Medications and Off-Label Drugs

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➲ Instructions for Use

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Oklahoma

OAC Section 365:40-5-21, #7, Supplemental Health Care Services

http://okrules.elaws.us/oac/365:40-5-21

Supplemental health care services of an HMO may include the following:

7. Prescribed drugs and medicines incidental to outpatient care. Supplemental coverage for prescription drugs shall also provide coverage of off-label uses of prescription drugs used in the treatment of cancer or the study of oncology. Coverage shall include the approval of oncology (chemotherapeutic) drugs for off-label indications when used for malignant disease, when the safety and effectiveness of use for this indication has been recommended, supported and demonstrated by at least one controlled clinical trial published in a nationally recognized peer reviewed journal or when at least one of the standard pharmacy compendia (United States Pharmacopoeia Dispensing Information [USPDI], American Society of Health-System Pharmacists Drug Information [AHFS Drug Information] or American Medical Association Drug Evaluations [AMADE]) lists the drug to be accepted as safe and effective for this indication. This will not include the off-label use of these agents in the treatment of **non-**malignant disease.

Oklahoma Statute Title 63 Section 1-2604: Individual policy Coverage for Prescription Drugs for Cancer Treatment or Study of Oncology , Exclusion Prohibited

https://law.justia.com/codes/oklahoma/2021/title-63/section-63-1-2604/

No individual policy of accident and health insurance issued which provides coverage for prescription drugs, nor any group blanket policy of accident and health insurance issued which provides coverage for prescription drugs shall exclude coverage of prescription drugs for cancer treatment or the study of oncology because the off-label use of such prescription drug has not been approved by the Federal Food and Drug Administration for that indication in one of the standard reference compendia, as defined in paragraph (d) of Section 1-1401 of Title 63 of the Oklahoma Statutes.
Any coverage of a prescription drug required by this section shall also include provisions for coverage of medically necessary services associated with the administration of the prescription drug.

Nothing in this section shall be construed as altering existing law with regard to provisions limiting the coverage of prescription drugs that have not been approved by the Federal Food and Drug Administration.

Oklahoma Statute Title 63 Section 1-2605 Off-label Uses of Prescription Drugs for Cancer Treatment Coverage Under Health Maintenance Contracts

https://law.justia.com/codes/oklahoma/2021/title-63/section-63-1-2605/

Any group or non-group health maintenance contract which provides coverage for prescription drugs shall also provide coverage of off-label uses of prescription drugs used in the treatment of cancer or the study of oncology.

Oregon

ORS Section 743A.062: Prescription Drugs

https://www.oregonlaws.org/ors/743A.062

(1) As used in this section, "medical assistance program" means the state program that provides medical assistance as defined in ORS 414.025 (Definitions for ORS chapters 411, 413 and 414).
(2) An insurance policy or contract providing coverage for a prescription drug to a resident of this state may not:
  (a) Exclude coverage of the drug for a particular indication solely on the grounds that the indication has not been approved by the United States Food and Drug Administration if the Health Evidence Review Commission established under ORS 414.688 (Commission established) or the Pharmacy and Therapeutics Committee established under ORS 414.353 (Committee established) determines that the drug is recognized as effective for the treatment of that indication:
    (A) In publications that the commission or the committee determines to be equivalent to:
      (i) The American Hospital Formulary Service drug information;
      (ii) "Drug Facts and Comparisons" (Lippincott-Raven Publishers);
      (iii) The United States Pharmacopoeia drug information; or
      (iv) Other publications that have been identified by the United States Secretary of Health and Human Services as authoritative;
    (B) In the majority of relevant peer-reviewed medical literature; or
    (C) By the United States Secretary of Health and Human Services; or
  (b) For an insured who is enrolled in the medical assistance program:
    (A) Except as provided in subsection (3) of this section, require a prescription for the drug to be filled or refilled at a mail order pharmacy; or
    (B) Require a prescription for the drug to be filled or refilled at a pharmacy that is not a local pharmacy enrolled in the medical assistance program.
(3) Subsection (2)(b)(A) of this section does not prohibit an insurer from requiring a medical assistance recipient to fill or refill a prescription for a specialty drug at a mail order pharmacy that is a specialty pharmacy.
(4) Required coverage of a prescription drug under this section shall include coverage for medically necessary services associated with the administration of that drug.
(5) Nothing in this section requires coverage for any prescription drug if the United States Food and Drug Administration has determined use of the drug to be contraindicated.
(6) Nothing in this section requires coverage for experimental drugs not approved for any indication by the United States Food and Drug Administration.
(7) This section is exempt from ORS 743A.001 (Automatic repeal of certain statutes on individual and group health insurance). [Formerly 743.697; 2011 c.720 §222; 2021 c.339 §1]

ORS Section 743A.060: Definition for ORS Section 743A.062

https://www.oregonlaws.org/ors/743A.060

As used in ORS 743A.062 "peer-reviewed medical literature" means scientific studies printed in journals or other publications that publish original manuscripts only after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity and reliability. "Peer-reviewed medical literature" does not include internal publications of pharmaceutical manufacturers. (Formerly 743.695)

ORS Section 743B.601 Synchronization of Prescription Drug Refills

https://www.oregonlaws.org/ors/743B.601

(1) As used in this section:
  (a) "Health plan" means:
    (A) "health benefit plan" as defined in ORS 743B.005 and
    (B) A self-insured health plan offered by the Oregon Health and Science University.

(b) "Synchronization policy" means a procedure for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently.
(2) A health plan that includes prescription drug coverage shall implement a synchronization policy for the dispensing of prescription drugs to the plan's enrollees.
(3) A health plan shall reimburse the cost of prescription drugs dispensed in accordance with the plan's synchronization policy.
(4) If a drug is dispensed in less than a 30-day supply for the purpose of synchronizing a patient's prescription drug refills, a health plan shall:
(a) Prorate the copayment; or
(b) Adjust the copayment using a method approved by the Department of Consumer and Business Services.
(5) A health plan shall fully reimburse the dispensing fee for partially filled or refilled prescription drugs.
(6) This section does not apply to prescription drugs that:
(a) Are in unit-of-use packaging for which synchronization is not possible;
(b) Are controlled substances; or
(c) Have been identified by the United States Drug Enforcement Administration as having a high risk of diversion.
(7) The coverage required by this section may be limited by formulary restrictions applied to a prescription drug by a health plan.
(8) (a) This section does not apply to a prepaid group practice health plan with at least 200,000 enrollees in this state.
(b) As used in this subsection, "prepaid group practice health plan" means a health care service contractor that provides physician services to its enrollees through an integrated health care delivery system using, primarily, a single group of physicians contracted on a prepaid, capitated basis. [2014 c.25 §2; 2015 c.800 §1; 2017 c.309 §6]

Note: 743B.601 was added to and made a part of the Insurance Code by legislative action but was not added to ORS chapter 743B or any series therein. See Preface to Oregon Revised Statutes for further explanation.

Texas

TIC Section 1369.001: Definitions

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1369&Phrases=1369&HighlightType=1&ExactPhrase=False&QueryText=1369

In this subchapter:
(1) "Contraindication" means the potential for, or the occurrence of:
(A) an undesirable change in the therapeutic effect of a prescribed drug because of the presence of a disease condition in the patient for whom the drug is prescribed; or
(B) a clinically significant adverse effect of a prescribed drug on a disease condition of the patient for whom the drug is prescribed
(2) "Drug" has the meaning assigned by Section 551.003, Occupations Code.
(2-a) "Enrollee" means an individual who is covered under a health benefit plan, including a covered dependent
(3) "Indication" means a symptom, cause, or occurrence in a disease that points out the cause, diagnosis, course of treatment, or prognosis of the disease.
(4) "Peer-reviewed medical literature" means scientific studies published in a peer-reviewed national professional journal.

TIC Section 1369.002: Applicability of Subchapter

This subchapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:
(1) An insurance company;
(2) A group hospital service corporation operating under Chapter 842;
(3) A fraternal benefit society operating under Chapter 885;
(4) A stipulated premium company operating under Chapter 884;
(5) A reciprocal exchange operating under Chapter 942;
(6) A health maintenance organization operating under Chapter 843;
(7) A multiple employer welfare arrangement that holds a certificate of authority under Chapter 846; or
(8) An approved nonprofit health corporation that holds a certificate of authority under Chapter 844.

TIC Section 1369.004: Coverage Required

(a) A health benefit plan that covers drugs must cover any drug prescribed to treat an enrollee for a chronic, disabling, or life-threatening illness covered under the plan if the drug:

(1) Has been approved by the United States Food and Drug Administration for at least one indication; and
(2) Is recognized by the following for treatment of the indication for which the drug is prescribed:
(A) A prescription drug reference compendium approved by the commissioner for purposes of this section; or
(B) Substantially accepted peer-reviewed medical literature

(b) Coverage of a drug required under Subsection (a) must include coverage of medically necessary services associated with the administration of the drug.

(c) A health benefit plan issuer may not, based on a "medical necessity" requirement, deny coverage of a drug required under Subsection (a) unless the reason for the denial is unrelated to the legal status of the drug use.

(d) This section does not require a health benefit plan to cover:
(1) Experimental drugs that are not otherwise approved for an indication by the United States Food and Drug Administration;
(2) Any disease or condition that is excluded from coverage under the plan; or
(3) A drug that the United States Food and Drug Administration has determined to be contraindicated for treatment of the current indication

Washington

WAC Section 284-30-450, Insurance Policies and Contacts – Coverage for Drugs

https://apps.leg.wa.gov/wac/default.aspx?cite=284-30-450

(1) Authority and purpose.
(a) Some insurers deny payment for drugs that have been approved by the Federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labelling approved by the FDA (off-label use) while other insurers with similar coverage terms pay for off-label use. Denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness.
(b) Equity among insured residents of this state and fair claims settlement practices and fair competition among companies providing coverage to residents of this state require comparable reimbursement for prescribed drugs among insurers, health care service contractors, and health maintenance organizations.
(c) Use of off-label indications often provides efficacious drugs at a lower cost.
(d) To prevent unfair methods of claims settlements, unfair competition, and unfair or deceptive acts or practices of insurers and prohibited acts or practices of health care service contractors or health maintenance organizations, this rule is adopted.

(2) Scope.
This regulation affects all insurance and health benefit policies and contracts providing coverage for drugs to a resident of this state which are issued, amended, delivered or renewed on or after January 1, 1995.

(3) Definitions. The following definitions are used in this section:
(a) "Drug" or "drugs" means any substance prescribed by a physician taken by mouth, injected into a muscle, the skin, a blood vessel, or a cavity of the body, or applied to the skin to treat or prevent a disease, and specifically includes drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication or for the treatment of people with HIV or AIDS.
(b) "Off-label" means the prescribed use of a drug which is other than that stated in its FDA approved labelling.
(c) "Peer-reviewed medical literature" means scientific studies printed in journals or other publications in which original manuscripts are published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. Peer-reviewed medical literature does not include in-house publications of pharmaceutical manufacturing companies.
(d) "Physician" means a medical doctor or other health care provider acting within the scope of his or her professional license.
(e) "Policy" or "contract" means any individual, group or blanket policy of insurance or health benefit contract issued by a disability insurer, health care service contractor, or health maintenance organization which is issued, amended, delivered or renewed on or after January 1, 1995, and which provides coverage for drugs to a resident of this state.
(f) "Standard reference compendia" means:
(i) The American Hospital Formulary Service-Drug Information;
(ii) The American Medical Association Drug Evaluation;
(iii) The United States Pharmacopoeia-Drug Information; or
(iv) Other authoritative compendia as identified from time to time by the Federal Secretary of Health and Human Services or the insurance commissioner.

(4) Standards of coverage.

(a) No insurance policy or contract which provides coverage for prescription drugs to a resident of this state shall exclude coverage of any such drug for a particular indication on the grounds that the drug has not been approved by the Federal Food and Drug Administration for that indication, if such drug is recognized as effective for treatment of such indication:
  (i) In one of the standard reference compendia;
  (ii) In the majority of relevant peer-reviewed medical literature if not recognized in one of the standard reference compendia; or
  (iii) By the Federal Secretary of Health and Human Services
(b) Coverage of a prescription drug required by this section shall also include medically necessary services associated with the administration of the drug.
(c) This regulation shall not be construed to require coverage for any drug when the Federal Food and Drug Administration has determined its use to be contra-indicated.
(d) This regulation shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the Federal Food and Drug Administration.

WAC Section 284-43-5060 General Prescription Drug Benefit Requirements

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5060

A health carrier must not offer, renew, or issue a health benefit plan providing a prescription drug benefit, which the commissioner determines results or can reasonably be expected to result in an unreasonable restriction on the treatment of patients. A carrier may restrict prescription drug coverage based on contract or plan terms and conditions that otherwise limit coverage, such as a preexisting condition waiting period, or medical necessity.

(1) A carrier must ensure that a prescription drug benefit covers Federal Drug Administration approved prescribed drugs, medications or drug therapies that are the sole prescription drug available for a covered medical condition.
(2) A prescription drug benefit that only covers generic drugs constitutes an unreasonable restriction on the treatment of patients.
(3) A prescription drug benefit or formulary must not exclude coverage for a nonformulary drug or medication if the only formulary drug available for an enrollee's covered condition is one that the enrollee cannot tolerate or that is not clinically efficacious for the enrollee.
(4) Nothing in this chapter is intended to limit or deter the use of "Dispense as Written" prescriptions, subject to the terms and conditions of the health plan.

WAC Section 284-43-5080 Prescription Drug Benefit Design

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5080

(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 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 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.
(5) A non-grandfathered health plan issued or renewed on or after January 1, 2023, that provides coverage for prescription drugs must comply with RCW 48.43.435.
  (a) For the purposes of this subsection, any cost sharing amount paid directly by or on behalf of the enrollee by another person for a covered prescription drug, at the time it is rendered, must be applied in full toward the enrollee's applicable cost-sharing as defined in WAC 284-43-0160 and out-of-pocket maximum as defined in RCW 48.43.005 consistent with RCW 48.43.435.
  (b) If an enrollee requests an exception under RCW 48.43.420 or appeals a denial of an exception request, and the request or appeal is still pending, any amount paid by or on behalf of an enrollee for a covered prescription drug must be applied towards the enrollee's contribution to any applicable deductible, copayment, coinsurance, or out-of-pocket maximum until the review is resolved and the status of the request is communicated to the carrier.

(c) The health carrier must disclose to the enrollee information about when third-party payments, including payments made through application of a manufacturer drug coupon or other manufacturer discount, are applied towards the enrollee's annual cost-sharing obligations, including applicable deductibles, copayments, coinsurances, or out-of-pocket maximums. The disclosure shall be included in the certificate of coverage (also commonly referred to as the member booklet or member handbook). Carriers are not required to use verbatim language from either the statute or regulation; however, the information provided to the enrollee about the application of third-party payments must be sufficiently detailed to address the situations set forth in RCW 48.43.435 (1)(a)(i) through (iii).

WAC Section 284-43-5100 Formulary Changes

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5100

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 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 web site 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 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.

WAC Section 284-43-5110 Cost Sharing for Prescription Drugs

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5110

(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) If a carrier requires cost-sharing for enrollees receiving an emergency fill as defined in WAC 284-170-470, then issuers must disclose that information to enrollees within their policy forms.
(6) For individual and small group plans, if 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.

WAC Section 284-43-5170 Prescription Drug Benefit Disclosures

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5170

(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) For health plans delivered, issued, or renewed on or before 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.
  (c) For health plans delivered, issued, or renewed on or after January 1, 2021, a clear explanation of the exception and substitution processes required under WAC 284-43-2021, 284-43-2022, and 284-43-5080.
  (d) 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.
  (e) 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.
  (f) 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.
  (g) The disclosure must state whether drugs may move between tiers during a plan year and whether this may affect cost-sharing.
  (h) 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.
  (i) 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 web site 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 web site). 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.

WAC Section 284-43-2021 Prescription Drug Utilization Management Exception and Substitution Process

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-2021

(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 non-specialty 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.]

WAC Section 284-43-2022 Time Frame for Exception and Substitution Request Determinations

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-2022

(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 provider does not receive a response to an exception request within the time frames in this section.

(2) A carrier must maintain a sufficient record of each exception request to establish its compliance with the required exception process and time frames under chapter 284-43 WAC and RCW 48.43.420. Upon the commissioner's

request, a carrier must make all records and documentation available and 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. A carrier must notify the provider 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. This time frame must be communicated to the provider or enrollee with a carrier's request for additional information. If the additional information is not received within that time frame, a carrier may deny the request.

(4) When a carrier receives sufficient information to make a decision regarding a nonurgent exception request, a carrier must make its determination and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) no later than three business days following receipt of the request.

(5) When a carrier receives sufficient information to make a decision regarding an urgent exception request, a carrier must make its determination and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) no later than one business day following receipt of the request.

(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 a 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 a carrier's determination with respect to coverage or payment for a substitute drug.

[Statutory Authority: RCW 48.02.060, 48.43.400, 48.43.410, and 48.43.420. WSR 20-24-105, § 284-43-2022, filed 12/01/2020, effective 01/01/2021.]

WAC Section 284-43-5200 Anti-Cancer Medication

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5200

A carrier and health plan must cover prescribed, self-administered anticancer medication that is used to kill or slow the growth of cancerous cells on at least a comparable basis to the plan's coverage for the delivery of cancer chemotherapy medications administered in a clinical or medical setting.

(1) A carrier may not impose dollar limits, copayments, deductibles or coinsurance requirements on coverage for orally administered anticancer drugs or chemotherapy that are less favorable to an insured or enrollee than the dollar limits, copayments, deductibles or coinsurance requirements that apply to coverage for anticancer medication or chemotherapy that is administered intravenously or by injection.

(2) A carrier may not reclassify an anticancer medication or increase an enrollee’s out-of-pocket costs as a method of compliance with the requirements of this section.

WAC Section 284-43-5420 Clinical Trials

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5420

A carrier must not restrict coverage of routine patient costs for enrollees who participate in a clinical trial. "Routine costs" means items and services delivered to the enrollee that are consistent with and typically covered by the plan or coverage for an enrollee who is not enrolled in a clinical trial. A carrier may continue to apply its limitations and requirements related to use of network services.

(1) A carrier may require enrollee’s to meet the eligibility requirements of the clinical trial according to the trial protocol. While not required to impose such a condition, a carrier may refuse coverage under this section if the enrollee does not provide medical and scientific information establishing that the individual's participation in such trial would be appropriate based on the individual meeting the eligibility requirements for the clinical trial, unless the enrollee is referred to the clinical trial by a health care provider participating in the carrier's network.

(2) This includes the cost of prescription medication used for the direct clinical management of the enrollee, unless the trial is for the investigation of the prescription medication or the medication is typically provided by the research sponsors free of charge for any enrollee in the trial.
(3) The requirement does not apply to:
  (a) A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
  (b) For items and services provided solely to satisfy data collection and analysis needs;
  (c) Items and services that are not used in the direct clinical management of the enrollee; or
  (d) The investigational item, device, or service itself
(4) Clinical trial means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition, funded or approved by:
  (a) One of the National Institutes of Health (NIH);
  (b) An NIH cooperative group or center which is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group including, but not limited to, the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;
  (c) The federal Departments of Veterans Affairs or Defense
  (d) An institutional review board of an institution in this state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH; or
  (e) A qualified research entity that meets the criteria for NIH Center Support Grant eligibility.
  "Life threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Washington 2023-SB6127, Increasing Access to Human Immunodeficiency Virus Postexposure Prophylaxis Drugs or Therapies (Effective Date 01/01/2025)

http://lawfilesext.leg.wa.gov/biennium/2023-24/Pdf/Bills/Session%20Laws/Senate/6127-S.SL.pdf

AN ACT Relating to increasing access to human immunodeficiency virus postexposure prophylaxis drugs or therapies; amending RCW 70.41.480; reenacting and amending RCW 41.05.017; adding a new section to chapter 70.41 RCW; adding a new section to chapter 48.43 RCW; adding a new section to chapter 74.09 RCW; and providing an effective date.

Be it enacted by the legislature of the State of Washington:

Section 1 (New Section)

A new section is added to chapter 70.41 RCW to read as follows:
(1) A hospital must adopt a policy and have procedures in place, that conform with the guidelines issued by the centers for disease control and prevention, for the dispensing of human immunodeficiency virus postexposure prophylaxis drugs or therapies.
(2) This policy must ensure that hospital staff dispense or deliver as defined in RCW 18.64.011 to a patient, with a patient's informed consent, a 28-day supply of human immunodeficiency virus postexposure prophylaxis drugs or therapies following the patient's possible exposure to human immunodeficiency virus, unless medically contraindicated, inconsistent with accepted standards of care, or inconsistent with centers for disease control and prevention guidelines. When available, hospitals shall dispense or deliver generic human immunodeficiency virus postexposure prophylaxis drugs or therapies.
(3) Nothing in this section shall be construed to alter the coverage for reimbursement of postexposure prophylaxis drugs through:
  (a) The crime victims' compensation program, established in chapter 7.68 RCW, for drugs dispensed or delivered to sexual assault victims; or
  (b) The industrial insurance act for drugs dispensed or delivered to a worker exposed to the human immunodeficiency virus through the course of employment.

Section 2

RCW 70.41.480 and 2022 c 25 s 1 are each amended to read as follows:
(1) The legislature finds that high quality, safe, and compassionate health care services for patients of Washington state must be available at all times. The legislature further finds that there is a need for patients being released from hospital emergency departments to maintain access to emergency medications when community or hospital pharmacy services are not available, including medication for opioid overdose reversal and for the treatment for opioid use disorder as appropriate. It is the intent of the legislature to accomplish this objective by allowing practitioners with

prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available.

(2) A hospital may allow a practitioner to prescribe prepackaged emergency medications and allow a practitioner or a registered nurse licensed under chapter 18.79 RCW to distribute prepackaged emergency medications to patients being discharged from a hospital emergency department in the following circumstances:
   (a) During times when community or outpatient hospital pharmacy services are not available within 15 miles by road; or
   (b) When, in the judgment of the practitioner and consistent with hospital policies and procedures, a patient has no reasonable ability to reach the local community or outpatient pharmacy; or
   (c) When a patient is identified as needing human immunodeficiency virus postexposure prophylaxis drugs or therapies.

(3) A hospital may only allow this practice if: The director of the hospital pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following:
   (a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed;
   (b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW;
   (c) Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;
   (d) Assurances that any practitioner authorized to prescribe prepackaged emergency medication or any nurse authorized to distribute prepackaged emergency medication is trained on the types of medications available and the circumstances under which they may be distributed;
   (e) Procedures to require practitioners intending to prescribe prepackaged emergency medications pursuant to this section to maintain a valid prescription either in writing or electronically in the patient's records prior to a medication being distributed to a patient;
   (f) Establishment of a limit of no more than a 48 hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within 48 hours. In no case may the policy allow a supply exceeding 96 hours be dispensed, or when antibiotics or human immunodeficiency virus postexposure prophylaxis drugs or therapies are required;
   (g) Assurances that prepackaged emergency medications will be kept in a secure location in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy; and
   (h) Assurances that nurses or practitioners will distribute prepackaged emergency medications to patients only after a practitioner has counseled the patient on the medication.

(4) The delivery of a single dose of medication for immediate administration to the patient is not subject to the requirements of this section.

(5) Nothing in this section restricts the authority of a practitioner in a hospital emergency department to distribute opioid overdose reversal medication under RCW 69.41.095.

(6) A practitioner or a nurse in a hospital emergency department must dispense or distribute opioid overdose reversal medication in compliance with RCW 70.41.485.

(7) For purposes of this section:
   (a) "Emergency medication" means any medication commonly prescribed to emergency department patients, including those drugs, substances or immediate precursors listed in schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, as now or hereafter amended.
   (b) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
   (c) "Opioid overdose reversal medication" has the same meaning as provided in RCW 69.41.095.
   (d) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs as defined in RCW 18.64.011(29).
   (e) "Nurse" means a registered nurse or licensed practical nurse as defined in chapter 18.79 RCW.

Section 3 (New Section)

A new section is added to chapter 48.43 RCW to read as follows:

(1) Except as provided in subsection (2) of this section, for non-grandfathered health plans issued or renewed on or after January 1, 2025, a health carrier may not impose cost sharing or require prior authorization for the drugs that comprise at least one regimen recommended by the centers for disease control and prevention for human immunodeficiency virus postexposure prophylaxis.

(2) For a health plan that is offered as a qualifying health plan for a health savings account, the health carrier must establish the plan's cost sharing for the coverage required by this section at the minimum level necessary to preserve the enrollee's ability to claim tax exempt contributions and withdrawals from the enrollee's health savings account under the internal revenue service laws and regulations.

(3) Notwithstanding the coverage requirements of this section, a health plan shall reimburse a hospital that bills for a 28-day supply of any human immunodeficiency virus postexposure prophylaxis drugs or therapies dispensed or delivered to a patient in the emergency department for take-home use, pursuant to section 1 of this act, as a separate reimbursable expense. This reimbursable expense is separate from any bundled payment for emergency department services.

Section 4 (New Section)

A new section is added to chapter 74.09 RCW to read as follows:

(1) The authority and all Medicaid contracted managed care organizations shall provide coverage without prior authorization for the drugs that comprise at least one regimen recommended by the centers for disease control and prevention for human immunodeficiency virus postexposure prophylaxis.

(2) Notwithstanding the coverage requirements of this section, the authority or a Medicaid contracted managed care organization shall reimburse a hospital that bills for a 28-day supply of any human immunodeficiency virus postexposure prophylaxis drugs or therapies dispensed or delivered to a patient in the emergency department for take-home use, pursuant to section 1 of this act, as a separate reimbursable expense. This reimbursable expense is separate from any bundled payment for emergency department services.

Section 5

RCW 41.05.017 and 2022 c 236 s 3, 2022 c 228 s 2, and 2022 c 10 s 2 and are each reenacted and amended to read as follows:

Each health plan that provides medical insurance offered under this chapter, including plans created by insuring entities, plans not subject to the provisions of Title 48 RCW, and plans created under RCW 41.05.140, are subject to the provisions of RCW 48.43.500, 70.02.045, 48.43.505 through 48.43.535, 48.43.537, 48.43.545, 48.43.550, 70.02.110, 70.02.900, 48.43.190, 48.43.083, 48.43.0128, 48.43.780, 48.43.435, 48.43.815, section 3 of this act, and chapter 48.49 RCW.

Section 6 (New Section)

This act takes effect January 1, 2025.

State Market Plan Enhancements

Human growth hormone injections for the treatment of idiopathic short stature may or may not be covered. Refer to the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB) to determine coverage eligibility.

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

Note: Members may have supplemental outpatient prescription drug benefit. Refer to the member's EOC/SOB to determine coverage eligibility.

Oklahoma, Oregon, Texas, and Washington

Injectable Drugs

- **Intravenous Infusion Therapy:** the therapeutic administration of drugs or other prepared or compounded substances by the Intravenous route (includes chemotherapy) and when provided as part of a treatment plan and authorized by a members primary care provider, contracting/network medical group or UnitedHealthcare.
  Note: The infusions must be administered in the member's home, network /contracting provider's office, ambulatory/outpatient infusion center or in an institution such as board and care, custodial care, or assisted living facility that is not a hospital or institution mainly engaged in providing skilled nursing services or rehabilitation services.
- **Outpatient Injectable Medications** include drugs or preparations which are not usually self-administered and which are given by the intramuscular or subcutaneous route are covered when administered as part of a physician's office visit, and when not otherwise limited or excluded.
  Note: Outpatient injectable medications must be obtained through a network provider, the member's

network/contracting medical group or a UnitedHealthcare designated pharmacy and may require preauthorization services.

- **Self-Injectable Medications** which are either generally self-administered by the subcutaneous route regardless of the frequency of administration, or by the Intramuscular route at a frequency of one or more times per week and when prescribed by a contracting/network provider as authorized by the member's contracting/network medical group or UnitedHealthcare.
  Note: Self-injectable medications must be obtained through a member's contracting/network medical group or a UnitedHealthcare designated pharmacy and may require preauthorization services. A separate co-payment/co-insurance applies to all self-injectable medications for a 30-day supply (or for the prescribed course of treatment if shorter), whether self-administered or injected in the physician's office, and is applied in addition to any office visit co-payment/co-insurance.

Off-Label Drug Use

Off-label drug use means the use of a drug for the purpose that is different from the use for which the drug has been approved by the Food and Drug Administration (FDA) including off-label self-injectable drugs, only when all of the following criteria are met:

- The drug is approved by the FDA (for label usage);
- The drug is prescribed by a network/contracting provider for the treatment of a life-threatening condition or for a chronic and seriously debilitating condition;
- The drug is medically necessary to treat the condition;
- The member has failed, is intolerant of, or has contraindications to standard therapies;
- The drug has been recognized for treatment of the life-threatening or chronic and seriously debilitating condition by one of the following: The American Hospital Formulary Service Drug Information, DRUGDEX System by Micromedex, The United States Pharmacopoeia Dispensing Information or in two articles from major peer-reviewed medical journals that present data supporting the proposed Off-Label Drug Use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal;
- The drug is covered under the member's injectable drug benefit described in the outpatient benefits section of the member's EOC.

Oregon

Coverage of Particular Drugs

No prescription drugs will be denied to a Member solely on the basis that the indication has not been approved by the United States Food and Drug Administration (FDA) if Oregon Health Evidence Review Commission or the Oregon Pharmacy and Therapeutics Committee determines that the drug is recognized as effective for the medically necessary treatment of the illness or injury for which it was prescribed for:

- In publications the Commission and Committee determines to be equivalent to:
  - *The American Hospital Formulary Services Drug Information;*
  - *Drug Facts and Comparisons (Lippincott-Raven Publishers);*
  - *The United States Pharmacopoeia Drug Information; or*
  - *Other publications that have been shown by the United States Secretary of Health and Human Services (HHS) as authoritative;*
- In the majority of relevant peer-reviewed medical literature, or
- By the United States Secretary of Health and Human Services (HHS).

Tobacco Use Cessation Programs

Covered for members fifteen years or older. Coverage includes both educational and medical treatments to help a member overcome nicotine addiction. Qualifying programs must follow the United States Public Health Service guidelines for tobacco use cessation.

For more information about the tobacco cessation program, contact the Customer Service department at 1-800-624-8822, or visit the UnitedHealthcare website.

Not Covered

- Human growth hormone for idiopathic short stature syndrome.
- Outpatient drugs and prescription medications except when listed as covered in the *Federal/State Mandated Regulations* or *Covered Benefits* sections or when covered under the member's supplemental outpatient prescription benefit.
- **Oklahoma, Texas and Washington Only:** Tobacco cessation medications.

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
08/01/2024	All	**Supporting Information** • Archived previous policy version BIP099.L
	Washington	**Federal/State Mandated Regulations** • Added language pertaining to *Washington Engrossed Substitute Senate Bill 6127*

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.