

# Step Therapy

Insurance companies have policies, such as step therapy, that are designed to help control costs but sometimes block patients' access to medications and limit the decision making of patients and physicians<sup>1</sup>

## STEP THERAPY requires patients to<sup>1</sup>:



TAKE OTHER  
POTENTIALLY INEFFECTIVE  
MEDICATIONS FIRST



FAIL ON  
THESE  
MEDICATIONS

BEFORE  
INSURERS  
PAY

DOCTOR'S  
ORIGINAL  
PRESCRIPTION

There is little oversight and few regulations that require insurers to prove the effectiveness of their step therapy policies in ensuring quality patient care

In some cases, patients must step through FDA branded boxed warning drugs before being prescribed FDA branded non-boxed warning drugs<sup>2</sup>

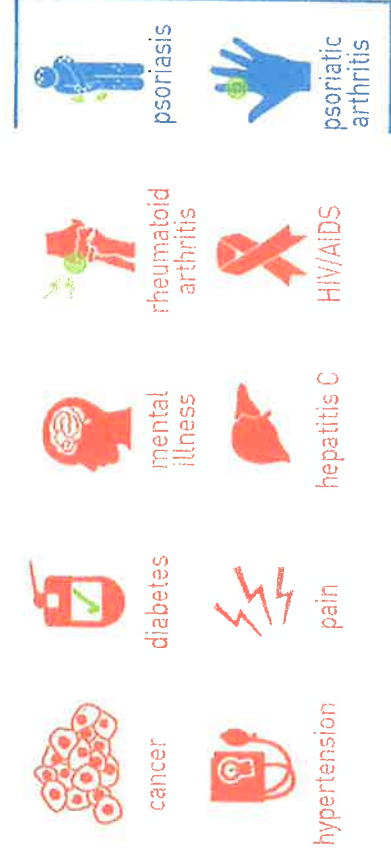
**WARNING**

## STEP THERAPY is on the rise<sup>1</sup>:



THESE POLICIES  
MAY NOT TAKE  
INTO ACCOUNT  
A PERSON'S  
MEDICAL  
SITUATION  
OR HISTORY

## Major health conditions affected by STEP THERAPY:



### FOR EXAMPLE:

Patients with psoriasis and psoriatic arthritis, treatment access was delayed or denied



If you or a loved one has been affected by step therapy, speak with an advocacy group in your disease area. Visit [www.prescriptionprocess.com/steptherapy](http://www.prescriptionprocess.com/steptherapy) for more information/tips and to share your story.

### REFERENCES:

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2. Branning, G., Schaafs, R., Hourrning, J., et al. Formulary Management of Branded Boxed Drugs and Non-Boxed Warning Drugs within Therapeutic Categories. Abstract 4020. Data presented at the International Society for Pharmacoeconomics and Outcomes Research 20th Annual International Meeting, May 16-20, 2015, Philadelphia.
3. Covance. Otzla Support Plus. February 2015
4. Dermatology Nurses Prior Authorization Advisory Board. Macon, GA. Feb 2015.

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February 22, 2016

House Select Committee on Step Therapy  
House of Representatives, North Carolina General Assembly  
Raleigh, NC 27601-1096

Dear Mr. Chairman and Honorable Members of the House Select Committee on Step Therapy:

The National Patient Advocate Foundation (NPAF) serves as a voice for patients across America in regard to legislation and regulation that will benefit patient rights and needs. Our sister organization, Patient Advocate Foundation (PAF), provides direct assistance to patients throughout the country by helping to eliminate obstacles for patients trying to access quality healthcare. I am writing on behalf of these organizations and the North Carolina patients we serve to explain why step therapy is such a serious concern to North Carolina patients and why it is of the utmost importance to our organization to address this significant issue.

Step therapy is a type of utilization management tool used by payers to help control and contain rising health care costs. Sometimes called "fail first", step therapy policies require patients to try and *fail* another lower cost medication before the prescribed medication can be given, consequently preventing patients from accessing the prescribed care or treatments they need in a timely manner. Under step therapy, the fate of patients requiring treatment rests in the hands of health plans who make the final medical decision, ignoring the physician-patient relationship. Furthermore, the step therapy protocols which form the basis of these critical decisions vary widely and lack transparency.

More than other utilization management tools such as formulary tiering, step therapy raises important ethical concerns regarding the proper balance between cost control and the ability of patients and clinicians to tailor care to the needs of the individual patient. While NPAF recognizes the importance of cost containment and shares the concern that the rising cost of health care delivery is placing new and dangerous risks onto patients, we are concerned that step therapy, if applied inappropriately, will lead to less robust patient outcomes and could potentially even be harmful to patients. By requiring patients to first prove that another medication is not effective, particularly when the patient is already seeing results from an existing course of treatment, is equivalent to telling a patient that she must harm herself before being allowed to get better. For many treatments, proving "failure" on an alternate medication is tantamount to causing damage to the body, thus putting the patient at significant risk. It is in that light that we believe that step therapy protocols must be drafted and applied with consideration for the patient's background and the medical provider's professional judgment and expertise. The easiest way to do this without placing undo risk onto payers, providers, or patients is to ensure that payers have a clear, expedient, and easily-navigable exceptions process for all step therapy protocols that allow those protocols to be overridden at the judgment of the medical provider.

Patients in need often cannot afford long wait times for specialty medications that would otherwise be subject to step therapy protocols. In the case of many medical conditions, a patient's health will deteriorate rapidly if she does not have access to the proper treatment. At NPAF, we firmly believe that health care decisions, be they mundane or significant, deserve to be made between patients and their health care providers. Administrative choices should not come between a patient's need and a provider's expertise. It is for this reason that we believe that efforts to clarify the process for utilization reviews are worthwhile and will facilitate better health outcomes for patients.

As stated, NPAF's mission is to serve as the voice and advocate for all patients battling illnesses, particularly those who often have neither the strength nor the resources to champion their own cause. The 2,663 North Carolina patients who contacted the Patient Advocate Foundation in 2014 did so because of barriers, like step therapy, to accessing quality healthcare. NPAF strongly supports legislative or regulatory efforts that would reform step therapy protocols and we look forward to working with you to ensure that all patients have access to high quality health care.

Sincerely,

A handwritten signature in black ink that reads "Melissa J. Williams". The script is fluid and cursive, with the first name "Melissa" and last name "Williams" clearly legible.

Melissa Lorenzo Williams  
Coordinator of State Government Relations

# Insurers win, patients lose with step therapy

## HIGHLIGHTS

I suffer from chronic rheumatoid arthritis

My doctor prescribed a drug that would help, but my insurer made me go through six others first

That had a devastating effect on me to save the insurer some money

BY ARLOISHIA ISRAEL

*Special to the Observer*

I've spent much of the last year in constant pain – all because my health insurance company decided it wouldn't cover the medication that my doctor prescribed to treat my chronic rheumatoid arthritis.

I was diagnosed early last year after collapsing at work. My doctor prescribed a biologic infusion treatment, but my health insurer required me to first fail on six other drugs before I could gain access to the biologic.

It's taken me more than a year to go through this so-called "step therapy" process as I tried, and failed, on each insurance-mandated treatment. During that time my rheumatoid arthritis progressed so much that I lost my job, can no longer drive or care for my son by myself, and need help with simple tasks like taking a bath. The medications my insurance company required me to try also came with their own side effects, including dangerously high blood pressure, eyesight issues, nausea and hair loss. I've been hospitalized and had several emergency room visits.

A few months ago, after my doctor provided proof that the last insurer-mandated medication did nothing to help me, I finally received treatment my doctor originally prescribed. And while the new therapy is starting to work, I can't help but think about what I've already lost: precious time with my son, my independence, my career and so much more.

Step therapy protocols are entirely based on cost. There is no medical justification for them, and often there is no clear or quick way for physicians to appeal and stop the insurance company from making a patient try and fail on other drugs first. It's also significant to note that health insurers often mandate step therapy not only for people living with arthritis, but also for those battling cancer, multiple sclerosis, diabetes and a range of other conditions.

So now I'm fighting back – not only against my rheumatoid arthritis but against the policies that have hurt me and my family. I'm asking state lawmakers to act on a proposal that will help protect North Carolinians like me.

Fortunately, the General Assembly just formed a committee to consider establishing a clear process for health care providers to request exceptions to step-therapy protocols. Most importantly, the proposal would require insurers to make exceptions when a physician determines that the insurer-required drug is not in the best interest of the patient.

Like many North Carolinians, I will battle my chronic condition of rheumatoid arthritis for the rest of my life. But I shouldn't have to fight with my health insurer to obtain a treatment that works. We need doctors, not insurance companies, to decide what's best.

*Arloishia Israel is a member of the Arthritis Foundation. She lives in Matthews.*

## CORRECTION

A Forum letter in Monday's Observer misidentified the candidate challenging Gov. Pat McCrory in the Republican primary. He is former state Rep. Robert Brawley of Mooresville.





# Lawmakers examine insurers' effort to control drug prices

Tags: Insurance, Health Care

Posted December 14, 2015

62

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 3 Reactions



**RALEIGH, N.C.** — A new state House committee on Monday began considering whether North Carolina should regulate how insurance companies restrict the use of expensive drugs to save money.

Step therapy, also known as fail first, requires that patients start with cheaper drugs, even if their doctors prescribe something else. The insurance company won't approve more expensive drugs until cheaper ones have been proven not to work.

Insurers say the practice keeps drug prices under control, but patients with severe chronic illnesses say it causes health problems by delaying needed treatment.

Twelve-year-old Logan Govan has polyarticular juvenile idiopathic arthritis and waited a painful three years while his condition spread to different joints to get approval for the drug he needed. Meanwhile, the drugs he was required to try first had dangerous side-effects, said his mother, Mindy Govan.

"Why am I having to keep my son on this very potentially risky medication just to get to the right one?" Misty Govan asked lawmakers.

Michele McArthur, who has rheumatoid arthritis, is still waiting for insurance approval for the drug her doctor wants her to take.

"I'm on my fourth drug trying to get to the original treatment he wanted to give me two-and-a-half years ago," McArthur said.

Doris Ann Price, who pushed lawmakers earlier to limit the use of step therapy in North Carolina, had to send a letter to the House Select Committee on Step Therapy because she had to move to Boston in recent months to participate in a drug trial that she said she needed because here insurance company denied the treatments her oncologists sought for her metastatic breast cancer.

"Please stand alongside me today in the fight for my life," Price wrote in the letter, which was read by Donna Kaufman of the National Patient Advocate Foundation.

State Rep. Greg Murphy, R-Pitt, said he sees the problem of step therapy every day as a surgeon – and as a parent.

"My son developed epilepsy at age 14, and we went through five drugs in seven months of him seizing before we'd use the drug that we should have used originally," Murphy told his colleagues.

Murphy criticized the insurance industry's use of a panel of doctors and pharmacists to write formularies for cancer specialists.

"These fellows, this is what they do for a living, and having a family practitioner tell them which drug that they can use for oncology is, in my opinion, ludicrous," he said.

Insurers said they have processes in place for doctors to seek exceptions for certain patients, but the patients said those processes are not working.

Lu-Ann Perryman, a lobbyist for America's Health Insurance Plans, said changes could mean higher premiums for everyone.

"Limiting the ability of health plans to utilize step therapy only encourages the unsustainable increases in pharmaceutical costs and has a serious potential to harm patients," Perryman told lawmakers.

Step therapy works fine 90 percent of the time, said Ben Twilley of Express Scripts, who noted that his company only requires one step, not four or more.

"Ten percent is a decent number," Murphy said of the cases where step therapy doesn't work. "When it's you, it's 100 percent. So, there is work to do in that regard."

Rep. Pat McElraft, R-Carteret, echoed Murphy's concerns.

"I'm actually appalled at the other 10 percent and what they're having to go through," McElraft said.

Gregg Thompson, state director of the National Federation of Independent Businesses, said employers need the ability to control drug costs as part of their health insurance plans, and step therapy is part of that strategy.

"The last thing they need is a new mandate to be passed that limits their ability to control costs," Thompson said.

## CREDITS

<b>Reporter</b>	Laura Leslie
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# NC Legislators Discuss Step Therapy

By Amy Elliott

Time Warner News

Monday, December 14, 2015 at 04:12 PM EST

RALEIGH -- On Monday, N.C. House Select committee members held a hearing about step therapy.

The protocol requires patients to try less expensive and many times less potent medications before the initial prescription is approved.

Raleigh resident Logan Govan, 12, has battled juvenile rheumatoid arthritis for the past three years. He was initially prescribed a medication by his doctor but could not get it due to step-therapy.

"I wish my doctor would have just put me on the right medicine to start so that maybe it wouldn't have spread to my other joints," said Govan during the hearing.

Another arthritis sufferer Michelle McArthur said she's been waiting more than two years to receive her initial prescription.

"I haven't been able to work," the Goldsboro resident said. "I have been at home going through injections, pills, just to get to the drug that my Duke-educated doctor wanted to give me in the first place."

The committee also heard from people who talked about the benefits of step-therapy. Many say it's a useful tool in keeping rising health care costs down.

"I urge you to not add any new regulations or mandates that will increase the cost of health care by limiting this ability," said Gregg Thompson, NC director of the National Federation of Independent Business. "The bottom line is each new mandate, no matter how well intentioned, comes with a cost to policy holders."

Members of the House Select Committee say they want to make the process easier for everyone involved.

"We have to control cost, no doubt about it. We have to help small businesses, no doubt about it," said Pitt County Representative Gregory Murphy. "But we also have to have a way where folks are on the other side of the stream who are just seeing these understand there are patients behind the forms."

The committee is expected to meet again in January.