

Medical Necessity

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[Instructions for Use](#)

Table of Contents	Page
Federal/State Mandated Regulations	1
State Market Plan Enhancements	2
Covered Benefits	2
Not Covered	3
Definitions	3
Policy History/Revision Information	4
Instructions for Use	4

Related Policies
None

Federal/State Mandated Regulations

Oklahoma

Title 63. Public Health and Safety §63-7310. Health insurance Plans – Step Therapy Protocol - Requirements

Universal Citation: [63 OK Stat § 63-7310 \(2020\)](#)

- A. As used in this section:
1. "Clinical practice guidelines" means a systematically developed statement to assist decision-making by healthcare providers and patients about appropriate healthcare or specific clinical circumstances and conditions;
 2. "Health insurance plan" means any individual or group health insurance policy, medical service plan, contract, hospital service corporation contract, hospital and medical service corporation contract, fraternal benefit society or health maintenance organization, municipal group-funded pool, the Oklahoma Medicaid Program and the state health care benefits plan that provides medical, surgical or hospital expense coverage. For purposes of this section, "health insurance plan" also includes any utilization review organization that contracts with a health insurance plan provider;
 3. "Medical necessity" means that, under the applicable standard of care, a health service or supply is appropriate to improve or preserve health, life or function, to slow the deterioration of health, life or function or for the early screening, prevention, evaluation, diagnosis or treatment of a disease, condition, illness or injury;
 4. "Step therapy protocol" means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a health insurance plan;
 5. "Step therapy exception" means a process by which a step therapy protocol is overridden in favor of immediate coverage of the healthcare provider's selected prescription drug;
 6. "Utilization review organization" means an entity that conducts utilization review, not including a health insurance plan provider performing utilization review for the provider's own health insurance plan; and
 7. "Pharmaceutical sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
- B. For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2020, and that utilizes a step therapy protocol, a health carrier, health benefit plan or utilization review organization shall use recognized, evidence-based and peer-reviewed clinical practice guidelines when establishing any step therapy protocol, when such guidelines are available.

- C. 1. For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2020, and that restricts coverage of a prescription drug for the treatment of any medical condition pursuant to a step therapy protocol, the health insurance plan provider shall provide to the prescribing healthcare provider and patient access to a clear, convenient and readily accessible process to request a step therapy exception. Any health insurance plan provider that utilizes a step therapy protocol shall make such process to request a step therapy exception accessible on the health insurance plan provider's website.
2. A health insurance plan shall grant a requested step therapy exception if the submitted justification of the prescribing provider and supporting clinical documentation, if needed, is completed and supports the statement of the provider that:
- The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient,
 - The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug,
 - The patient has tried the required prescription drug while under the patient's current or a previous health insurance plan and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event,
 - The required prescription drug is not in the best interest of the patient, based on medical necessity, or
 - The patient is stable on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on the patient's current or a previous health insurance plan.
3. A health insurance plan provider shall permit a patient to appeal any decision rendered on a request for a step therapy exception.
- D. A health insurance plan provider shall respond to a request for a step therapy exception, or any appeal therefor, within seventy-two (72) hours of receipt of the request or appeal. If a patient's prescribing healthcare provider indicates that exigent circumstances exist, the health insurance plan provider shall respond to such a request or appeal within twenty-four (24) hours of receipt of the request or appeal. If the health insurance plan provider fails to respond within the required time, the step therapy exception or appeal shall be deemed granted. Upon granting a step therapy exception, the health insurance plan provider shall authorize coverage for and dispensation of the prescription drug prescribed by the patient's healthcare provider.
- E. This section shall not be construed to prevent a healthcare provider from prescribing a prescription drug that is determined to be medically appropriate.
- F. Nothing in this section shall be construed to authorize the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy exception.
- G. Nothing in this section shall be construed to prevent the substitution of a drug in accordance with current statutes and regulations of this state.
- H. The Oklahoma Insurance Department and the Oklahoma Health Care Authority shall adopt rules necessary to implement and administer this act prior to January 1, 2020.

Added by Laws 2019, c. 69, § 1, eff. Nov. 1, 2019.

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State Market Plan Enhancements

None

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.

An Intervention will be covered under the UnitedHealthcare Health Plan if it is an otherwise covered category of service, not specifically excluded, and Medically Necessary.

An Intervention may be medically indicated yet not be a covered benefit or meet the definition of Medical Necessity.

An Intervention is Medically Necessary if, as recommended by the Treating Physician and determined by the Medical Director of UnitedHealthcare or the Network Medical Group, it is (all of the following):

- A Health Intervention for the purpose of treating a Medical Condition
- Oregon Only: A health intervention for the purpose of treating a medical, mental, nervous condition or Substance Related and Addictive Disorder including alcoholism.
- The most appropriate supply or level of service, considering potential benefits and harms to the member
- Known to be Effective in improving the health outcomes. For existing Interventions, effectiveness is determined first by Scientific Evidence, then by professional standards, then by expert opinion. For New Interventions, effectiveness is determined by Scientific Evidence.

If more than one Health Intervention meets the requirements listed above, provided in the most Cost Effective manner that may be provided safely and effectively to the member. "Cost-effective" does not necessarily mean lowest price.

Not Covered

None

Definitions

Cost Effective: An intervention is considered cost effective if the benefits and harms relative to costs represent an economically efficient use of resources for patients with this condition. In the application of this criterion to an individual case, the characteristics of the individual patient shall be determinative.

Effective: The intervention is considered effective if it can reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

Health Intervention: An item or service delivered or undertaken mainly to treat (that is, prevent, diagnose, detect, treat, or palliate) a medical condition or to maintain or restore functional ability. A health intervention is defined by the intervention itself, the medical condition and the patient indications for which it is being applied.

Health Outcomes: Outcomes that affect health status as measured by the length or quality (mainly as perceived by the patient) of a person's life.

Medical Condition: A disease, illness, injury, genetic or congenital defect, pregnancy, or a biological condition that lies outside the range of normal, age appropriate human variation

Medically Necessary (or Medical Necessity): refers to an intervention, if, as recommended by the treating Physician and determined by the Medical Director of UnitedHealthcare or the Network Medical Group, it is all of the following:

- A health intervention for the purpose of treating a medical, mental, nervous condition or Substance-Related and Addictive Disorder including alcoholism;
- The most appropriate supply or level of service, considering potential benefits and harms to the Member;
- Known to be effective in improving health outcomes. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion. For new interventions, effectiveness is determined by scientific evidence; and
- If more than one health intervention meets the requirements listed above, provided in the most cost-effective manner that may be provided safely and effectively to the Member. "Cost-effective" does not necessarily mean lowest price.

New Intervention: An intervention that is not yet in widespread use for the medical condition and patient indications being considered. New interventions for which clinical trials have not taken place because of epidemiological reasons (e.g., rare or new diseases or orphan populations) shall be evaluated on the basis of professional standards of care. If professional

standards of care do not exist, or are outdated or contradictory, decisions about such new interventions should be based on convincing expert opinion.

Scientific Evidence: Consists mainly of controlled clinical trials that either directly or indirectly show the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that suggest a causal relationship between the intervention and health outcomes can be used. Such studies do not by themselves show a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential experimental biases. For existing interventions, the scientific evidence should be considered first and, to the greatest extent possible, should be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care should be considered. If professional standards of care do not exist, or are outdated or contradictory, decisions about existing interventions should be based on expert opinion. Giving priority to scientific evidence does not mean that coverage of existing interventions should be denied in the absence of conclusive scientific evidence. Existing interventions can meet the definition of medical necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care or, in the absence of such standards, convincing expert opinion.

Treating Physician: A Physician who has personally evaluated the patient.

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
01/01/2022	All	Supporting Information <ul style="list-style-type: none">Archived previous policy version BIP097.H
	Oklahoma	Federal/State Mandated Regulations <ul style="list-style-type: none">Added language pertaining to <i>Oklahoma Statutes Title 63, Section 63.7310</i>

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.