


## U.S. PAIN FOUNDATION POSITION STATEMENT – STEP THERAPY OR FAIL FIRST

U.S. Pain Foundation believes when step therapy stands in the way of treatments that are medically necessary, patients and their health care providers should have access to a clear and speedy process for seeking an exemption from an insurer's step therapy protocol.

Step therapy is a technique that insurers commonly use to help control drug costs. Under step therapy, an insurer places a coverage restriction on certain prescription medications. Before the plan will authorize coverage for a medication on that list, a patient is required to first try other, generally less expensive, drugs to see if they will be effective. These protocols are applied to drugs used to treat a wide range of diseases and conditions, including cancer, diabetes, HIV/AIDS, mental health, multiple sclerosis and other rare diseases. By limiting the array of medication options, both physicians and consumers are forced to compromise their treatment decisions in a way that is dangerous, time consuming and more expensive in the long-term.

In some instances, step therapy can be an effective tool. But if its duration and effectiveness are not carefully managed, step therapy can also lead to significant negative consequences for a patient. A number of factors contribute to this. First, the drug sequences required under step therapy are not based on the medical profile of a specific patient or on assessments provided by a patient's treating physician. Rather, these sequences are based on cost and on general expectations about potential treatment responses. Also, insurers may require patients to try the same drug repeatedly and over any length of time, as the law does not place any constraints on the duration of a step therapy protocol. That means patients may be obligated – for an indefinite period of time – to delay taking the medication that was initially prescribed by their health care providers.

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With appropriate reforms, step-therapy can be an effective tool to reduce cost and improve care.

- Step-therapy protocols should not require off-label use of a medication or therapy.
- Patients should not be required to fail more than once on the same medication.
- Patient incentives should be aligned to promote treatment adherence.
- States should consider studying the cost and safety of step-therapy programs before allowing the use of “multi-step” protocols.

From the moment of diagnosis, patients should know that they will have access to the treatment plan determined by their medical team to offer the greatest clinical benefit.

