Step Therapy: Dispelling the Myths

"Step therapy is not widely used by health insurers."

- Step therapy is applied to prescription drugs used to treat a range of life-threatening diseases and chronic conditions, including, among others, cancer, diabetes, HIV/AIDS, mental health, and multiple sclerosis
- Step therapy utilization is steadily increasing: from 1993 to 2003, use of step therapy grew ten-fold.[1] In 2010, almost 60 percent of commercial insurers were utilizing step therapy nationally[2] and, in 2013, 75 percent of large employers reported offering employees plans that utilize step therapy.[3]
- The trend is growing within coverage for oncology products, where traditionally insurers have not extensively used step therapy. In 2012, 54 percent of plans applied step therapy to oncology products, up from 36 percent the year before.[4]

"Step therapy is safe; it has not been shown to have a damaging impact on patients."

- Patients have reported serious side effects from medications they were required to take as part of a step therapy protocol. In many of these cases, the insurer was notified of an expected adverse reaction but still required the patient to follow the step process.
- Some patients have experienced disease progression as a result of delays in access to the initially prescribed treatment. This is an especially serious outcome for patients living with diseases and conditions that are already severe, debilitating, and/or life-threatening.
- A significant number of patients, when faced with a step therapy program, end up receiving no medication at all. According to a recent study, a total of 67 percent of patients whose drugs were rejected under step therapy did not receive an alternate drug within a 30-day window.[5]
- There are few, if any, existing regulations that require insurers to prove the safety and efficacy of their step therapy protocols.

"Insurers are not 'practicing medicine' by using step therapy."

- In theory, an insurer's step therapy protocols do not prevent healthcare providers from writing prescriptions as they see fit. However, the reality is that most patients are unable to fill a prescription if the insurer withholds coverage for the prescribed medication. So while requiring patients to undergo step therapy does not qualify as 'practicing medicine,' it does give insurers extensive control over a patient's course of treatment. This bill ensures that patients and their physicians can select medically necessary treatments.

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[1] Sipkoff, Martin. "Reports Confirm High Value of Step-Value Programs." *Managed Care.* December 2005
[2] Motheral, Brenda. *Journal of Managed Care Pharmacy*. Vol. 17, No. 2. March 2011.
[3] "Step therapy comeback continues." *Journal of Managed Care.* September 2012. http://www.managedcaremag.com/archives/1209/1209.outlook.html
[4] Report from Health Strategies Group, published by *Managed Care Oncology* during the 4th quarter of 2012.
[5] Belazi, Dea. *The American Journal of Managed Care.* Vol. 19, Special Issue 4. May/June 2013.

"Insurers already have exceptions processes in place."

- This bill would allow patients and providers to use existing processes to request a step therapy exception. Payers could *choose* to establish a separate, stand-alone process to be used only for step therapy requests, but this bill would not obligate them to do so. If using an existing process, the insurer must make the details of that process clear and transparent for the patients and providers.

"Insurers have internal and external appeals procedures which are sufficient for addressing concerns related to step therapy."

- Under certain conditions, patients have the right to seek an independent, or "external," appeal when denied coverage for a particular benefit or service. However, to be eligible for an external appeal, an enrollee must: (1) submit an appeal directly to his/her health plan, via the plan's internal appeals process and (2) receive a final adverse determination from the insurer. Only then may a patient file paperwork requesting an external appeal. This process is not only time-consuming, but it is also confusing and onerous, especially for a patient living with a serious medical condition.

"Prohibiting insurers from using step therapy will lead to increases in cost."

- This bill would not prohibit insurers from using step therapy. Rather, the bill simply requires insurers to honor certain rules and requirements when using step therapy.
- Exceptions would be granted *only* if a prescriber demonstrates that the initially prescribed treatment is medically necessary.
- Effective cost-control is best achieved by allowing clinical considerations and medical expertise to drive treatment decisions. This will help avoid the costly episodes of care that often arise from unnecessary delays in treatment, side effects, and/or drug abandonment.

"This bill would enable providers to *automatically override* step therapy programs. This will effectively prevent insurers from using step therapy for any real cost-control."

- Exceptions are not automatically granted. Like other authorization and exceptions requests, providers would be required to provide documentation making their case for an exception. The insurer would then assess that documentation and determine whether to issue an exception.

"According to the Affordable Care Act, this bill is considered a mandate; as a result, the state would have to cover the cost of implementing this bill, should it become law."

- The Affordable Care Act provision requiring states to defray the cost of recently enacted insurance mandates does not apply to this bill. According to federal regulations,[6] it only applies to state laws that require the coverage of *new* benefits and/or services. This legislation addresses the way a utilization management technique is applied to drugs that are already available under a patients health plan.

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[6] Department of Health and Human Services. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR Parts 147, 155, and 156. Available at http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf