "Out-patient therapeutic visit" or "out-patient visit" means a clinical treatment session with a mental health provider of a duration consistent with relevant professional standards used by the carrier to determine medical necessity for the particular service being rendered, as defined in *Physicians Current Procedural Terminology*, published by the American Medical Association.

(26) "Participating provider" and "participating facility" means a facility or provider who, under a contract with the health carrier or with the carrier's contractor or subcontractor, has agreed to

provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments, or deductibles, from the health carrier rather than from the covered person.

(27) "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity, or any combination of the foregoing.

(28) "Pharmacy services" means the practice of pharmacy as defined in chapter 18.64 RCW and includes any drugs or devices as defined in chapter 18.64 RCW.

(29) "Predetermination request" means a voluntary request from an enrollee or provider or facility for a carrier or its designated or contracted representative to determine if a service is a benefit, in relation to the applicable plan.

(30) "Preservice requirement" means any requirement that a carrier places on a provider or facility that may limit their ability to deliver a service that requires prior authorization. Examples include limits on the type of provider or facility delivering the service, a service that must be provided before a specific service will be authorized, site of care/place of service, and whether a

provider administered medication needs to be obtained from a specialty pharmacy.

(31) "Primary care provider" means a participating provider who supervises, coordinates, or provides initial care or continuing care to a covered person, and who may be required by the health carrier to initiate a referral for specialty care and maintain supervision of health care services rendered to the covered person.

(32) "Preexisting condition" means any medical condition, illness, or injury that existed any time prior to the effective date of coverage.

(33) "Premium" means all sums charged, received, or deposited by a health carrier as consideration for a health plan or the continuance of a health plan. Any assessment or any "membership," "policy," "contract," "service," or similar fee or charge made by a health carrier in consideration for a health plan is deemed part of the premium. "Premium" shall not include amounts paid as enrollee point-of-service cost-sharing.

(34) "Prior authorization" means a mandatory process that a carrier or its designated or contracted representative requires a provider or facility to follow to determine if a service is a benefit and meets the requirements for medical necessity, clinical

appropriateness, level of care, or effectiveness in relation to the applicable plan. Prior authorization occurs before the service is delivered. For purposes of WAC 284-43-2050 and 284-43-2060, any term used by a carrier or its designated or contracted representative to describe this process is prior authorization. For example, prior authorization has also been referred to as "prospective review," "preauthorization," or "precertification."

(35) "Service area" means the geographic area or areas where a specific product is issued, accepts members or enrollees, and covers provided services. A service area must be defined by the county or counties included unless, for good cause, the commissioner permits limitation of a service area by zip code. Good cause includes geographic barriers within a service area, or other conditions that make offering coverage throughout an entire county unreasonable.

(36) "Small group plan" means a health plan issued to a small employer as defined under RCW 48.43.005(33) comprising from one to fifty eligible employees.

(37) "Standard prior authorization request" means a request by a provider or facility for approval of a service where the request is made in advance of the enrollee obtaining a service that is not required to be expedited.

(38) "Step therapy protocol" means a drug utilization management prior authorization protocol or program that establishes the specific sequence in which prescription drugs are covered by a health carrier for a medical condition.

(39) "Substitute drug" means a prescription medication, drug or therapy that a carrier covers based on an exception request. When the exception request is based on therapeutic equivalence, a substitute drug means a therapeutically equivalent substance as defined in chapter 69.41 RCW.

~~((39))~~ (40) "Supplementary pharmacy services" or "other pharmacy services" means pharmacy services involving the provision of drug therapy management and other services not required under state and federal law but that may be rendered in connection with dispensing, or that may be used in disease prevention or disease management.

[Statutory Authority: RCW 48.02.060, 48.43.510, 48.43.515, 48.43.520, 48.43.525, 48.43.530, and 48.165.030. WSR 17-12-069 (Matter No. R 2016-19), § 284-43-0160, filed 6/5/17, effective 7/6/17. Statutory Authority: RCW 48.02.060, 48.43.510. WSR 17-01-166 (Matter No. R 2016-16), § 284-43-0160, filed 12/21/16, effective 7/1/17. WSR 16-01-081, recodified as § 284-43-0160, 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), § 284-43-130, filed 11/25/15, effective 7/1/16. Statutory Authority: RCW 48.02.060, 48.18.120, 48.20.460, 48.43.505, 48.43.510, 48.43.515, 48.43.530, 48.43.535, 48.44.050, 48.46.200, 48.20.450, 48.44.020, 48.44.080, 48.46.030, 45 C.F.R. §§ 156.230, 156.235, and 156.245. WSR 14-10-017 (Matter No. R 2013-22), § 284-43-130, filed 4/25/14, effective 5/26/14. Statutory Authority: RCW 48.02.060, 48.43.525, 48.43.530, 48.43.535, and The Patient Protection and Affordable Care Act, P.L. 111-148, as amended (2010). WSR 12-23-005 (Matter No. R 2011-11), § 284-43-130, filed 11/7/12, effective 11/20/12. Statutory Authority: RCW 48.02.060, 48.18.120, 48.20.450, 48.20.460, 48.30.010, 48.44.050, 48.46.100, 48.46.200, 48.43.505, 48.43.510, 48.43.515, 48.43.520, 48.43.525, 48.43.530, 48.43.535. WSR 01-03-033 (Matter No. R 2000-02), § 284-43-130, filed 1/9/01, effective 7/1/01. Statutory Authority: RCW 48.02.060, 48.20.450, 48.20.460, 48.30.010, 48.44.050, 48.46.200, 2000 c 79 § 26, and RCW 48.30.040, 48.44.110, 48.46.400. WSR 01-03-032 (Matter No. R 2000-04), § 284-43-130, filed 1/9/01, effective 2/9/01. Statutory Authority: RCW 48.02.060, 48.30.010, 48.44.050, 48.46.200, 48.30.040, 48.44.110 and 48.46.400. WSR 99-19-032 (Matter No. R 98-7),

§ 284-43-130, filed 9/8/99, effective 10/9/99. Statutory Authority:
RCW 48.02.060, 48.20.450, 48.20.460, 48.30.010, 48.44.020, 48.44.050,
48.44.080, 48.46.030, 48.46.060(2), 48.46.200 and 48.46.243. WSR 98-
04-005 (Matter No. R 97-3), § 284-43-130, filed 1/22/98, effective
2/22/98.]

AMENDATORY SECTION (Amending WSR 16-01-081, filed 12/14/15, effective
12/14/15)

WAC 284-43-2020 Drug utilization review—Generally. (1) These
definitions apply to this section only:

(a) "Nonurgent review request" means any request for approval of
care or treatment where the request is made in advance of the patient
obtaining medical care or services, or a renewal of a previously
approved request, and is not an urgent care request.

(b) "Urgent care review request" means any request for approval
of care or treatment where the passage of time could seriously
jeopardize the life or health of the patient, seriously jeopardize the
patient's ability to regain maximum function or, in the opinion of a
provider with knowledge of the patient's medical condition, would

subject the patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.

(2) Each issuer must maintain a documented drug utilization review program. The program must include a method for reviewing and updating criteria. Issuers must make drug review criteria available upon request to a participating provider. Beginning January 1, 2021, an issuer must post its drug utilization management review criteria on its website and require any entity performing prescription drug benefit administration on the issuer's behalf to post the criteria used for the issuer's enrollees on the entity's website. The review criteria must be accessible to both providers and consumers, and presented in a format and in language that is user tested for readability ease and usability. An issuer may present different content for consumers and one for providers if the technical language required to communicate with a provider results in a low readability score, but the criteria may not differ between the two web pages.

(3) The drug utilization review program must meet accepted national certification standards such as those used by the National Committee for Quality Assurance except as otherwise required by this chapter.

(4) The drug utilization review program must have staff who are properly qualified, trained, supervised, and supported by explicit written clinical review criteria and review procedures.

(5) Each issuer must have written procedures to assure that reviews are conducted in a timely manner.

(a) If the review request from a provider is not accompanied by all necessary information, the issuer must tell the provider what additional information is needed and the deadline for its submission. Upon the sooner of the receipt of all necessary information or the expiration of the deadline for providing information, the time frames for issuer determination and notification must be no less favorable than United States Department of Labor standards, and are as follows:

(i) For urgent care review requests:

(A) Must approve the request within forty-eight hours if the information provided is sufficient to approve the claim and include the authorization number, if a prior authorization number is required, in its approval;

(B) Must deny the request within forty-eight hours if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or

(C) Within twenty-four hours, if the information provided is not sufficient to approve or deny the claim, the issuer must request that the provider submits additional information to make the prior authorization determination:

(I) The issuer must give the provider forty-eight hours to submit the requested information;

(II) The issuer must then approve or deny the request within forty-eight hours of the receipt of the requested additional information and include the authorization number in its approval;

(ii) For nonurgent care review requests:

(A) Must approve the request within five calendar days if the information is sufficient to approve the claim and include the authorization number in its approval;

(B) Must deny the request within five calendar days if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or

(C) Within five calendar days, if the information provided is not sufficient to approve or deny the claim, the issuer must request that the provider submits additional information to make the prior authorization determination:

(I) The issuer must give the provider five calendar days to submit the requested additional information;

(II) The issuer must then approve or deny the request within four calendar days of the receipt of the additional information and include the authorization number in its approval.

(b) Notification of the prior authorization determination must be provided as follows:

(i) Information about whether a request was approved must be made available to the provider;

(ii) Whenever there is an adverse determination resulting in a denial the issuer must notify the requesting provider by one or more of the following methods; phone, fax and/or secure electronic notification, and the covered person in writing or via secure electronic notification. Status information will be communicated to the billing pharmacy, via electronic transaction, upon the issuer's receipt of a claim after the request has been denied. The issuer must transmit these notifications within the time frames specified in (a) (i) and (ii) of this subsection in compliance with United States Department of Labor standards.

(6) When a provider or enrollee requests an exception to a carrier's drug utilization program, the time frames established in RCW 48.43.420 and WAC 284-43-2023 apply.

(7) No issuer may penalize or threaten a pharmacist or pharmacy with a reduction in future payment or termination of participating provider or participating facility status because the pharmacist or pharmacy disputes the issuer's determination with respect to coverage or payment for pharmacy service.

[WSR 16-01-081, recodified as § 284-43-2020, 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), § 284-43-420, filed 11/25/15, effective 7/1/16.]

NEW SECTION

WAC 284-43-2021 Prescription drug utilization management exception and substitution process. (1) For purposes of this section only, "medically appropriate" means prescription drugs that are appropriate under the applicable standard of care:

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

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

(c) 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 their in-network 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 request procedures. A carrier must treat an exception request as urgent if the enrollee is experiencing a health condition that may seriously jeopardize their life, health or ability to regain maximum function, or when the enrollee is undergoing a current course of treatment using a nonformulary drug.

(3) 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.

(4) The exception request procedures must:

(a) Clearly explain the process a provider and patient may use to request approval from the carrier or its benefit manager 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 in-network 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 restriction applied by the carrier or its benefit manager, 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.

(5) 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 in-network 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 issuer 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.

(6) 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.

(7) 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 in support of the exception request:

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

(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 substitution request;

(c) The enrollee's in-network 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 in-network 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 in-network 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 patient. A carrier's exception program must include uniform standards for the type of clinical documentation required to establish that an adverse reaction, 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 patient. 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 patient's use of the required drug to either create a barrier to the patient's adherence to or compliance with their plan of care, to negatively impact a comorbid condition of the patient, cause a clinically predictable negative drug

interaction or to decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

(8) 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 patient stable while the exception request is being processed.

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

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

(c) The emergency fill exception request process under this rule provides an exception to the carrier's emergency fill policy as required by WAC 284-170-470(8).

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NEW SECTION

WAC 284-43-2023 Time frame for exception and substitution

request determinations. (1) A carrier must make an exception request determination in a timely manner as defined in this section. A carrier may not deny the exception request if the enrollee or in-network provider does not receive a response to an exception request within the time frames in this section without good cause and without reaching a decision.

(2) A carrier must maintain a sufficient record of each exception request to establish its compliance with the required time frame for decision, and adherence to a compliant exception process under chapter 284-43 WAC and RCW 48.43.420. The carrier must make all records and documentation available to the commissioner upon request and be able to produce all requested documentation from any entity providing benefit administration or exception request decisions on its behalf within the time frame set by the commissioner.

(3) If a provider fails to submit sufficient information for the carrier to approve or deny an exception request, a carrier must notify the provider of the specific information needed within three business days of receiving a nonurgent exception request and one business day of receiving an urgent exception request that the documentation is insufficient and must explain what information is missing. A carrier

may establish a specific reasonable time frame for submission of the additional information, and may deny the request if the information is not received within that time frame.

(4) When a carrier receives sufficient information to make a decision, a carrier must make its determination on a nonurgent exception request and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) not later than three business days following receipt of the request.

(5) When an enrollee requests an exception on an urgent basis, a carrier must make its coverage determination not later than one business day following receipt of the urgent request, provided the carrier received sufficient information from the prescribing provider to make the determination.

(6) Use of a carrier's exception process is not a grievance or appeal pursuant to RCW 48.43.530 and 48.43.535. Denial of an exception 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.

(7) A carrier's denial of an exception request is subject to the requirements of RCW 48.43.535 and chapter 284-43A WAC, which grants

enrollees access to independent external review of carrier decisions to deny, modify, reduce or terminate coverage of or payment for a health care service or if the carrier exceeds the timelines for making an exception request decision and denies coverage. While the external review is conducted, the carrier must cover the drug if the exception request was urgent or was for an emergency fill. If such an exigency ceases, any drug previously covered under such exigency may only be reauthorized through the standard exception request process. If the independent external review reverses the carrier's denial of either an urgent or nonurgent exception request, the carrier must retrospectively cover the nonformulary drug and continue coverage for the duration of the prescription.

(8) A carrier may not penalize or threaten a provider with a reduction in future payment or termination of a participating provider agreement because the provider disputes the carrier's determination with respect to coverage or payment for a substitute drug.

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AMENDATORY SECTION (Amending WSR 17-03-087, filed 1/12/17, effective 2/12/17)

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)) 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.

(4) A health 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.

[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.]

AMENDATORY SECTION (Amending WSR 16-01-081, filed 12/14/15, effective 12/14/15)

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 (~~substitution~~) 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 (~~thirty~~) 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.

[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.]

AMENDATORY SECTION (Amending WSR 17-01-166, filed 12/21/16, effective 1/21/17)

WAC 284-43-5170 Prescription drug benefit disclosures. (1) A carrier must include the following information in the certificate of

coverage issued for a health benefit plan, policy or agreement that includes a prescription drug benefit in addition to those required elsewhere in Titles 48 RCW and 284 WAC. The commissioner may disapprove any contract issued on or after January 1, 2018, if the requirements of this subsection are not met.

(a) A clear statement explaining that the health benefit plan uses the following in its coverage of drugs (as applicable):

(i) Exclusion of certain brand name or other medications from its formulary;

(ii) Therapeutic drug substitution;

(iii) Incentives for use of generic drugs (such as step-therapy protocols);

(iv) Prior authorization requirements;

(v) Mid-plan year formulary changes; or

(vi) Other limits of its prescription drug benefit.

(b) Until January 1, 2021, a clear explanation of the substitution process required under WAC 284-43-5080 that the enrollee or their provider must use to seek coverage of a prescription drug or medication that is not in the formulary or is not the carrier's preferred drug or medication for the covered medical condition. After

January 1, 2021, the exception request process required under WAC 284-43-2021 and 284-43-2023 must also be explained.

(c) A clear statement explaining that consumers may be eligible to receive an emergency fill for prescription drugs under the circumstances described in WAC 284-170-470. The disclosure must include the process for consumers to obtain an emergency fill, and cost-sharing requirements, if any, for an emergency fill.

(d) The process for developing coverage standards and formularies, including the principal criteria by which drugs are selected for inclusion, exclusion, restriction or limitation.

(e) The process of changing formularies and coverage standards, including changes in the use of substitute drugs. If the plan has provisions for "grandfathering" certain ongoing prescriptions or other coverage exceptions, these practices must be disclosed.

(f) The disclosure must state whether drugs may move between tiers during a plan year and whether this may affect cost-sharing.

(g) Any medication management, disease management, or other pharmacy-related services reimbursed by the plan in addition to those required under state and federal law in connection with dispensing drugs, such as disease management services for migraine, diabetes, smoking cessation, asthma, or lipid management.

(h) The general categories of drugs excluded from coverage must be disclosed. Such categories may include items such as appetite suppressants, dental prescriptions, cosmetic agents or most over-the-counter medications. This subsection does not require that any particular category of coverage for drugs or pharmacy services should be excluded, reduced, or limited by a health plan.

(2) When a carrier eliminates a previously covered drug from its formulary, or establishes new limitations on coverage of the drug or medication, at a minimum a carrier must ensure that prior notice of the change will be provided as soon as is practicable, to enrollees who filled a prescription for the drug within the prior three months.

(a) Provided the enrollee agrees to receive electronic notice and such agreement has not been withdrawn, either electronic mail notice, or written notice by first class mail at the last known address of the enrollee, are acceptable methods of notice.

(b) If neither of these notice methods is available because the carrier lacks contact information for enrollees, a carrier may post notice on its website or at another location that may be appropriate, so long as the posting is done in a manner that is reasonably calculated to reach and be noticed by affected enrollees.

(3) A carrier and health plan may use provider and enrollee education to promote the use of therapeutically equivalent generic drugs. The materials must not mislead an enrollee about the difference between biosimilar or bioequivalent, and therapeutically equivalent, generic medications.

(4) A carrier must include the following statement in the certificate of coverage issued for a health benefit plan, policy, or agreement that includes a prescription drug benefit, and provide current contact information as prompted below:

YOUR PRESCRIPTION DRUG RIGHTS

You have the right to safe and effective pharmacy services. You also have the right to know what drugs are covered by your plan and the limits that apply. If you have a question or concern about your prescription drug benefits, please contact us (the health carrier) at (health carrier's contact phone number) or visit (health carrier's website). If you would like to know more about your rights, or if you have concerns about your plan, you may contact the Washington state office of insurance commissioner at 1-800-562-6900 or www.insurance.wa.gov. If you have a concern about the pharmacists or pharmacies serving you, please contact the Washington state department of health at 360-236-4700, www.doh.wa.gov, or HSQACSC@doh.wa.gov.

[Statutory Authority: RCW 48.02.060, 48.43.510. WSR 17-01-166 (Matter No. R 2016-16), § 284-43-5170, filed 12/21/16, effective 1/21/17; WSR 16-19-086 (Matter No. R 2016-08), § 284-43-5170, filed 9/20/16, effective 10/21/16. Statutory Authority: RCW 48.02.060. WSR 16-14-106 (Matter No. R 2016-11), § 284-43-5170, filed 7/6/16, effective 8/6/16. WSR 16-01-081, recodified as § 284-43-5170, 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), § 284-43-825, filed 10/8/12, effective 11/8/12.]