

Step Therapy: An Obstacle Course to Optimal Health



Slide 1. Title slide

Hello, I'd like to welcome you to this program on **Step Therapy – An Obstacle Course to Optimal Health**.

Slide 2: Support and Sponsorship

We'd like to thank the supporters who supported this program, including Celgene Corporation as well as sponsorships from Pfizer, Takeda Pharmaceuticals USA, and UCB.

Slide 3: Presenter - Sandra Kim, MD

My name is Sandra Kim. I am a pediatric gastroenterologist and co-director of the Pediatric Inflammatory Bowel Disease Program at the Children's Hospital of Pittsburgh of UPMC. In addition, I co-chair government and industry affairs for the Crohn's & Colitis Foundation on the National Scientific Advisory Committee.

Slide 4: Disclosures

And, you can see my conflict of interest disclosures on the slide.

Slide 5: Presenter - David Rubin, MD

And, I'm Dr. David Rubin. I'm a professor of medicine. I'm chief of the Section of Gastroenterology, Hepatology and Nutrition at the University of Chicago. I'm the other co-chair of the Government and Industry Affairs Committee for the National Scientific Advisory Committee of the Crohn's & Colitis Foundation.

Slide 6: Disclosures

And, my disclosures are also displayed.

Slide 7: Agenda

Sandy and I are going to be discussing step therapy and explaining what it is, the impact on the IBD community, the Crohn's & Colitis Foundation's efforts to reform step therapy and address this important issue, and how you can get involved.

Slide 8: What is Step Therapy?

So, thank you, David. So, let's start off and define what step therapy is. So, step therapy is a protocol used by health insurance companies, which requires patients to try and fail at least 1 or more of what they deem lower cost medications before they will provide coverage for the medication originally prescribed by the patient's provider. So, to look at this in a very practical way, if your healthcare provider prescribed you a medication that they feel is the best medication for you, but your insurance company requires you to try something else first, you have been directly impacted by the concept of step therapy. And, one of the difficult things for both patients and healthcare providers alike is that step therapy really second guesses a healthcare provider's decisions and orders by assuming that the insurance company knows much more as to what is best for the patient than the healthcare provider themselves. And, often these protocols have no clear medical justification.

Slide 9: History of Step Therapy

In fact, in the history of step therapy, these have been predominantly used as cost-containment strategies by payers and specifically insurance companies, by requiring that patients and providers work through specific therapies that are, quote, preferred. It really has to do more with the contractual arrangements and costs than it does with the doctor's recommendations, the patient's preferences, or, in many cases, what may be actually recommended or guided in terms of medical management.

There have been some studies that show there's no guarantee that current step-therapy protocols are even based on the most appropriate clinical practices, challenging what we would consider to be medical ethics, as well as potentially medical-legal aspects of all of this.

In fact, in a study comparing spending on schizophrenia medications, step therapy saved \$19.62 per member per month in atypical antipsychotic expenditures, but these savings were accompanied by a \$31.59 per member per month increase in expenditures for outpatient services. In other words, by using step therapy to save in the short run, it was costing other monies in other management strategies that were required after this was performed. We certainly believe the same is happening in inflammatory bowel disease (IBD).

Slide 10: Prevalence of Step Therapy

I'd like to look at the prevalence of step therapy in our current healthcare environment.

So, when you look at this graphic on this slide, it shows you that in 2005, a little bit over a decade ago, just over 25% of all insurance companies utilized step-therapy policies. In 2013, over 67% utilized them.

Slide 11: Prevalence of Step Therapy

So, if we look at this a little bit more in detail, in regard to the prevalence of step therapy, if you look at the left, you can see in 2013 that approximately two-thirds of all commercial insurers used what they called fail-first requirement, to try to control the cost of pharmaceuticals. And, looking at employer plans on the right side in 2010, a little bit over 50% of these employer plans used step-therapy protocols, and by 2013 that number jumped to 75%.

Slide 12: Step Therapy in the IBD Community

The Crohn's & Colitis Foundation has been a leader in addressing and understanding step therapy for IBD patients. In December 2016, a survey conducted by the Foundation of approximately 2600 IBD patients, identified that nearly 40% of those who responded had been a subject to step therapy in getting their prescription medications. Of the respondents who had been subjected to step-therapy protocols, 57% of the patients were required to fail 2 or more drugs before having access to the originally prescribed therapy, 60% were unable to have a doctor intervene to stop the step-therapy process on their behalf, 32% were delayed from their optimal treatment plans for over 7 months, and 94% believed that step therapy was a barrier to timely appropriate care. We certainly know this to be true in our own practices and Sandy and I have both experienced this on behalf of our patients, as have many of our colleagues.

Slide 13: Potential Impact on Patients with IBD


So, let's talk about the potential impact on patients who live with IBD. And, I'm just going to emphasize that step therapy is not patient-centered. It fails to consider the individual needs that each patient who lives with IBD encounters, and it imposes a one-size-fits-all approach to care when that's not the reality of how IBD care should be sort of directed or performed. And so, a couple of things for us to think about include the delayed or lower quality of care that our patients who live with IBD face. And, with this you often get disease progression, adverse reactions or other side effects from medications that were not the primary consideration, or just bad effects from not having disease adequately controlled. And again, as I said, it really does not recognize that you need individualized treatment plans and not a one-size-fits-all approach when you care for patients who live with IBD. And unfortunately, this can lead to some patients not even receiving any medications. There's research that suggests that 1 out of 5 patients often get discouraged through this process and just stop taking medications altogether, rather than switching to a lower-cost treatment, which is not the effective treatments that they need.

And so, as we look at this, and I know that David mentioned this previously, in that short-term approach of insurers approving medications which they feel will be lower cost, it actually increases the overall cost of care, because there is delay in getting patients into remission. And, not only the medical implications, but also the impact on lives of these patients. They lose time, whether it's from work or in the case of the children and teens that I care for, lost time from school. And overall, a lower quality of life, which is not what we want for our patients.

Slide 14: Eitan – Ulcerative Colitis

We can think of many examples and I'm sure that anyone listening to this is aware of either themselves being affected or a friend or family member or if this is one of our physician or professional nurse colleagues, we can think about many of our patients. But allow me to present 1 example that I think is emblematic of the risks of step therapy when it comes between the recommendation by the provider and the patient who needs the treatment.

Eitan was diagnosed with ulcerative colitis (UC) at age 22. He grew up wanting to be an actor and to accomplish his goal he went on to study at NYU. While studying abroad in 2014, this very healthy college senior developed and was diagnosed with ulcerative colitis. The physician started him on steroids and other medications and he was not responding to them and actually required escalation and presented to an emergency department. The physician taking care of him recognized that he had



moderate-to-severely active ulcerative colitis and recommended a biological therapy, which is both indicated and part of the standard guidelines for management of such patients.

Eitan was relieved that his physician had chosen this therapy and that there were good options to try and treat his colitis. However, after a few weeks of back and forth, his insurance company told him they would not pay for the biologics until he tried and failed other medications. This is what is called step therapy. And, in fact, while he was waiting for these other therapies that were not recommended by his physician to be tried and given his condition, he actually progressed and ultimately required surgery for his colitis.

Now of course, when we share anecdotes like this, we can't know that had he received a biologic in a timely fashion he wouldn't have also ended up needing surgery, but I will definitely say that what happened here has happened to many patients. And, having patients fail what are historically used therapies rather than what the current evidence and even guidelines suggest, just because payers would like to save money or have not kept up on the standard of care and practice, is coming between patients and, obviously in this case of Eitan, affected the quality and the outcome of his care.

Slide 15: McCarthy – Crohn's Disease

But, I'd like to tell another story. And, we're going to talk about McCarthy in just a moment, but I'll tell you as a pediatric gastroenterologist who's devoted my life to taking care of infants, young children, teens, and young adults who live with inflammatory bowel diseases like Crohn's disease and ulcerative colitis, the impact of not diagnosing and treating their inflammatory bowel disease has really significant consequences, not just with the gastrointestinal symptoms, but also the impact on the psychosocial functioning, getting to school, growth, and all the other issues that come with it.

So, I'm going to tell you a little bit about McCarthy's struggle and this just strikes me because this is not an unusual story, unfortunately.

So, in 2014 McCarthy was diagnosed with Crohn's disease. It took him over 3 months to get a diagnosis and at the time he was diagnosed, he was 5' 6" and only weighed 63 pounds. He couldn't keep food or water down because of the inflammation and everything that came with having Crohn's disease and, in fact, was admitted to the hospital immediately after he was diagnosed.

His pediatric gastroenterologist prescribed him infliximab, which is a biologic therapy, which would be warranted in this situation, but his insurance company denied coverage and stated that he needed to be treated with corticosteroids first. The physician and the family appealed and were denied twice, even with multiple tries and documentation.

So, after months of suffering from all the side effects that come from being on steroids, including a puffy face, the night sweats, and agitation, which are known side effects of steroids, without any improvement of his Crohn's disease, along with ongoing appeals, his mother Nicole took to social media to talk about McCarthy's symptoms and his diagnosis, and finally the insurance company, after this effort, eventually approved his treatment.

So, thankfully McCarthy had his mother to fight for him. And, because of this, both McCarthy and his family, have continued to advocate for step therapy reform in their state by staying in contact with their legislators and taking part in advocacy efforts in their state's capital. But the reality is, it shouldn't have taken multiple appeals, denials, and finally a family that had to reach out publicly. Families should not have to suffer and work so hard to get the basic therapies that their healthcare provider had deemed necessary.

Slide 16: McCarthy – Before and After

So, on a happier note, I'd like to show a picture of how McCarthy looks now. So, you can see on the left how McCarthy looked before he was diagnosed, so again, he was 5' 6" and only 63 pounds. And finally, on the right side you can see McCarthy after being on the correct medication, which was the original therapy that his gastroenterologist had prescribed. You can see that he is doing much better, he looks healthier, and most importantly, is having a much better quality of life.

Slide 17: Physician Perspective

So, Sandy and I, as co-chairs of government and industry affairs for the Crohn's & Colitis Foundation, have personally experienced these barriers to care among many of our patients. And, we have chosen to become active both in the Foundation, but also in government advocacy, which is part of our role, of course. And, we've learned that by voicing these concerns, by sharing them with others, and by obviously educating our patients and our colleagues about what this is, we can put a name to it, and what our steps can be to address it and to encourage others to speak out, we really believe that we are making some progress. We have seen, through our efforts, changes in some local policies and we have continued to see ongoing discussions about these important topics, both among our patients as well as among our professional colleagues.

David, I have to agree. This is a fight that we have every day. And, we talk about our approaches as healthcare providers and the countless amount of time that we have to spend to show the justification for our medical decision-making. But, it really impacts ultimately our patients. And so, one of the things I've said is that until this can become a much more seamless process, you know, folks like you and I, along with our colleagues on our government affairs committee, will continue to fight for our patients and we will continue to educate both our patients and our colleagues alike, so that we can empower our patients and we can also get the right information to our providers as to how we need to approach getting the necessary approvals.

Slide 18: How do I know if I am impacted?

So, you may be asking how do I know if I'm impacted? Well, start with something simple. Have you been recommended a therapy that after some delay or even when you just went to the pharmacy you found out that you couldn't fill the prescription, or you weren't able to get the treatment that was originally recommended, and after a discussion about risks and benefits with your physician or your advanced practice provider, is not what you agreed upon? Well then, you have been impacted by step therapy.

The medications that we've seen most commonly affected and come up over and over again include the list that you see here. We have both the generic names as well as the brand names, to help clarify for those who are learning about this with us. This includes all of the monoclonal antibody therapies, whether they are specifically those therapies or the sequencing of those therapies after someone loses response or doesn't respond to one of them. It also includes some of the special formulations of gut-selective or gut-specific steroid-based treatments.

It has also affected and been seen in all different types of insurance plans, commercial, employer-sponsored, and even public plans, such as Medicaid and the state employee health plans. This is a pervasive challenge. On the one hand, we certainly understand the need to appreciate cost containment as healthcare costs continue to escalate, but on the other hand, we recognize that the most expensive result in managing patients with IBD is not getting them on the right medicines, it's about what happens to them when they're not on the right medicines.



Slide 19: Foundation's Efforts to Reform Step Therapy

So, the Crohn's & Colitis Foundation is dedicated to working with payers and legislators alike to reform step therapy. So, the Foundation has been advocating for legislation at both the state as well as the federal levels, to provide for patient protection by allowing for exceptions from step-therapy protocols when protocols are determined to be medically inappropriate by the patient's healthcare provider.

So, a couple of ways that they're doing this include proactively advocating for state legislation in multiple states. And in fact, if you look at this map you can see where the states are highlighted, where there's been strong step therapy reform legislation, and you can see where the Foundation will be targeting subsequent efforts in the upcoming year.

The other area that the Foundation has been actively involved in is to support the federal legislative efforts. And so, the state and federal bills are often complementary to each other, the state bills affect state-regulated insurance, usually individual and small group plans, whereas the federal bill affects the Employee Retirement Income Security Act (ERISA) or E-R-I-S-A plans, so these are the employer plans. And so, to make sure that we have everyone protected, we really need to pursue both state and federal legislation and that's what the Crohn's & Colitis Foundation is doing.

And then finally, the Foundation is participating in state, as well as federal coalitions of like-minded stakeholders, including patient and healthcare provider groups, which advocate for step therapy reform.

Slide 20: State-Based Step-Therapy Reform

There have been some state-based step therapy reforms that have been put in place. They increase safety and effectiveness of step-therapy protocols by implementing the following patient protections. The first is called alignment. In other words, it creates a basic framework to ensure that step-therapy protocols are aligned with the existing clinical guidelines. The second is transparency, a standardized, transparent appeal process that patients and their provider can use to override a step-therapy protocol. And, I want to emphasize that regardless of how a private payer chooses to implement coverage, I think that it should be mandated that they are transparent and efficient in the way we have to communicate with them or to appeal decisions. Third, there are exception standards, treatment decisions that are based on a patient's medical history and recognized clinical standards. In other words, if there are specific situations that should be acknowledged by the payers as ways that we can get immediately to the therapy that's being recommended, without having to step through others. Fourth is timeliness, an expedited timeline for determination of certain appeals. I think that this is absolutely necessary. Whether it's true or not, the perception by my colleagues and by me is that many payers intentionally delay trying to wait out the provider or wear us down, so that we finally give in to the therapy they're forcing us to use. And, I think that there should be a mandatory response by them or they should have to cover the therapy we're recommending if they don't respond in a timely way. And lastly, this should apply to state-regulated health insurance plans.

So, there are a variety of different state-based therapy reforms that have to do with the step therapy challenges that we all face, and we're going to continue to push on all these important issues.

Slide 21: Federal Step-Therapy Reform

I'd like to discuss the federal step-therapy reform, also known as the Restoring the Patient's Voice Act. It's a bipartisan bill, introduced by Representatives Brad Wenstrup from Ohio and Raul Ruiz from California. So, like the state bills, this federal act does not eliminate step therapy, but it does provide a clear and transparent process to seek exceptions and approvals for medications that are subject to step therapy review by health insurance plans. In addition, it establishes a reasonable and clear timeframe to override decisions. Like the state bill, in circumstances where the drug is contraindicated, expected to be ineffective, has been tried by the patient or the patient is already stable on the medication, but it was covered under a previous but not current plan, the approval or denial must be completed no later than 3 days after the request. And, in cases where life, health, or ability to regain maximum function is seriously jeopardized, a request must be granted no later than 24 hours after the request. So, if this law is passed, it would apply to health plans across the entire country, governed by ERISA, which is usually the employer plans.

Slide 22: How can I advocate for Step-Therapy Reform

So how can you advocate for step-therapy reform? Well, there's a variety of ways that we'd encourage. Number one, you should make sure you're a Crohn's & Colitis Foundation member because this way you will be part of our efforts, you will show your support, and you'll be tied in to get information in a timely manner from the Foundation.

Secondly, we encourage you to join the Advocacy Network to receive updates and timely action alerts. And, there's a link to that Advocacy Network.


Third, we want you to call, write, and visit your senators and representatives to tell them to support the Restoring the Patient's Voice Act. And, you can find your legislators' contact information and talking points at the other link that is available to you on this slide.

And lastly, we want you to contact your local chapter to share your story and get involved in state campaigns. So, after you finish joining the Crohn's & Colitis Foundation, find out which chapter is closest to you and get involved.

I might throw in just another plug to start following on both Twitter the Crohn's & Colitis Foundation, on Facebook the Crohn's & Colitis Foundation, and there are some of your physician colleagues and other professional members who are available on social media who try to advocate and be outspoken about some of these issues.

Slide 23: What can I do if a bill has already passed in my state?

So, what can you do if a bill has already been passed in your state? And, you can refer back to that previous graphic that we showed of the country and the places where bills have been enacted. So, work with your healthcare provider and apply for an exception through your insurance company. It's really important to keep that open line of communication with your healthcare team throughout this whole process. So, if you apply for an exception and you're denied, your insurer has to provide you with a separate appeals process through an external, independent review organization. And, insurance companies in all states must participate in this external review process that meets consumer protection standards. So, these are in place to protect you, the patient, as determined by federal healthcare law.



And, stay proactive. And, I always say that just as we need healthcare providers who are educated and vocal and willing to fight for their patients, we want you to also stay actively involved. We need patients and families to serve as watchdogs, to really ensure that these laws are being carried out. And, if you find your insurer is not compliant, file a complaint with your state Department of Insurance or the appropriate regulatory agency. I think you really need to do this. We need to ensure that you have the protections that are in place for you.

And, if you need any help through this process, don't hesitate to contact our Crohn's & Colitis Foundation IBD Help Center.

Slide 24: More About Step Therapy

And, in fact, you can visit this link on the Crohn's & Colitis Foundation and step therapy to see what you can do specifically in your state.