129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

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H.P. 751	House of Representatives, February 26, 2019

An Act To Provide Protections for Maine Patients Facing Step Therapy

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative WARREN of Hallowell.
Cosponsored by Senator SANBORN, H. of Cumberland and
Representatives: GRAMLICH of Old Orchard Beach, PIERCE of Falmouth, PRESCOTT of Waterboro, TEPLER of Topsham, Senators: FOLEY of York, ROSEN of Hancock, SANBORN, L. of Cumberland, VITELLI of Sagadahoc.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 24-A MRSA §4320-L is enacted to read:

§4320-L. Step therapy

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Clinical practice guidelines" means a systematically developed statement to assist prescriber and enrollee decisions about appropriate health care for specific clinical circumstances and conditions.

B. "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by a carrier or utilization review organization to determine the medical necessity and appropriateness of health care services.

C. "Medically necessary," with respect to health services and supplies, means appropriate, under the applicable standard of care, 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.

D. "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.

E. "Step therapy override exception determination" means a determination based on a review of an enrollee's or prescriber's request for an override, along with supporting rationale and documentation, that the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

F. "Step therapy protocol" means a protocol that establishes a specific sequence in which prescription drugs for a specified medical condition are medically necessary for a particular enrollee and are covered under a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs.

G. "Utilization review organization" means an entity that conducts a utilization review, other than a carrier performing a utilization review for its own health benefit plans.

2. Clinical review criteria. Clinical review criteria used to establish a step therapy protocol must be based on clinical practice guidelines that:

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

B. 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:

(1) Requiring members to disclose any potential conflicts of interest with entities, including carriers and pharmaceutical manufacturers, and recuse themselves from voting if they have a conflict of interest;

(2) 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

(3) Offering opportunities for public review and comments;

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

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

(1) Minimizes biases and conflicts of interest;

(2) Explains the relationship between treatment options and outcomes;

(3) Rates the quality of the evidence supporting recommendations; and

(4) Considers relevant patient subgroups and preferences; and

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

3. Absence of clinical practice guidelines. In the absence of clinical practice guidelines that meet the requirements in subsection 2, peer-reviewed publications may be substituted.

4. Consideration of atypical populations and diagnoses. When establishing a step therapy protocol, a utilization review organization shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

5. Construction. This section may not be construed to require carriers or the State to set up a new entity to develop clinical review criteria used for step therapy protocols.

6. Exceptions process. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier or utilization review organization through the use of a step therapy protocol, the enrollee and prescriber must have access to a clear, readily accessible and convenient process to request a step therapy override exception determination from that carrier or utilization review organization.

A. A carrier or utilization review organization may use its existing medical exceptions process to provide step therapy override exception determinations, and the process established must be easily accessible on the carrier's or utilization review organization's website.

B. A carrier or utilization review organization shall expeditiously grant a step therapy override exception determination if:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction in or physical or mental harm to the enrollee;

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen;

(3) The enrollee has tried the required prescription drug while under the enrollee's current or previous health insurance or 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 reaction;

(4) The required prescription drug is not in the best interest of the enrollee, based on medical necessity; or

(5) The enrollee is stable on a prescription drug selected by the enrollee's health care provider for the medical condition under consideration while on a current or previous health insurance or health plan.

Nothing in this paragraph may be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for the granting of a step therapy override exception determination.

C. Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the prescriber.

D. A carrier or utilization review organization shall grant or deny a request for a step therapy override exception determination or an appeal of a determination within 48 hours after receipt of the request. If exigent circumstances exist, a carrier or utilization review organization shall grant or deny the request within 24 hours after receipt of the request. If a carrier or utilization review organization does not grant or deny the request within the time required under this paragraph, the exception or appeal is granted.

E. An enrollee may appeal a step therapy override exception determination.

F. This section does not prevent:

(1) A carrier or utilization review organization from requiring an enrollee to try a generic drug, as defined in Title 32, section 13702-A, subsection 14, prior to providing coverage for the equivalent brand-name prescription drug; or

(2) A health care provider from prescribing a prescription drug that is determined to be medically necessary.

7. Rules. The superintendent may adopt rules to implement this section. The superintendent shall adopt a rule defining the circumstances under which a carrier or utilization review organization is required to grant or deny a request within 24 hours pursuant to subsection 6, paragraph D. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Application. The requirements of this Act apply to all policies, contracts and certificates executed, delivered, issued for delivery, continued or renewed in this State on or after January 1, 2020. For purposes of this Act, all contracts are deemed to be renewed no later than the next yearly anniversary of the contract date.

SUMMARY

This bill requires health insurance carriers to establish a process for prescription drug step therapy exceptions.