Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1879

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

Sponsors: Representatives Jinkins, Cody, Harris, Macri, DeBolt, Pollet, Robinson, Tharinger and Doglio.

Brief Summary of Bill

- Requires clinical review criteria used to establish a prescription drug utilization management protocol be based on certain clinical practice guidelines.
- Requires a health carrier or health plan that restricts coverage of a prescription drug through a prescription drug utilization management protocol to provide the patient and the prescribing practitioner with access to a clear, readily accessible, and convenient process to request an exception.

Hearing Date: 2/12/19

Staff: Kim Weidenaar (786-7120).

Background:

Step therapy is a form of prior authorization whereby 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 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 analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

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 of Bill:

For health plans issued or renewed on or after January 1, 2021, clinical review criteria used to establish a prescription drug utilization management protocol must be based on clinical practice guidelines that 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:
    - requiring members to disclose any potential conflicts of interest, and to recuse themselves from voting if there is a conflict;
    - using a methodologist to work with writing groups to provide objective data analysis and ranking or evidence; and
    - offering opportunities for public review and comment;
- based on high quality studies, research, and medical practice;
- created by an explicit and transparent process that;
    - minimize biases and conflicts of interest;
    - explains the relationship between treatment options and outcomes;
    - rates the quality of the evidence support recommendations; and
- continually updates through review of new evidence, research, and newly developed treatments.

A utilization review organization (organization) must take into account the needs of atypical patient populations and diagnosis when establishing clinical review criteria.

If a health carrier (carrier), health plan (plan), or organization restricts coverage of a prescription drug through a prescription drug utilization management protocol, the patient and the prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception. A carrier, plan, or organization 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 related to the prescription drug utilization management process to all participating providers, including the information and documentation that must be completed in order for a request to be complete.

An exception must be expeditiously granted if:

- the required prescription drug is:
    - contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient;
    - expected to be ineffective based on known clinical characteristics of the patient and prescription drug regimen;
    - not in the best interest of the patient based on medical necessity;

- the patient has tried the required prescription drug while under the current or a previous health insurance, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; and
- the patient is stable on a prescription selected by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.

Upon granting an exception, the carrier, plan, or organization must authorize coverage for the prescription drug prescribed by the patient's treating health care provider. Exception requests and appeals must be responded to within 72 hours of receipt, except where exigent circumstances exist, in which case responses must be within 24 hours of receipt.

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 prior authorization request.

When responding to a prescription drug utilization management request, a carrier, plan, or organization must clearly state in the response if the service was approved or denied. The carrier must provide a specific reason for the denial and use evidence-based peer review literature as the basis. If the denial is based on specific payer policy, clinical criteria, or peer reviewed literature, the denial must include the policy language and an external appeals process.

If it is denied for administrative reasons, or for not including all of the necessary information, the carrier, plan, or organization must inform the provider or facility what additional information is needed and the deadline for its submission.

The carrier, plan, or organization must allow a stabilized patient to remain on a drug while the prescription drug utilization management is addressed, including the appeals process. Carriers must provide 90 days-notice for any new rules that apply to prescription drug utilization management protocols. New rules or policies may not be applied retroactively.

A carrier, plan, or organization may require a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded drug.

The insurance commissioner may adopt rules necessary to implement this act.

Appropriation: None.

Fiscal Note: Requested on February 5, 2019.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.