MEDICATIONS AND OFF-LABEL DRUGS

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Related Benefit Interpretation Policies:
• Chemical Dependency/Substance Abuse
• Detoxification
• Chemotherapy
• Clinical Trials
• Diabetic Management, Services and Supplies
• Experimental and Investigational Services
• Family Planning: Birth Control
• Family Planning: Infertility Services
• Gender Dysphoria (Gender Identity Disorder) Treatment
• Medical Necessity
• Preventive Care Services
• Sexual Dysfunction

Covered benefits are listed in three (3) Sections-A, B and C. 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.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit document to determine benefit coverage.
A. FEDERAL/STATE MANDATED REGULATIONS

OKLAHOMA:
OAC 365:40-5-21, #7 - Supplemental health care services
Supplemental health care services of an HMO may include the following:
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 Stat. Title 63 section 1-2604: Individual policy Coverage for Prescription Drugs
for Cancer Treatment or Study of Oncology - Exclusion prohibited.
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 Stat. Title 63 Section 1-2605 Off-label Uses of Prescription Drugs for Cancer
Treatment Coverage Under Health Maintenance Contracts.
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 §743A.062: Prescription Drugs
(1) No insurance policy or contract providing coverage for a prescription drug to a resident of this
state shall exclude coverage of that 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 or the Pharmacy
and Therapeutics Committee established under ORS 414.353 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:
   (A) The American Hospital Formulary Service drug information;
   (B) "Drug Facts and Comparisons" (Lippincott-Raven Publishers);
   (C) The United States Pharmacopoeia drug information; or
   (D) 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.
(2) Required coverage of a prescription drug under this section shall include coverage for
medically necessary services associated with the administration of that drug.
(3) 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.

(4) Nothing in this section requires coverage for experimental drugs not approved for any indication by the United States Food and Drug Administration.

(5) This section is exempt from ORS 743A.001 [Formerly 743.697; 2011 c.720 §222].

ORS §743A.060: Definition for ORS 743A.062.
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 743B.601 Synchronization of Prescription Drug Refills
(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 §1369.001-Definitions
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 § 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 §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 284-30-450, Insurance Policies and Contacts – Coverage for Drugs
(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 284-43-5060 General Prescription Drug Benefit Requirements.
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 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.

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 ineffectual, 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.

WAC 284-43-5110 Cost Sharing For Prescription Drugs:
(1) A carrier and health plan unreasonably restrict the treatment of patients if an ancillary charge, in addition to the plan's normal copayment or coinsurance requirements, is imposed for a drug that is covered because of one of the circumstances set forth in either WAC 284-43-5080 or 284-43-5100. An ancillary charge means any payment required by a carrier that is in addition to or excess of cost-sharing explained in the policy or contract form as approved by the commissioner. Cost-sharing means amounts paid directly to a provider or pharmacy by an enrollee for services received under the health benefit plan, and includes copayment, coinsurance, or deductible amounts.
(2) When an enrollee requests a brand name drug from the formulary in lieu of a therapeutically equivalent generic drug or a drug from a higher tier within a tiered formulary, and there is not a documented clinical basis for the substitution, a carrier may require the enrollee to pay for the difference in price between the drug that the formulary would have required, and the covered drug, in addition to the copayment. This charge must reflect the actual cost difference.
(3) When a carrier approves a substitution drug, whether or not the drug is in the carrier's formulary, the enrollee's cost-sharing for the substitution drug must be adjusted to reflect any discount agreements or other pricing adjustments for the drug that are available to a carrier. Any charge to the enrollee for a substitution drug must not increase the carrier's underwriting gain for the plan beyond the gain contribution calculated for the original formulary drug that is replaced by the substitution.
(4) If a carrier uses a tiered formulary in its prescription drug benefit design, and a substitute drug that is in the formulary is required based on one of the circumstances in either WAC 284-43-5080 or 284-43-5100, the enrollee's cost sharing may be based on the tier in which the carrier has placed the substitute drug.
(5) 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 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) 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) 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 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 284-43-5200 Anti-Cancer Medication.
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 284-43-5420 Clinical Trials.
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.

B. 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 EOC/SOB to determine coverage eligibility.

C. COVERED BENEFITS

**IMPORTANT NOTE:** Covered benefits are listed in Sections A, B and C. Always refer to Sections A and B for additional covered benefits not listed in this Section.

1. Injectable drugs
   a. 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.

b. **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.

c. **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.

2. **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:

   a. The drug is approved by the FDA (for label usage);
   b. 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;
   c. The drug is medically necessary to treat the condition;
   d. The member has failed, is intolerant of, or has contraindications to standard therapies;
   e. 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;
   f. The drug is covered under the member’s injectable drug benefit described in the outpatient benefits section of the member’s EOC.

3. **Tobacco Use Cessation Programs (Oregon)** are 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.

D. **NOT COVERED**

1. **Human Growth Hormone** for idiopathic short stature syndrome. Refer to the member’s EOC/SOB to determine coverage eligibility.

2. **Tobacco Cessation Medications:** Refer to the member’s EOC/SOB to determine coverage eligibility.

3. **Outpatient Drugs and Prescription Medications** except when listed as covered in Sections A or C or when covered under the member’s Supplemental Outpatient prescription benefit. Refer to the member’s EOC/SOB to determine coverage eligibility.
### E. POLICY HISTORY/REVISION INFORMATION

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<th>Date</th>
<th>State(s) Affected</th>
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| 08/01/2019 | All               | **Related Policies**<br>• Added reference to the Benefit Interpretation Policy titled *Gender Dysphoria (Gender Identity Disorder) Treatment*<br>**Covered Benefits**<br>• Modified language pertaining to the following services to indicate:<br>  o **Intravenous Infusion Therapy** is the therapeutic administration of drugs or other prepared or compounded substances by the intravenous route (includes chemotherapy) and is covered when provided as part of a treatment plan and authorized by a member’s primary care provider contracting/network medical group or UnitedHealthcare<br>  o **Outpatient Injectable Medications** include drugs or preparations which are not usually self-administered and which are given by the Intramuscular or subcutaneous route and are covered when administered as part of a Physician’s office visit and when not otherwise limited or excluded<br>**Not Covered**<br>• Revised list of non-covered services; added:<br>  o Human growth hormone for idiopathic short stature syndrome<br>  o Tobacco cessation medications<br>• Added instruction to refer to the member’s Evidence of Coverage (EOC)/Schedule of Benefits (SOB) to determine coverage eligibility<br>**Supporting Information**<br>• Archived previous policy version BIP099.F
| Oregon     | **Covered Benefits**<br>• Added language to indicate **Tobacco Use Cessation Programs** are covered for members fifteen years or older<br>  o Coverage includes both educational and medical treatments to help a member overcome nicotine addiction<br>  o Qualifying programs must follow the United States Public Health Service guidelines for tobacco use cessation |