MODERATOR: Michele Guadalupe, Arthritis Foundation

12:00 pm Welcome from Moderator
Introduce yourself and the Arthritis Foundation, including being part of the SAIM coalition and an explanation of how the town hall will flow; how to submit questions, etc.

12:02 – 12:07 pm Overview of Step Therapy from Moderator

MODERATOR: Let’s start our virtual town hall with a short video that provides a detailed overview of the issue:

Show Step Therapy Quick Draw video

(Note: Moderator, after video, please provide any additional background information necessary):

Step therapy is used by insurers to control costs. Step therapy is a tool insurers use to limit how much they spend covering patients’ medications. Under step therapy, a patient must try one or more drugs chosen by their insurer – usually based on financial, not medical, considerations – before coverage is granted for the drug prescribed by the patient’s health care provider.

Patients must take drugs selected by the insurer. Patients may be required to try one or more alternative prescription drugs that are of lower cost to the insurer, but may not be the best therapy for some patients; these substitutes sometimes include an over-the-counter medicine, which shifts 100% of the cost to the patient.

Step therapy use is increasing steadily. In 2010, nearly 60% of commercial insurers were using step therapy. As of 2013, 75% of large employers reported offering employees plans that utilize step therapy.

Step therapy is applied to many diseases. Step therapy is applied to drugs treating a wide range of diseases and chronic conditions, including:

- Alzheimer’s disease
- Autoimmune diseases
- Cancer
- Diabetes
- Epilepsy
- Glaucoma
- Hemophilia
- HIV/AIDS
- Mental health
ILLINOIS VIRTUAL TOWN HALL RUN OF SHOW
& KEY TALKING POINTS

Why Should We Care or Be Concerned?
Insurers claim that step therapy helps to lower health care costs while maintaining or possibly improving care quality. In some cases, step therapy has played a role in achieving these outcomes. But, in other situations, data clearly shows that step therapy can have the opposite impact.

Step therapy can delay or lower care quality. Since step therapy requires patients to try one or several medications before being covered for the drug selected by their health care provider, it can delay access to the best therapy. In the course of these delays, patients may experience disease progression, a serious risk for anyone living with a debilitating or life threatening illness. Step therapy can also prevent patients from receiving treatment at all. Studies have shown this to be true for 1 in 5 patients.

Step therapy can lead to increases in cost. In a study comparing spending on schizophrenia medications in Georgia’s Medicaid program, step therapy saved the state $19.62 per member per month (PMPM) in atypical antipsychotic expenditures. However, these savings were “accompanied by a $31.59 per member per month increase in expenditures for outpatient services.” As a result, step therapy did not have the intended effect of reducing overall costs; rather, it increased health care costs. Similar findings have been observed when step therapy was applied to blood pressure medications.

12:07 – 12:10 pm  Moderator to Introduce Panelists

- Illinois State Representative Laure Fine (Glenview, 17th district), who is the Prime Sponsor of this year’s step therapy legislation HB 3549
- Dr. Mark Heyrman, who is a Clinical Law Professor at the University of Chicago and facilitator for the Mental Health Summit
- B. Jang Mi Johnson, PA-C, Senior Physician Assistant at Illinois Dermatology Institute
- Dr. Stephen Stone, a Dermatologist and Director of Clinical Research in Dermatology at Southern IL University
- Dr. Dareen Siri, from the Midwest Allergy Sinus Asthma clinic who specializes in pediatric and adult asthma, allergy and immunology

MODERATOR: Thanks to all of our panelists for being here today. Let’s begin with Dr. Mark Heyrman:

12:10 – 12:20 pm  Patient Advocate – Dr. Mark Heyrman (10 minutes including Q&A)

MODERATOR: How have health plans’ step therapy protocols affected patients in Illinois, including those that you represent with mental illness?

DR. MARK HEYRMAN: Please provide your perspective on how step therapy impacts mental health patients in Illinois (Suggested talking points below - please add personal thoughts/stories to illustrate your experience with step therapy).

- At least 250,000 people in Illinois live with serious types of mental illness, while another 2 million live with other forms. Under step therapy programs for a patient with mental illness, a person must try one or more prescriptions chosen by their insurer before
coverage is granted for the drug prescribed by that person’s doctor. This policy is based on financial, not medical, reasons. Insurance companies are cutting down on costs, but limiting patients’ ability to get effective medications.

- When a person with a mental illness is not prescribed the proper medications for their condition, it could have traumatic results. When people with serious mental illness visit their doctors, the last thing they should have to worry about is being prescribed a medicine that will not help them and may even make them worse! No one should be required to take medicine that their doctor believes will not work before being allowed to take medicine that will work. Mentally ill individuals across our state are experiencing this exact type of treatment.

- As a lawyer for individuals in state mental hospitals and the community for 35 years, I know how important it is for people to get the correct medicine. Medicines are a necessary treatment for most people with the most serious mental illnesses.

- It is often difficult for doctors to find the right medication for mental health patients, but once they do, it is important to not interrupt the regimen. I have seen many of my clients harmed when their medication was discontinued because their insurance company or other payer stopped paying. This has resulted in hospitalizations, homelessness and much suffering for patients and their families I know and have worked with closely.

- As one of the founding members of the Mental Health Summit, which represents the mental health community across the state, my experience has allowed me to witness firsthand how imperative it is to protect the doctor-patient relationship. We need to make sure clinical judgment of a health care professional is used whenever medications are prescribed or changed. There is a great deal of research that shows when people with serious mental illnesses are denied access to medications, it ends up costing more money because of increased hospitalizations and other bad outcomes.

- We must not waste our health care dollars. But studies have consistently shown that reducing access to psychotropic medications ends up costing more than it saves because it results in more expensive treatment down the road. I’m afraid if people don’t get the proper medications, we will end up with more people losing jobs and in hospitals, homeless shelters and in the criminal justice system.

MODERATOR: Thank you Dr. Heyrman for your insights on how step therapy is affecting the state’s mental health community and patients (Add any appropriate commentary).

12:20 – 12:30 pm Physician #1 – Dr. Stephen Stone (10 minutes- including Q&A)

MODERATOR: Dr. Stone, how have health plans become more aggressive with step therapy?

DR. STEPHEN STONE: Please provide your perspective on how step therapy impacts your patients and practice (Suggested talking points below. Please add personal thoughts/stories to illustrate your experience with step therapy.).
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- Step therapy practices have evolved significantly in the past few years. It used to be a common scenario was a patient having to try and fail on a cheaper generic drug before getting access to certain brand name drugs that may be more expensive. Now what we’re seeing are far more egregious practices in step therapy and in some extreme cases, psoriasis patients, for example, may be required to utilize two therapies with black box warnings before being granted access to a safer, oral therapy.

- In some cases, step therapy can unnecessarily prolong ineffective treatment and prevent patients from immediately starting (or continuing to access) the most effective treatment recommended by their physician. Step therapy can lead to adverse outcomes for patients if duration and effectiveness of required step therapy protocols are not carefully managed. Delays in optimal treatment can add costs to our health care system with return trips back to the hospitals, hospitalizations, and disease progression for patients.

MODERATOR: How does step therapy interfere with the doctor-patient relationship?

- Despite my years of medical training, my prescribing rights and those of my fellow physician colleagues, are being negated, and insurers are dictating what medications are available to patients, with no consideration of an individual’s medical situation or history.

MODERATOR: Thank you Dr. Stone for your insight. Let’s now turn to Dr. Siri, who specializes in pediatric and adult asthma, allergy and immunology

12:30 – 12:40 pm  Physician #2 – Dr. Dareen Siri (10 minutes- including Q&A)

MODERATOR: Dr. Siri, can you tell us a little bit about how step therapy has impacted your practice and the health of your patients?

DR. DAREEN SIRI: Please provide your perspective on how step therapy impacts your patients and practice (Suggested talking points below. Please add personal thoughts/stories to illustrate your experience with step therapy.).
- Insurers are now dictating patient care, which can have an extremely negative impact on their health and well-being.
- Some patients are required to use 3 over the counter medications for their condition before they can receive the medication I prescribe.
- It can also impact them financially--having to purchase various ineffective over the counter medications before getting access to the drug that will work, the drug I prescribe.
- The practice of step therapy has gotten out of control. It’s bad for patients and providers.
ANECTODAL
- Provide examples of patients having to get inferior therapies and it’s impact on the patients health
- Highlight any extreme step therapy cases in allergy/asthma/immunology
MODERATOR: Thank you Dr. Siri for your insight. Let’s hear from Jang Mi Johnson, Senior Physician Assistant at Illinois Dermatology Institute in the Chicago area.

12:40 – 12:50 pm  Physician Assistant – Jang Mi Johnson (10 minutes – including Q&A)

MODERATOR: Jang Mi, as a physician assistant, you see the impacts of step therapy every day. How does step therapy impact a physician and his/her staff?

JANG MI JOHNSON: Please provide your perspective on the administrative burden of step therapy and burden to patients (Suggested talking points - Please add personal thoughts/stories to illustrate your experience with step therapy.)

- Unfortunately, step therapy has made it very difficult for physicians to ensure that patients are getting the right medications to treat their conditions in a timely manner. In many cases, practices have to hire additional staff just to handle the amount of paperwork required with step edits.

MODERATOR: What does office staff have to do to file an exception/appeal - success rates/time/burden?

ANECDOHAL:

- Please provide examples from your practice: number of step therapy cases/patients in your practice, hours required weekly, cost to the practice, etc.

For example: With some plans, we’re required to fill out the step paperwork as well as a PASI grid for each patient to file appeals.

MODERATOR: How can the time spent waiting for approval impact health outcomes?

ANECDOHAL:

- Please provide specific examples from your practice- worsening conditions, long term impact on health, hospitalizations/additional medical issues arising, etc.

MODERATOR: Thank you Jang Mi for your insight. It is apparent there must be protections put in place on step therapy protocols that recognize that medical professionals along with their patients should have the final say about the details of a patient’s treatment plan and what’s best for the patient.

To address the increasing concern of health plan step therapy protocols, some states have already taken action, including recent legislation introduced in Illinois by State Rep. Laura Fine.

Rep. Fine, please provide us with a brief overview of what is happening in the states and in Illinois?
To address the concern that health plans can implement step therapy protocols without demonstrating that patients have safe health outcomes or are in the best interest of the patient, a handful of states have passed laws targeting commercial health plans and their use of step therapy, including Connecticut, Louisiana, Kentucky and Vermont. These states’ regulations establish clear criteria for physician override, limit the duration for a step therapy protocol, increase a patient’s ability to appeal an insurer’s refusal to cover a medication, or prohibit the use of step therapy in certain situations.

Additionally, many more states have introduced legislation to curb step therapy practices this year, including California, New York, North Carolina, Florida, Missouri and Illinois.

This year, I introduced House Bill 3549, which would ensure that step therapy programs in our state are based on clinical guidelines developed by independent experts, guarantee the step therapy exemptions process is transparent and accessible to patients and health care providers and would establish a framework for when it is medically appropriate to exempt patients from step therapy and establishes circumstances for a step therapy override - for instance when a patient has tried the step therapy-required drug and discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event or when a patient is currently stable on a prescription drug.

HB 3549 went as far as passing out of the House Human Services Committee, on which I serve, with a unanimous bipartisan vote, however we ran into significant opposition from the various health plans across the state which stalled our progress.

I, along with my Senate colleague, IL State Senator Julie Morrison, are committed to continuing to fight and bring step therapy legislation back next session. We have a great broad-based coalition across the state, including representatives from the Illinois State Medical Society, Illinois Dermatological Society, the Arthritis Foundation, Mental Health Summit, American Cancer Society, Epilepsy Foundation and many others who are continuing to advocate on this issue.

MODERATOR: Thank you Rep. Fine. For all the advocates watching today, how can we all make a difference in this effort?

If I could recommend, if you have not already, please reach out (by email, phone or letter) to your state legislators about step therapy and ask them to support legislation that will ensure patients have access to the right medication prescribed by their doctor at the right time. They need to hear from advocates across the state – the more they hear from you, the more likely we will be more successful the next time.

Additionally, advocates can help identify patient stories that we can share with policymakers, the media and others who need to hear about our cause. There is nothing
more powerful at our hearings than hearing the personal stories from patients who have faced challenges with step therapy in their treatment.

MODERATOR: Thank you Rep. Fine for bringing this issue to the legislature and being a champion for patients. At this time, I would like to open up the town hall for any questions for our panelists. We only have a few minutes left.

1:00 Final Questions with Moderator & Closing

MODERATOR: Thank you everyone for participating in our virtual Illinois Step Therapy town hall today. A special thank you to our panelists for their insights.

Before we conclude, I want to mention just a few more items. This town hall will be archived online, and for those who would like to learn more or find additional online resources, visit www.prescriptionprocess.com/step therapy.

Thanks again for everyone’s time today and that concludes our IL Step Therapy Town hall.