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Approved by:	
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Owner: Leslie Procell, Sr. Manager Utilization Management
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PURPOSE

To establish a process/program that requires patients to try a lower cost prescription drug that treats a given condition before "stepping up" to a similar-acting, but more expensive drug. It is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. Other names for step therapy (ST) are "step protocol" and "fail first" requirements.

SCOPE

Self-insured plans are regulated under federal law (ERISA, the Employee Retirement Income Security Act of 1974) rather than state law, so state rules regarding step therapy do not apply to the plans that cover nearly two-thirds of all Americans who have employer-sponsored health insurance.

ERISA does include a provision requiring health plans to allow members to appeal claim denials and authorization rejections, and the Affordable Care Act requires all non-grandfathered health plans (including self-insured plans) to give members access to both internal and external review processes when a claim or pre-authorization request is denied. However, federal legislation to amend ERISA with a specific exception process for step therapy rules has not been enacted.

Step therapy requires patients to try --and fail--one or more medications chosen by their health insurer or pharmacy benefit manager (PBM) before they can access the treatment prescribed by their healthcare provider.

DEFINITIONS

"Clinical practice guidelines" means a systematically developed statement to assist decision making by health care providers and patients about appropriate healthcare for specific clinical circumstances and conditions;
"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by the insurer, health plan, pharmacy benefit manager, or private review agent to determine the medical necessity and appropriateness of health care services;
"Health plan":

1. Means any state-regulated policy, certificate, contract, or plan that offers or provides coverage in this state, by direct payment, reimbursement, or otherwise, for prescription drugs pursuant to a step therapy protocol, regardless of whether the protocol is described as a step therapy protocol; and

2. Shall include but not be limited to a health benefit plan;

"Pharmacy benefit manager" has the same meaning as in KRS 304.9-020;
"Private review agent" has the same meaning as in KRS 304.17A-600;
"Step therapy exception" means a determination that a step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug; and
"Step therapy protocol" means a protocol, policy, or program that establishes the specific sequence in which prescription drugs that are for a specified medical condition and medically appropriate for a particular insured are covered by an insurer or health plan.

POLICY

Clinical Review Guidelines

Clinical review criteria developed by an insurer, health plan, pharmacy benefit manager, or private review agent to establish a step therapy protocol shall be based on clinical practice guidelines that:

1. Recommend that prescription drugs be taken in the specific sequence required by the step therapy protocol;

2. Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

   a. Requiring members to:

      i. Disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers; and

      ii. Recuse himself or herself from voting if the member has a conflict of interest;

   b. Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

   c. Offering opportunities for public review and comments;

3. Are based on high quality studies, research, and medical practice;

4. Are created by an explicit and transparent process that:

   a. Minimizes biases and conflicts of interest;

   b. Explains the relationship between treatment options and outcomes;

   c. Rates the quality of the evidence supporting recommendations; and

   d. Considers relevant patient subgroups and preferences; and

5. Are continually updated through a review of new evidence, research, and newly developed treatments.

In the absence of clinical practice guidelines that meet the requirements above, an insurer, health plan, pharmacy benefit manager, or private review agent may use peer-reviewed publications to establish step therapy protocols.

When establishing clinical review criteria for a step therapy protocol, an insurer, health plan, pharmacy benefit manager, or private review agent shall take into account the needs of atypical patient populations and diagnoses.

An insurer, health plan, pharmacy benefit manager, or private review agent shall, upon written request, provide all specific written clinical review criteria relating to a particular condition or disease, including clinical review criteria relating to a step therapy exception determination.

The clinical review criteria and other clinical information shall be made available:

a. On the insurer's, health plan's, pharmacy benefit manager's, or private review agent's Web site; and

b. To a health care professional on behalf of an insured upon written request.

An insurer, health plan, pharmacy benefit manager, or private review agent is not required to establish a new entity to develop clinical review criteria used for step therapy protocols.

When coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, private review agent, or a pharmacy benefit manager by a step therapy protocol, the insured and prescribing provider shall have access to a clear, readily accessible, and convenient process to request a step therapy exception.

An insurer, health plan, private review agent, or pharmacy benefit manager:

1. May use its existing medical exceptions process

2. Shall make the step therapy protocol easily accessible on its Web site; and
3. Shall, upon request, disclose all rules and criteria related to the step therapy protocol to all prescribing providers, including the specific information and documentation that must be submitted by a prescribing provider or insured to be considered a complete request for a step therapy exception.

Exception process

If a health carrier, health benefit plan, or utilization review organization denies coverage of a prescription drug for the treatment of a medical condition through the use of a step therapy protocol, then the health carrier, health benefit plan, or utilization review organization must provide access to a clear, readily accessible, and convenient process for a patient or prescribing practitioner to request a step therapy exception.
The process must be easily accessible on the website of the health carrier, health benefit plan, or utilization review organization. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this.

A health carrier, health benefit plan, or utilization review organization shall grant a step therapy exception if one (1) of the following applies:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction to, or physical or mental harm to, the patient due to a documented adverse event with a previous use of the required prescription drug or a documented medical condition, including a comorbid condition;

(2) 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 regimen;

(3) The required prescription drug is not in the best interest of the patient, based on clinical appropriateness, because the patient's use of the drug is expected to:

(A) Cause a significant barrier to the patient's adherence to or compliance with the patient's plan of care;

(B)Worsen a comorbid condition of the patient; or

(C) Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; or

The patient is currently receiving a positive therapeutic outcome on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan, and the patient's healthcare provider gives documentation to the health insurance, health benefit plan, or utilization review organization that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

Upon granting a step therapy exception, the health carrier, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating healthcare provider if the prescription drug is covered under the current health insurance, health benefit plan, or utilization review organization.

The health carrier, health benefit plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within the turnaround times If a response by a health carrier, health benefit plan, or utilization review organization is not received within that time period, then the exception is granted.

A step therapy exception is eligible for appeal by an insured.

This section does not prevent:
(1) A health carrier, health benefit plan, or utilization review organization from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;
(2) A health carrier, health benefit plan, or utilization review organization from requiring a pharmacist to substitute a prescription drug consistent with the laws of this state; or
(3) A healthcare provider from prescribing a prescription drug that is determined to be medically appropriate.
(g) The use of pharmaceutical samples of a required prescription drug is not considered a trial of the required prescription drug as part of a step therapy protocol.

Procedure
When medications for the treatment of any medical condition are restricted for use by an affected entity by a step therapy or fail-first protocol, the prescribing practitioner shall have access to a clear and convenient process to request an override of the restriction from the insurer.

An override of the restriction shall be granted by the insurer or the PBM within 48 hours, if all necessary information to perform the override review has been provided, under the following documented circumstances:
• The prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred treatment required under step therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or
• Based on sound clinical evidence or medical and scientific evidence: The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or
•The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol will cause or will likely cause an adverse reaction or other physical harm to the insured.

The duration of any step therapy or fail-first protocol shall not be longer than a period of 30 days if the treatment is deemed and documented as clinically ineffective by the prescribing practitioner. When the prescribing practitioner can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than 30 days to provide any relief or an amelioration to the insured, the step therapy or fail-first protocol may be extended up to 7 additional days.

Step Therapy Exception Request or Internal Appeal

A step therapy exception request, or an internal appeal of a step therapy exception request denial, shall be granted by the insurer, health plan, private review agent, or the pharmacy benefit manager within forty-eight (48) hours if:

1. All necessary information to perform the step therapy exception review, or make the appeal determination, has been provided; and
2. One (1) of the following apply:
    a. The required prescription drug is:
        i. Contraindicated or will likely cause an adverse reaction by physical or mental harm to the insured; or
        ii. Expected to be ineffective based on the known clinical characteristics of the insured and the prescription drug regimen;
    b. Based on clinical appropriateness, the required prescription drug is not in the best interest of the insured because the insured's use of the required prescription drug is expected to:
        i. Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;
        ii. Worsen a comorbid condition of the insured; or
        iii. Decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities;
    c. The insured has tried the required prescription drug while under the insured's current or a previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
    d. The insured is stable on the prescription drug selected by the insured's health care provider for the medical condition under consideration while under a current or previous health plan.

If a request for a step therapy exception, or an internal appeal of a step therapy exception request denial, is incomplete or additional clinically relevant information is required, the insurer, health plan, pharmacy benefit manager, or private review agent shall notify the prescribing provider within forty-eight (48) hours of submission of the request or appeal:

1. That the request or appeal is incomplete; and
2. What additional or clinically relevant information is required in order to approve or deny the step therapy exception.

If a step therapy exception request determination, notification or internal appeal determination of a step therapy exception request denial by an insurer, health plan, pharmacy benefit manager, or private review agent is not received by the prescribing provider within the time period specified above, the step therapy exception request or internal appeal shall be deemed granted.

An insured or a provider may:

(a) Initiate an internal appeal upon the denial of a step therapy exception request under this section; and

(b) Request an external review u upon the denial of an internal appeal under paragraph (a) of this subsection.

An insurer, health plan, pharmacy benefit manager, or private review agent shall:

(a) Upon the granting of a step therapy exception request, internal appeal, or external review, authorize coverage for the prescription drug selected by the insured's health care provider; or

(b) Upon the denial of a step therapy exception request or internal appeal, inform the insured of the internal appeal or external review process, as applicable.

Except as provided in above, the duration of any step therapy protocol shall not be longer than a period of thirty (30) days if the treatment is deemed and documented as clinically ineffective by the prescribing provider.

(a) When the prescribing provider can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than thirty (30) days to provide any relief or an amelioration to the insured, the step therapy protocol may be extended up to seven (7) additional days.

Coverage for Tobacco cessation medications and services:

(1) A health benefit plan shall at a minimum, provide coverage for all for all United States Food and Drug Administration-approved tobacco cessation medications, all forms of tobacco cessation services recommended by the United States Preventive Services Task Force, including but not limited to individual, group, and telephone counseling, and any combination thereof.

(2) The following conditions shall not be imposed on any tobacco cessation services provided pursuant to this section:

(a) Counseling requirements for medication;

(b)Limits on the duration of services, including but not limited to annual or lifetime limits on the number of covered attempts to quit; or

(c)Copayments or other out-of-pocket cost sharing, including deductibles.

(3) Utilization management requirements, including prior authorization and step therapy, shall not be imposed on any tobacco cessation services provided pursuant to this section, except in the following circumstances where prior authorization may be required:

(a)For a treatment that exceeds the duration recommended by the most recently published United States Public Health Service clinical practice guidelines on treating tobacco use and dependence; or

(b)For services associated with more than two (2) attempts to quit within a twelve (12) month period.

(4) Nothing in this section shall be construed to prohibit a plan or issuer from providing coverage for tobacco cessation services in addition to those recommended or to deny coverage for services that are not recommended by the United States Preventive Services Task Force.

Adopted from 2020 KY revised statutes Chapter 304; Subtitle 304.17A Health Benefit Plans; 304.17A-168 Coverage for tobacco cessation medications and services.

Alcohol and Opioid UR Prohibition:

304.17A-611 Prohibition against retrospective denial of coverage for health care services under certain circumstances -- Prohibition against prospective or concurrent review of prescription drug for alcohol or opioid use disorder.

(1) A utilization review decision shall not retrospectively deny coverage for health care services provided to a covered person when prior approval has been obtained from the insurer or its designee for those services, unless the approval was based upon fraudulent, materially inaccurate, or misrepresented information submitted by the covered person, authorized person, or the provider.

(2) For health benefit plans issued or renewed on or after January 1, 2022, an insurer shall not require or conduct a prospective or concurrent review for a prescription drug:

(a) That: 1. Is used in the treatment of alcohol or opioid use disorder; and 2. Contains Methadone, Buprenorphine, or Naltrexone; or

(b) That was approved before January 1, 2022, by the United States Food and Drug Administration for the mitigation of opioid withdrawal symptoms. Effective: January 1, 2022 History: Amended 2021 Ky. Acts ch. 201, sec. 1, effective January 1, 2022. -- Created 2000 Ky. Acts ch. 262, sec. 6, effective July 14, 2000

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