

Good morning Representative Lewis and members of the committee. My name is Patrick Stone and I am the state government relations manager for the National Psoriasis Foundation. The National Psoriasis Foundation (NPF) is a non-profit, voluntary health agency dedicated to curing psoriatic disease and improving the lives of those affected. The Psoriasis Foundation is the leading patient advocacy group for the 7.5 million Americans and 248,600 North Carolinians living with psoriasis and psoriatic arthritis.

First and foremost I would like to thank Representative Lewis and the rest of the committee for taking on an issue that is vital to the health and well-being of North Carolina residents. The General Assembly truly has an opportunity to be a leader among the states on this issue, and we thank you for the opportunity to be here and for giving us this forum.

What is step therapy?

Step therapy is a cost containment tool used by health insurance plans that requires patients to first try and fail on one or more medications not prescribed by their physician before the plan will authorize coverage for the originally prescribed medication. Step therapy impacts a range of chronic and life-threatening diseases including psoriasis, psoriatic arthritis, multiple sclerosis, diabetes, cancer and mental health, among others.

The use of step therapy is common and still growing among private and public payers. In 2013, 67 percent of employer sponsored health insurance plans reported that they had implemented step therapy policies, an increase from 27 percent in 2005<sup>i</sup>.

While insurers and pharmacy benefit managers (PBMs) argue that step therapy protocols provide appropriate and affordable drug treatments, step therapy can have the opposite effect by unnecessarily prolonging ineffective treatment and preventing patients from immediately starting treatments recommended by their physician or health care practitioner.

Simply put actuarial tables and bureaucrats are being put in a position of power higher than doctors when it comes to determining what is in the best interest of a patient.

### **The Direct and Indirect Costs of Step Therapy**

- Step therapy is touted as a tool to reduce costs to insurers, but it may simply trade prescription costs for significant time costs to patients, providers, and pharmacists.
- According to one study, 28% of patients who had encountered a ST edit reported spending three or more hours trying to obtain second-line drugs from their physicians' offices<sup>ii</sup>.
- Step therapy also increases the administrative burden of medical providers. Physicians and their staff must spend time contacting insurance companies to determine if a drug will be covered, in addition to appealing denied treatments, which leaves less time for patient-centered healthcare. By some estimates, this increased administrative burden takes approximately two hours per patient<sup>iii</sup>.
- The time and administrative burden associated with ST presents an obstacle to access that may lead to unnecessary breaks in treatment. Indeed, several studies have found that, depending on

therapeutic class, 7% to 22% of patients did not submit any prescription claim to their insurance provider following a ST edit, instead forgoing treatment<sup>iv,v</sup>.

- While proponents of ST tout its cost-saving benefits, there are examples of cases where, in fact, ST increased costs over time.
- In a study comparing spending on schizophrenia medications in Georgia's Medicaid program, step therapy saved the state \$19.62 per member per month in pharmacy benefits but these savings were accompanied by a \$31.59 per member per month increase in expenditures for outpatient costs<sup>vi</sup>.

### **What is being done in the states?**

Over the past few years several states have addressed step therapy through either legislation or regulatory action.

Connecticut, Kentucky, Maryland, Louisiana, Mississippi, California and Washington State all currently have consumer protections codified

Arkansas, Florida, Illinois, Indiana, Massachusetts, Maine, Minnesota, Missouri, New York, Ohio and the Tarheel State have all considered or will be considering legislation

I mention all these states by name rather than purely citing numbers to illustrate a point. This is a bipartisan issue. Red or Blue, states have all seen that this is an issue which needs to be addressed. Furthermore, in states where legislation has passed, we have been successful because we have engaged all parties when considering this issue. Insurers, patient and provider groups, and regulators all had their voices heard and a consensus was reached.

None of the laws that have been passed ban step therapy. Instead they focus on ensuring that a clear pathway exists for an exception to step therapy being granted by an insurer and that the protocols in place are based on independent clinical evidence.

The safety and effectiveness of step therapy protocols can be significantly improved by enacting policies that protect the physician-patient relationship. We respectfully encourage the general assembly to consider adopting legislation that

- Require health plans to provide a clear and timely process for prescribers to request an exception to a step therapy protocol where it is medically necessary.
- Ensure that step therapy protocols developed by insurers are based on nationally recognized clinical practice guidelines.
- Give physicians the ability to immediately override the step therapy protocol in the following instances:
  - The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

- The required prescription drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen;
- The patient has tried the required prescription drug while under their current or a previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The required prescription drug is not in the best interest of the patient, based on medical appropriateness.
- The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

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<sup>i</sup> Rahul K. Nayak and Steven D. Pearson. The Ethics Of 'Fail First': Guidelines And Practical Scenarios For Step Therapy Coverage Policies. Health Affairs, 33, no.10 (2014):1779-1785

<sup>ii</sup> Cox, E.R., R. Henderson, and B.R. Motheral, Health plan member experience with point-of-service prescription step therapy. J Manag Care Pharm, 2004. 10(4): p. 291-8.

<sup>iii</sup> Yosipovitch, G., Step therapy stalls appropriate patient treatment, in Dermatology Times: Clinical Analysis for Today's Skincare Specialists 2015.

<sup>iv</sup> Delate, T., et al., Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. Am J Manag Care, 2005. 11(1): p. 29-36.

<sup>v</sup> Yokoyama, K., et al., Effects of a step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy. J Manag Care Pharm, 2007. 13(3): p. 235-44.

<sup>vi</sup> Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," Clinical Therapeutics, 30: 1524-1539, 2008.