House Democratic Research Staff
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BILL SUMMARY

Medication Step Therapy Protocol HF 233

Status of Bill: House Floor
Committee: Human Resources (passed Committee 21-0)
Lead Democrats: Rep. Mascher
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Background

Currently, there is no statewide standard regarding step therapy protocol or an override exception process. Step therapy protocol is the process of failing on an approved medication prior to obtaining the prescribed, un-approved medication. As result, many Iowans must try medications that are not specifically prescribed by their health professional if they change insurance or jobs, after they have had success on a specific medication. Due to the lack of statewide standards step therapy guidelines may lead to adverse reactions, disease progression, and deny patients access to prescription regimens that have proven effective, and ultimately delay a healthy outcome. They must fail on those medications prior to being able to take the specific medication prescribed by their health care professional.

Summary

House File 233 creates both the standardization and override exceptions for a uniform step therapy protocol. The bill outlines Legislative findings that insurance companies and provider benefit managers (PBM) are using step therapy protocols that make patients fail on one drug after another, rather than allowing access to medication the patient's physician believes is best, or is medically necessary. Such step therapy protocols, if passed on established medical guidelines, and administered with flexibility can work well. Step therapy protocols should preserve the physicians right to make treatment decisions that are in the best interest of the patient.

The bill defines many terms for the new provisions. Some of the new terms defined are:
Clinical practice guidelines is defined as a systematically developed statement to assist health care professionals and covered persons in making decisions about appropriate health care for specific clinical circumstances and conditions.

Medical necessity is defined as health care services and supplies that under the applicable standard of care are appropriate for any of the following:

- To improve or preserve health, life, or function.
- To slow the deterioration of health, life, or function.
- For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

Step therapy protocol is defined as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and are medically appropriate for a particular covered person. These medications are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization, including self-administered drugs and drugs administered by a health care professional.

Step therapy override exception is defined as a situation where a step therapy protocol should be overridden in favor of immediate coverage of the prescription drug selected by a health care professional. This determination is based on a review of the covered person's or health care professional's request for an override, along with supporting rationale and documentation.

Utilization review is defined as a program or process by which an evaluation is made regarding the necessity, appropriateness, and efficiency of the use of health care services, procedures, or facilities given or proposed to be given to an individual. Such evaluation does not apply to requests by an individual or provider for a clarification, guarantee, or statement of an individual's health insurance coverage or benefits provided under a health benefit plan, nor to claims adjudication. Unless it is specifically stated, verification of benefits, preauthorization, or a prospective or concurrent utilization review program or process shall not be construed as a guarantee or statement of insurance coverage or benefits for any individual under a health benefit plan.

Utilization review organization is defined as an entity that performs utilization review, other than a health carrier performing utilization review for its own health benefit plans.

The bill then establishes step therapy protocols by requiring insurance companies, PBMs, and utilization review organizations to do all of the following:

- Use clinical review criteria based on clinical practice guidelines that meet all of the following requirements:
  - Recommend that particular prescription drugs be taken in the specific sequence required by the step therapy protocol.
  - Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among members of the panel's writing and review groups by doing all of the following:
    - Requiring members to disclose any potential conflicts of interest with entities, including health carriers, health benefit plans, utilization review organizations, and pharmaceutical manufacturers, and requiring members to recuse themselves from voting if there is a conflict of interest.
    - Using a methodologist to work with the panel's writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and by facilitating consensus.
    - Offering opportunities for public review and comments.
  - Are based on high-quality studies, research, and medical practice.
  - Are created through an explicit and transparent process that does all of the following:
    - Minimizes biases and conflicts of interest.
    - Explains the relationship between treatment options and outcomes.
    - Rates the quality of the evidence supporting the recommendations.
    - Considers relevant patient subgroups and preferences.
  - Are continually updated through a review of new evidence, research, and newly developed treatments.
- Take into account the needs of atypical covered person populations and diagnoses when establishing clinical review criteria.
- In spite of the first main requirement, peer-reviewed publications may be substituted for the use of clinical practice guidelines in establishing a step therapy protocol.

Insurance companies, PBMs, and utilization review organizations are not required to establish a new entity to develop clinical review criteria for step therapy protocol.

Disclosure of Information

Insurance companies, PBMs and utilization review organizations must, upon written request by an insured, a prospective insured, or by a health care professional, provide specific written clinical review criteria relating to a particular condition or disease, including criteria relating to a request for a step therapy override exception, which may be used in utilization review or in making a determination to approve or deny a request for a step therapy override exception. If the information provided is proprietary the insured or prospective insured, then the information must use it only for purposes of evaluating covered services.

Exceptions Process to Step Therapy Protocol
When a medication for treatment of any condition is restricted by an insurance company, PBM, or an utilization review organization, due to the step therapy protocol, the insured and the prescribing health care professional must have access to a step therapy override exception. An insurance carrier, PBM, and utilization review organizations may use their existing medical exceptions process to meet this requirement. This information must be accessible on the internet.

An override exception must be approved quickly by an insurance company, PBM, or utilization review organizations if any of the following apply:

- The medication required under the step therapy protocol is contraindicated or is likely to cause an adverse reaction or physical or mental harm to the insured.
- The medication required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person and the known characteristics of the medication regimen.
- The insured has tried the medication required under the step therapy protocol while under the insured current or a previous health benefit plan, or another medication in the same pharmacologic class or with the same mechanism of action, and the medication was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- The medication required under the step therapy protocol is not in the best interest of the covered person, based on medical necessity.
- The insured is stable on a prescription drug selected by the insured health care professional for the medical condition under consideration while on the existing or a previous health benefit plan.

Approval/Denial Process
The insurance company, PBM, and utilization review organizations have seventy-two hours from the receipt of the request from the patient, or the patient's prescribing health care professional to deny or approve the request. In special circumstances, a decision must be made within twenty-four hours of receipt of the override exception request. If a decision is not made within this specified timeframe, the request is automatically approved.

If a request is denied, the insurance company, PBM, and utilization review organizations must provide the insured, or the insured authorized representative, and the prescribing health care professional the reasons for the denial and information regarding the appeal process for the denial. All denials have the opportunity to be appealed to the insurance company, PBM, and utilization review organizations by the insured, or the insured's authorized representative, and the prescribing health care professional. All appealed denials must be decided within seventy-two or twenty-four hours as applicable. If an appeal is not decided within the appropriate timeframe, the appeal is automatically approved.

If the appeal of the denial is upheld, the insurance company, PBM, and utilization review organizations must provide the insured, or the insured authorized representative, and the prescribing health care professional the reasons the appeal of the denial was upheld and information regarding the procedure to request external review of the denial. Any denial of a request for a step therapy override exception that is upheld on appeal will be considered a final adverse determination and is eligible for a request for external review by an insured or the insured authorized representative.

Upon approval of the override exception, the insurance company, PBM, and utilization review organizations must quickly authorize coverage for the medication selected by the insured health care professional.

Limitations
The new step therapy protocol requirements and override exceptions cannot be construed to do either of the following:

- Prevent an insurance company, PBM, and utilization review organizations from requiring a covered person to try an AB-rated generic equivalent prescription drug prior to providing coverage for the equivalent branded prescription drug.
- Prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

Applicability

These new standardizations take effect for health insurance plans that begin, delivered, continued, or renewed in Iowa on or after January 1, 2018.

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