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Written Testimony in Support of Step Therapy Reform (SB 394)
Insurance and Real Estate Committee
Public Hearing – March 13, 2014

Chairmen Crisco and Megna, and Members of the Committee:

On behalf of the Leukemia & Lymphoma Society (LLS) and the thousands of blood cancer patients we serve throughout the state of Connecticut, we thank you for the opportunity to comment on Raised Senate Bill No. 394, concerning the use of step therapy. LLS applauds the committee for raising this bill, as it would ensure that patients with commercial coverage have access to the same step therapy protections that the General Assembly extended last year to Medicaid enrollees.

Step therapy is a widely-used technique that insurers use to control drug costs. Under step therapy, an insurer places a coverage restriction on certain prescription medications. Before the plan will authorize coverage for those medications, the patient must first try other, generally less expensive drugs to see if they will be effective. In 2010, almost 60% of commercial insurers were utilizing step therapy nationally.¹ In Connecticut, the practice is 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.

While step therapy can be an effective tool in some instances, it can have significant negative consequences for a patient if the duration and effectiveness of the step therapy is not managed carefully. Note that the drug sequences required under step therapy are not based on a patient's specific medical profile or a physician's assessment of that patient's best treatment option. Rather, sequences are based on cost and on general expectations about potential treatment responses. Also, note that patients with commercial coverage may be required to try the same drug(s) repeatedly over any length of time, as the law does not place any constraints on the duration of a step therapy protocol.

If not managed carefully, step therapy can lead to delays in access to the medication offering the greatest medical benefit. Other patients may find themselves with no alternate therapy for an extended period of time. According to one recent study, 67% of patients whose specialty drugs were rejected under step therapy did not receive an alternate drug within a 30 day window.³ In these cases, patients may experience disease progression, a serious risk for patients dealing with life-threatening conditions. While Connecticut took an important first step last year by protecting Medicaid patients from inappropriate use of step therapy, those with commercial plans do not have access to the same protection.

For many cancer patients, every day is a battle. From the moment of diagnosis, patients rightfully want to know that they will have access to the treatment plan determined by their medical team to offer the greatest clinical benefit. Data from 2012 shows that an increasing percentage of plans are applying step therapy programs specifically to oncology products: 54% of plans, up from only 36% the year before.¹¹ This trend is deeply worrying to the cancer community, given that recent treatment breakthroughs are driven by the principles of "precision medicine": today, oncologists have access to more diagnostic information than ever before, allowing them to make treatment decisions based on a patient's specific profile. Yet those advantages can be diminished by step therapy, given its reliance on generalizations about large patient populations.

Fortunately, the Medicaid rules in Connecticut offer a common-sense, balanced solution that – if applied to the commercial space – would enable insurers to continue using step therapy for cost-savings purposes while *also*

ensuring that treatment decisions are left to the patient and his/her medical team. Medicaid does this by providing the prescriber with a process to request an override of the relevant step therapy protocol, when medically necessary. This override is granted *only* if the provider can demonstrate the presence of certain clinical characteristics – namely, that the preferred treatment required under the step therapy program:

1. Has been ineffective in the treatment of the patient’s condition in the past;
2. Is expected to be ineffective, based on relevant characteristics of the patient and the drug regimen;
3. Will cause or is likely to cause an adverse reaction or other physical harm to the patient; or
4. Is not in the best interest of the patient, based on considerations of medical necessity.

Also, in cases where step therapy is appropriate for use, the bill would limit the amount of time a patient could be subjected to step therapy so that patients cannot be obligated for an indefinite period of time to risk treatment delays or adverse reactions. That limit would be thirty days, after which point the healthcare provider may deem the treatment clinically ineffective for the patient at hand.

These simple protections can help facilitate a strong bottom line, as more effective cost-control can be achieved by allowing clinical considerations and medical expertise to play their intended role in treatment decisions. This will help avoid the costly episodes of care that arise from unnecessary delays in treatment and/or side effects.

Also regarding cost: we would like to clarify that the Affordable Care Act provision requiring states to defray the cost of recently enacted insurance mandates would not apply to SB 394. According to federal regulations,ⁱⁱⁱ this requirement applies only to state laws that require the coverage of *new* benefits and/or services. SB 394 does not require insurers to add drugs to their formularies or to make any other additions to a plan’s covered benefits and services. Rather, SB 394 addresses the way a utilization management technique is applied to drugs that are already on formulary.

Finally, it’s important to understand that currently available appeals processes do not offer sufficient patient protection when it comes to step therapy. Navigating these processes is typically difficult and time-consuming for patients, caregivers, and prescribers alike, which can delay care anywhere from days to weeks. This is often due to a lack of transparency in an insurer’s internal appeals process, which itself must be exhausted before a patient’s claim would be eligible for external appeals. Simply put, the likelihood of strong patient outcomes would be greatly enhanced if all prescribers – not just those treating Medicaid patients – have access to a procedure for requesting a step override that is less opaque and more direct and efficient.

With questions, please contact:

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ⁱ Motheral, Brenda. *Journal of Managed Care Pharmacy*. Vol. 17, No. 2. March 2011.

ⁱⁱ Report from Health Strategies Group, published by *Managed Care Oncology* during the 4th quarter of 2012.

ⁱⁱⁱ 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>