FINAL BILL REPORT
ESHB 1879

C 171 L 19
Synopsis as Enacted

Brief Description: Regulating and reporting of utilization management in prescription drug benefits.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Jinkins, Cody, Harris, Macri, DeBolt, Pollet, Robinson, Tharinger and Doglio).

House Committee on Health Care & Wellness
Senate Committee on Health & Long Term Care

Background:

Step therapy is a form of prior authorization where health carriers approve a prescription drug or class of drugs for a medical condition based on cost effectiveness and treatment best practices. Step therapy requires the patient to begin treatment with the approved drug. If the patient fails to respond to the drug or experiences an adverse effect, then coverage is generally allowed for another drug prescribed by the patient's health care provider.

In Washington, health carriers may design their prescription drug benefit plans 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. Carriers must also establish a process that a provider and an enrollee may use to request substitution for a prescribed therapy, drug, or medication that is not on the formulary.

This process may not unreasonably restrict an enrollee's access to non-formulary or alternative medicines for conditions that are not responsive to treatment. Carriers must also have a process for an enrollee to request an expedited review based on exigent circumstances such as experiencing a health condition that may jeopardize the enrollee's life or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

Summary:

For health plans delivered, issued, or renewed on or after January 1, 2021, clinical review criteria used to establish a prescription drug utilization management protocol must be

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evidence-based and updated on a regular basis through review of new evidence, research, and newly developed treatments.

When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and the prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception. A carrier or prescription drug utilization management entity may use its existing medical exceptions process to satisfy this requirement. The process and approval criteria must be easily accessible on the entity's website, in plain language, and understandable to providers and patients.

Carriers must disclose all rules and criteria related to the prescription drug utilization management process to all participating providers, including the information and documentation that must be submitted by a health care provider or patient for an exemption request to be considered complete.

A step therapy exception must be granted if the health carrier or prescription drug utilization management entity determines that the evidence submitted by the provider or patient is sufficient to establish that:

- the required prescription drug is:
    - contraindicated or will likely cause a clinically predictable adverse reaction to the patient;
    - expected to be ineffective based on known clinical characteristics of the patient and prescription drug regimen; and
    - not in the best interest of the patient based on medical appropriateness because the patient's use of the prescription drug is expected to:
        - create a barrier to the patient's adherence to or compliance with the patient's plan of care;
        - negatively impact a comorbid condition of the patient;
        - cause a clinically predictable negative drug interaction; or
        - decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities;
- the patient has tried the required prescription drug, another prescription drug in the same pharmacologic class, or drug with the same mechanism of action while under the current or a pervious health plan and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- the patient is currently experiencing a positive therapeutic outcome on a prescription drug recommended by their health care provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan, and changing to the required prescription drug may cause clinically predictable adverse reactions, or physical or mental harm, to the patient.

Upon granting an exception, the carrier or prescription drug utilization management entity must authorize coverage for the prescription drug prescribed by the patient's treating health care provider. For non-urgent exception requests, carriers or prescription drug utilization management entity must notify the provider within three business day if additional information is required to approve or deny the request. Once all required information is received, a health carrier or prescription drug utilization management entity must, within

three business days, approve a request if the information provided meets the exception criteria or if deemed medically appropriate, or deny the request.

For urgent exception requests, carriers or prescription drug utilization management entity must notify the treating health care provider within one business day if additional information is required to approve or deny the request. Once all required information is received, a carrier or prescription drug utilization management entity must within one business day approve a request if the information provided meets the exception criteria or if deemed medically appropriate, or deny the request. Requests are considered 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 an enrollee is undergoing a current course of treatment using a nonformulary drug.

If a response by a carrier or prescription drug utilization management entity is not received within the time allotted, the exception or appeal is deemed granted.

Carriers must cover an emergency supply fill if a health care provider determines an emergency fill is necessary to keep the patient stable while the exception is being processed. Emergency fill means a limited dispensed amount of medication that allows time for the processing of a step-therapy or prior authorization request. The exception may not be used to solely justify any further exemption.

When responding to a prescription drug utilization management exception request, a carrier or prescription drug utilization management entity must clearly state in the response if the service was approved or denied. The carrier must use clinical review criteria as a basis for any denial. The denial must include the specific clinical review criteria relied upon for the denial and information regarding how to request an appeal.

If an exception request is denied for administrative reasons, or for not including all of the necessary information, the carrier or prescription drug utilization management entity must inform the provider or facility what additional information is needed and the deadline for its submission.

The carrier or prescription drug utilization management entity must allow a stabilized patient to remain on a drug during the exemption request process. Carriers must provide 60 days notice to providers and patients for any new policies or procedures that apply to prescription drug utilization management protocols. New policies or procedures may not be applied retroactively.

A carrier or prescription drug utilization management entity may require a patient 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 drug.

The insurance commissioner may adopt rules necessary to implement these requirements.

Votes on Final Passage:

House 95 0

Senate	46	0	(Senate amended)
House	94	0	(House concurred)

Effective: July 28, 2019