

Step Therapy:
An Obstacle Course
to Optimal Health



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National Scientific Advisory Committee

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Disclosures – Sandra Kim, MD

Dr. Kim has no affiliations to disclose.

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Presenter

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Co-Chair, Government and Industry Affairs

National Scientific Advisory Committee

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Disclosures – David Rubin, MD

Consultant: Abbvie Inc., Abgenomics, Allergan, Inc., Amgen, Celgene Corporation, Forward Pharma, Genentech/Roche, Janssen Pharmaceuticals, Merck & Co., Inc., Miraca Life Sciences, Mitsubishi Tanabe Pharma Development America, Inc., Napo Pharmaceuticals, Pfizer, Salix Pharmaceuticals, Inc., Samsung Bioepis, Sandoz Pharmaceuticals, Shire Takeda, Target PharmaSolutions, Inc.

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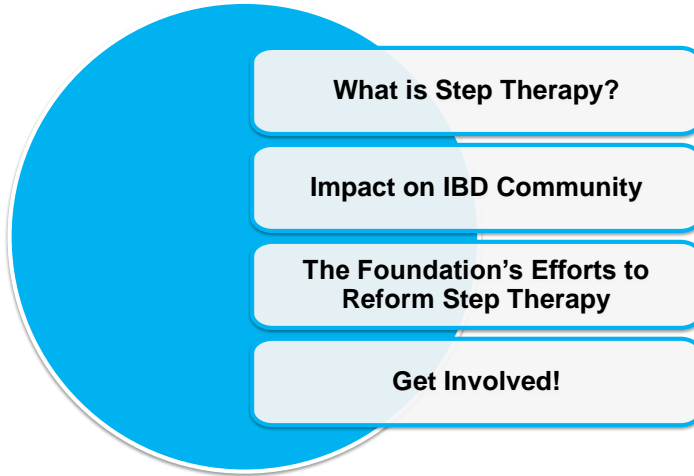
Board of Trustees: American College of Gastroenterology

Co-Founder, CFO: Cornerstones Health, Inc. (non-profit)

Co-Founder: GoDuRn, LLC



Agenda



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What is Step Therapy?

A protocol used by health insurance companies which requires patients to try and fail on one or more lower cost medications before they will provide coverage for the medication originally prescribed by the patient's provider



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History of Step Therapy

- Used as a cost-containment strategy by insurance companies
- These protocols are applied to prescription drugs to treat a wide range of diseases and chronic conditions, including cancers, diabetes, pain, HIV/AIDS, mental health, and, of course, IBD
- However, in some cases, studies have shown that less-effective medications often led to higher overall healthcare costs



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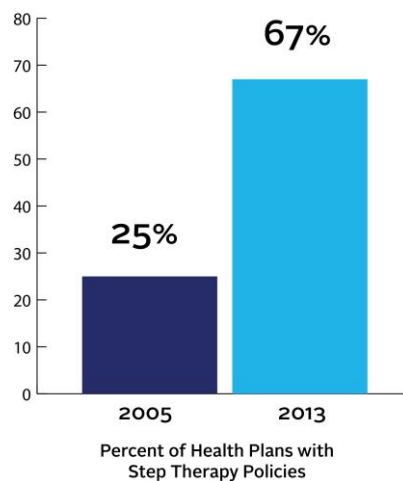
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Prevalence of Step Therapy

The number of health plans that utilize step-therapy protocols continues to rise

“Adoption of step therapy is quickly outpacing the market’s understanding of its clinical, humanistic, and economic outcomes.”

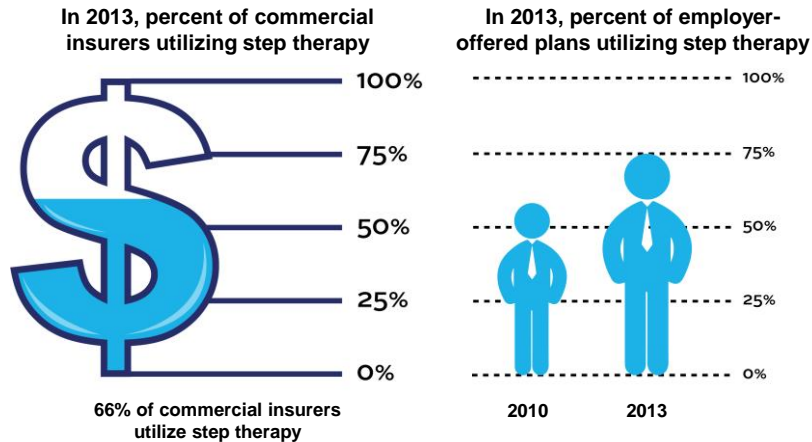
- *Journal of Managed Care Pharmacy*,
March 2011



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Prevalence of Step Therapy



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Image 1: Motheral BR. *J Manag Care Pharm.* 2011;17(2):143-155;

Image 2: Available at: <https://www.managedcaremag.com/archives/2012/9/step-therapy-comeback-continues>. September 2012.

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Step Therapy in the IBD Community

In December 2016, a survey conducted by the Foundation of approximately 2600 patients with IBD, indicated that nearly 40% of respondents had been subject to a step-therapy process for their prescription medications

Of the respondents who have been subject to step-therapy protocols:

- **57%** of patients were required to fail 2 or more drugs before having access to the originally prescribed drug
- **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.
- **94%** believed step therapy to be a barrier to timely and appropriate care

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Potential Impact on Patients with IBD

Delayed or lower quality of care

- Disease progression
- Adverse reactions / other serious side effects
- Does not recognize need for individualized treatment plans for patients with IBD
- Some patients end up receiving no medication at all

Increased overall costs of care

Lost time

Lower quality of life

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Eitan – Ulcerative Colitis

Diagnosed at 22



Originally treated with steroids and other medications



Due to lack of response, he was prescribed a biologic



Insurance required Eitan to try and fail on 2 insurer-preferred drugs before paying for the original provider prescribed biologic



After months of failing, Eitan's condition worsened – leading to multiple surgeries



14 Photo supplied courtesy of the patient.

McCarthy – Crohn’s Disease

Diagnosed at 14

Was 5’6” and weighed 63 lbs at diagnosis and was immediately admitted to the hospital, as he was not holding down any food or water

His physician prescribed him with a biologic, as it was believed to be the best chance at remission

McCarthy’s insurance company denied the biologic, instead, he was treated with steroids

His physician appealed the denial, yet the appeal was also denied

McCarthy’s mother staunchly fought for insurance coverage and finally got coverage after many denials in a long and unclear appeals process

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McCarthy – Before and After



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Photo supplied courtesy of the patient’s parent.

Physician Perspective

- Not based on evidence or guidelines
- Disrupts/delays treatment plans often leading to worsened outcomes
- Makes it difficult for a provider to exercise medical judgement
- Interrupts shared decision making between providers and their patients
- Excessive paperwork and unnecessary red tape take away precious time that physicians and nurses can be spending with patients



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How do I know if I am impacted?

- If you have been required to try a medication other than what was originally prescribed by your provider, you have been impacted by step therapy
- Additionally, if you have gone through the step-therapy process, you may be required to start all over again if you change insurance companies

Examples of medications affected

- Budesonide (Uceris™)
- Ustekinumab (Stelara®)
- Vedolizumab (Entyvio®)
- Infliximab (Remicade®)

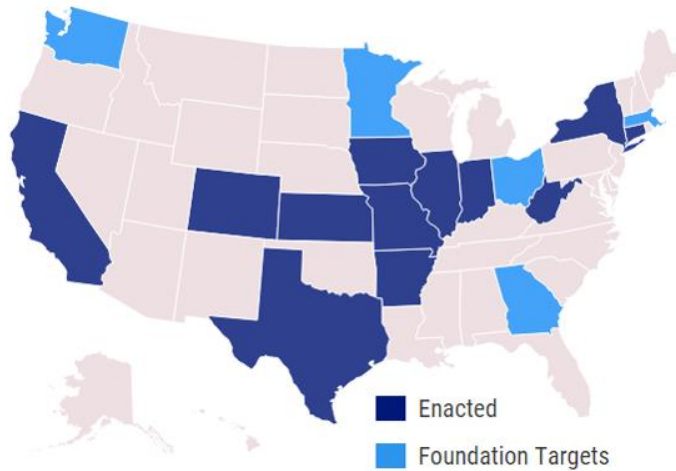
Insurance plans affected

- Commercial
- Employer-sponsored plans
- Public plans (Medicaid, state-employee health plans)

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Foundation's Efforts to Reform Step Therapy



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State-Based Step-Therapy Reform

Increases safety and effectiveness of step-therapy protocols by implementing the following patient protections:

- **Alignment:** Creates a basic framework to ensure that step-therapy protocols are aligned with clinical guidelines
- **Transparency:** A standardized, transparent appeal process that patients and their provider can use to override a step-therapy protocol
- **Exception standards:** Treatment decisions that are based on a patient's medical history and recognized clinical standards
- **Timeliness:** An expedited timeline for determination for certain appeals
- Applies to state-regulated health insurance plans



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Federal Step-Therapy Reform

Title: Restoring the Patient's Voice Act

Bi-partisan support – introduced by:

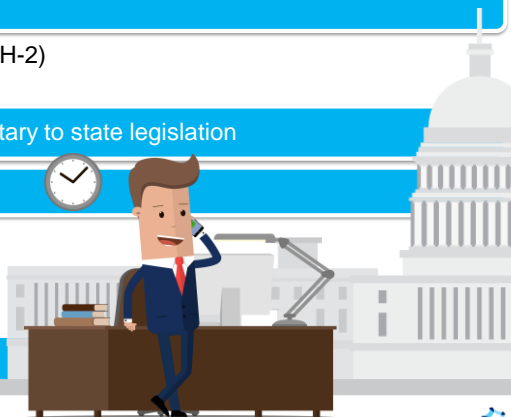
- Rep. Brad Wenstrup, DPM, (R-OH-2)
- Rep. Raul Ruiz, MD, (D-CA-36)

Applies to ERISA plans, complementary to state legislation

Based on the robust state bills:

- Creates an exception process with the 5 criteria
- Requires a 24 to 72 hour response from insurers

First introduced in 2017 as HR 2077



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How can I advocate for Step-Therapy Reform?



Join the Advocacy Network to receive updates and timely action alerts: <http://bit.ly/2ChTIZu>



Call, write, and visit your Senators and Representative to tell them to support the *Restoring the Patient's Voice Act*
Find your legislator's contact information and talking points at: <http://bit.ly/2gRSBlu>



Contact your local chapter to share your story and get involved in state campaigns:
www.crohnscolitisfoundation.org/chapters

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

- ✓ With your provider, apply for an exception through your insurance company
- ✓ Stay proactive! We need patients to serve as watchdogs to ensure that these laws are carried out
- ✓ If your insurer is not compliant, file a complaint with your state's Department of Insurance or the appropriate regulatory agency
- ✓ Contact the IBD Help Center for more guidance through this process
- ✓ Visit www.crohnscolitisfoundation.org/steptherapy to see what you can do in your state

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More About Step Therapy

For more information, visit www.crohnscolitisfoundation.org/steptherapy

Education and Support for Patients with IBD

www.crohnscolitisfoundation.org

IBD Help Center

(888) 694-8872

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