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TEXAS STEP THERAPY LAW
A Fact Sheet

WHAT IS STEP THERAPY?

Step therapy, also known as "fail first," are policies that require patients to try and fail on alternative treatments before the health plan will cover the originally prescribed treatment. Health plans implement these policies under the justification that these policies result in cost-savings for the plan.[1] However, while these policies may decrease health plan costs in the short-term, in the long-term these policies can increase health care costs.[2]

WHY ARE STEP THERAPY POLICIES HARMFUL?

Step therapy policies can be unethical and inconsistent with sound scientific and clinical evidence, resulting in interference with the practitioner-patient relationship and can result in significant delays in access to prescribed treatments.[3] Each patient has a unique medical history and background requiring personalized and individualized care.[4] This is why health care providers, not health plans, are best positioned to determine what treatments are most effective for each patient.[5] Certain treatments may be inappropriate for a particular patient due to a variety of considerations such as lack of efficacy, lack of therapeutic equivalence, or clinical characteristics unique to the patient that necessitate one treatment over another.[6] The time that the patient spends trying and failing on the alternative treatment could cause the patient's condition to progress or relapse.[7]

HOW DID TEXAS RESPOND?

In 2017, recognizing the need to protect prompt access to patient's treatments, Texas passed step-therapy reform.[8] The law became effective in September 2017.[9]

Specifically, the step-therapy law requires health benefit plans to develop step therapy protocols in accordance with clinical review criteria, taking into account the needs of atypical patient populations; and requires that plans establish an accessible, user-friendly exemption request processes.[10]

When must a health benefit plan grant a step therapy exemption?

A patient is entitled to an exemption from a step-therapy protocol when:[12]

1. The drug is contraindicated; will likely cause an adverse reaction; or is expected to be ineffective;
2. The patient previously tried and failed on the drug, or another prescription drug in the same pharmacologic class;
3. It is not in the best interest of the patient (expected to impede on patient's ability to complete daily tasks or adhere to plan of care, or worsen a comorbid condition); or
4. The patient is currently stable on a drug and the change is expected to be ineffective or cause harm to the patient based on known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.

What clinical review criteria must step therapy protocols be based on?

Clinical review criteria must consider generally accepted clinical practice guidelines that are:

- ✔ Developed and endorsed by a multidisciplinary panel of experts;
- ✔ Based on high quality studies, research, and medical practice;
- ✔ Created by an explicit and transparent process that minimizes bias and conflicts of interest, explains the relationship between treatment options and outcomes, rates the quality of the evidence supporting the recommendations, and considers relevant patient subgroups and preferences; and
- ✔ Updated at appropriate intervals after a review of new evidence, research, and treatments.[11]

What type of health plans does the law apply to?

The law applies to state regulated health insurers authorized to do business in the state, such as individual and small group plans, and employer sponsored plans that are fully funded.[13] The law does not apply to, plans issued under the state Medicaid program, the federal Medicare program, the Texas CHIP program, the TRICARE military health system, a workers' compensation plan, or an ERISA self-funded health benefit plan.[14]

How much time does the health benefit plan have to respond to an exemption request?

The health plan has up to 72 hours to respond to the exemption request. If a health plan does not deny the exemption request within 72 hours of receiving the request, the request is considered automatically granted.[15] In urgent circumstance, when a health care provider reasonably believes that denial of the request makes the death of, or serious harm to, the patient probable, the health plan has 24 hours to respond. If the health plan does not respond within 24 hours of receiving the request, the exemption is considered automatically granted.[16]

What if a patient's exemption request is denied?

An enrollee, a person acting on the enrollee's behalf, or the enrollee's physician or other health care provider may appeal the exemption denial or adverse determination.[17] Step-therapy exemptions requests involving continued hospitalization, prescription drugs or intravenous infusions are entitled to an expedited internal appeals process in which a resolution must be provided within one working day of receiving all necessary information.[18] In circumstances involving a life-threatening condition, the enrollee is entitled to an immediate appeal to an independent review organization.[19]

Learn more about the appeals process here.

WHERE CAN YOU GET MORE INFORMATION?

Visit the Texas Department of Insurance Consumer Protections.

Read the full statute.

REFERENCES

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