

**Written Testimony in Support of Step Therapy Reform  
Insurance and Real Estate Committee  
Public Hearing – February 18, 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. 7, concerning the use of step therapy. While LLS strongly applauds Senator Crisco for filing this bill, we respectfully request that the committee consider substituting SB 7 with language mirroring the step therapy protections passed by the General Assembly last year. These protections are both fair and robust but were extended only to Medicaid enrollees. By applying these protections to the commercial market, the committee would ensure that all patients – regardless of the source of their coverage – receive equal treatment when it comes to step therapy.

Step therapy, also known as “fail first,” is a widely-used technique that insurers use to control drug costs. Under step therapy, an insurer withholds coverage for a prescribed drug until after the patient has achieved “failure” on a different (usually cheaper) drug selected by the insurer. In 2010, almost 60% of commercial insurers were utilizing step therapy nationally.<sup>1</sup> 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.

When used in tandem with appropriate patient protections, step therapy can indeed function as an effective and safe strategy for controlling healthcare costs. Such protections ensure that the need for cost containment is balanced with the recognition that a healthcare professional – rather than an insurer – should ultimately determine what treatment a patient is on and for how long.

Unfortunately, these protections are not in place in many states. This has led to patient harm due to serious side effects from inadequate medications and to disease progression following delays in appropriate treatment. Also concerning are the studies showing that 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% of patients whose specialty drugs were rejected under step therapy did not receive an alternate drug within a 30 day window.<sup>2</sup> These situations could result in costly episodes of care that might have been avoided, if not for misuse of the step therapy technique. While Connecticut took an important first step last year by protecting Medicaid patients from misuse of step therapy, those with commercial plans do not have access to the same protection.

For many patients – including those with cancer – 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. Many of them who are forced to abide by step therapy programs will suffer for long periods of time on older, less effective, more toxic forms of treatment. 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.<sup>3</sup> 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. Fundamentally, an insurer using a step therapy approach is not taking into account unique patient responses to different forms of

treatment. That's because step therapy relies upon information that makes generalizations about large patient populations.

Fortunately, the Medicaid rules in Connecticut offer a common-sense, balanced solution that – if adopted in the commercial space – would enable insurers to realize their goals of cost-savings through step therapy 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 the known 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.

Legislatures around the country are taking steps to address this issue, having recognized the importance of establishing step therapy protocols<sup>4</sup>. Fortunately these simple protections do not lead to increases in cost for insurers. In fact, 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.

With questions, please contact:

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<sup>1</sup> Motheral, Brenda. *Journal of Managed Care Pharmacy*. Vol. 17, No. 2. March 2011.

<sup>2</sup> Belazi, Dea. *The American Journal of Managed Care*. Vol. 19, Special Issue 4. May/June 2013.

<sup>3</sup> Report from Health Strategies Group, published by *Managed Care Oncology* during the 4<sup>th</sup> quarter of 2012.

<sup>4</sup> In 2013 alone, four states passed legislation related to step therapy: CT, LA, NM, and VT.