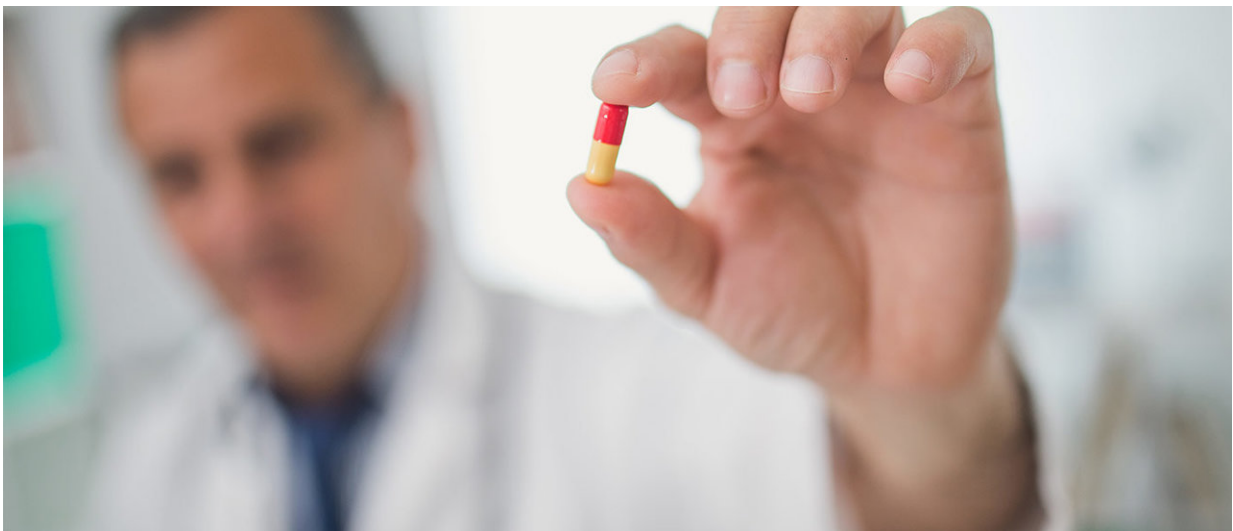


'Step therapy' approach to lowering health-care costs raises concerns, writes law professor

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Credit: Case Western Reserve University

To keep rising health-care costs in check, many health insurers have adopted a strategy known as "step therapy," a policy requiring patients to try cheaper drugs first—and find them to be ineffective—before approving pricier medication.

However, some health-care experts contend the approach, also known as "fail first," can yield poorer health outcomes and raises ethical and legal

concerns.

In an article just published in the *Food & Drug Law Journal*, Sharona Hoffman, professor of law and bioethics and co-director of the Law-Medicine Center at Case Western Reserve University, argues that the practice could reduce insurers' drug costs in the short term, but could actually cost more and harm [patients](#) in the long run. This is because patients who do not receive the right treatment may suffer complications and need further treatment or even hospitalization.

And, she writes, the practice often hurts chronically ill patients the most. Dr. Hoffman personally encountered step therapy when her husband was initially denied coverage for a [drug](#) prescribed for his Parkinson's disease.

"Some insurers are less than transparent with patients about their programs," she said. "They adhere to a one-size-fits-all approach, ignoring nuanced clinical and economic evidence, and implement their policies in a discriminatory way."

Hoffman's article—among the first law journal pieces dedicated to step therapy—also points out that several states have already taken a stand through legislation that establishes step therapy limits. The article also reviews mechanisms that federal law provides to appeal adverse insurance decisions.

"Step therapy has more complicated implications than initially meet the eye," Hoffman said. "Step therapy policies should be carefully designed to achieve cost savings while remaining flexible, responsive to patients' needs and consistent with relevant clinical data."

"Insurers should be careful not to strive single-mindedly to reduce short-term costs at the expense of ignoring patients' overall well-being,

physicians' treatment goals, and the prospect of increased long-term expenditures."

Hoffman further argues that states without "fail first" statutes should enact them and that federal law should address step therapy as well. Among her recommendations for such legislation are easy and fast ways to request exemptions and appeal insurance denials as well as clear and easily accessible explanations of step therapy terms.

Hoffman notes that, done well, step therapy can be a safe and effective approach to providing patients with cheaper but still appropriate drugs. She recommends that the health-insurance industry conduct further research to determine if and under what circumstances step therapy is an effective cost-reduction tool.

"Step [therapy](#) should not constitute a bludgeon used against patients and doctors," Hoffman said. "Instead it should be a vehicle for all stakeholders to work cooperatively to reduce treatment [costs](#) without compromising health outcomes."

More information: Step Therapy: Legal, Ethical, and Policy Implications of a Cost-Cutting Measure: www.fdpi.org/2018/02/step-therapy-cost-cutting-measure/

Provided by Case Western Reserve University

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