VIRTUAL IBD DAY ON THE HILL

CROHN'S & COLITIS FOUNDATION

Leave Behinds and Bill Texts 2021
Quick Facts about IBD

IBD = Inflammatory Bowel Disease

Two major types
- Crohn's disease (CD)
  - Inflammation anywhere in the gastrointestinal tract
- Ulcerative colitis (UC)
  - Inflammation limited to colon and/or rectum

Statistics
- An estimated 3.1 million Americans affected
- 70,000 new IBD cases per year
- Often diagnosed between ages 15–35

Disease Info
- Common symptoms are diarrhea, weight loss, feeling tired, and abdominal cramps and pain
- IBD can have an effect on areas outside of your digestive tract, such as eyes, skin, bones, and kidneys.
- IBD can also have an impact on mental and emotional well-being.

Diet and Nutrition
- Maintain a healthy diet:
  - www.MyPlate.gov
- Keep a food journal
- Stay hydrated
- Get enough calcium
- Consult with a dietician and your healthcare team to make sure you are getting all the nutrients your body needs.

Treatment Options
- Prescription medication (Rx)
- Over-the-counter (OTC) medication
- Surgery
- Nutritional support therapy
- Remember to take medication even when you don’t feel like it or you feel okay.

Coping Options
- Join a support group:
  - www.crohnscolitisfoundation.org/find-a-support-group
- Relax and de-stress with coping strategies, such as:
  - Yoga
  - Tai chi
  - Meditation
- Find other ways to stay connected with the IBD community and support programs
- Attend Camp Oasis:
  - www.crohnscolitisfoundation.org/get-involved/camp-oasis

Things You Can Do
- Regular exercise
  - At least 1 hour each day
- Get enough sleep, 7–9 hours each night
- Ask for school and workplace accommodations
- Be informed and educated to stay healthy and make decisions with your doctor about managing your disease
- Participate in research, and visit our Clinical Trials Community:
  - www.crohnscolitisfoundation.org/clinical-trials-community

Use Our Tools and Resources
- Download free brochures online.crohnscolitisfoundation.org/brochures
- Join a support group:
  - www.crohnscolitisfoundation.org/find-a-support-group
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  - Yoga
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For More Information:
www.crohnscolitisfoundation.org
888.694.8872
info@crohnscolitisfoundation.org
S. 464/H.R. 2163, SAFE STEP ACT OF 2021

Senator Murkowski (R-AK), Senator Hassan (D-NH), Senator Cassidy (R-LA), Senator Rosen (D-NV)
Representative Ruiz (D-CA-36), Representative Wenstrup (R-OH-2), Representative McBath (D-GA-6),
Representative Miller-Meeks (R-IA-2)

**Purpose:** Improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them.

**Background:** Step therapy is a tool used by health plans to control spending on patient’s medications. While step therapy can be an important tool to contain the costs of prescription drugs, in some circumstances, it has negative impacts on patients, including delayed access to the most effective treatment, severe side effects, and irreversible disease progression. Currently, when a physician prescribes a particular drug treatment for a patient, the patient’s insurance company may require them to try different medications and treatments before they can access the drug originally prescribed by their physician. This protocol is known as “step therapy” or “fail first.” Step therapy protocols may ignore a patient’s unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have dangerous side effects.

**The Safe Step Act of 2021:** The Safe Step Act amends the Employee Retirement Income Security Act (ERISA) to require a group health plan provide an exception process for any medication step therapy protocol. The bill:

- **Establishes a clear exemption process:** The Safe Step Act requires insurers implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.

- **Outlines 5 exceptions to fail first protocols.** Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
  1. **Patient already tried and failed on the required drug.** A patient has already tried the medicine and failed before.
  2. **Delayed treatment will cause irreversible consequences.** The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.
  3. **Required drug will cause harm to the patient.** The treatment is contraindicated or has caused/is likely to cause an adverse reaction.
  4. **Required drug will prevent a patient from working or fulfilling Activities of Daily Living.** The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).
  5. **Patient is stable on their current medication.** The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.

- **Requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.**
1. **Patient already tried and failed on the required drug.** Michael was eight years old when his parents noticed his foot turning in when he walked, prompting a series of doctor’s appointments. Following numerous misdiagnoses, Michael was finally diagnosed with Psoriatic Arthritis at the age of 12. The search to find an effective treatment for Michael’s disease proved to be a long, frustrating process. In Michael’s case, the first two drugs failed, and the “fail first” process he endured took nearly ten months during which he received no treatment. The first drug he tried did nothing to abate his pain; the second caused him to develop lupus-like symptoms, resulting in more appointments and tests. The insurance company then wanted Michael to try another remedy that was the same type he had already failed twice before covering his physician’s recommended medication. Finally, Michael’s doctor was able to get coverage approved for the medication he had initially prescribed. Despite the eventual success, this period of over a year without treatment caused Michael’s disease to progress rapidly, resulting in Michael developing an additional chronic illness.

2. **Delayed treatment will cause severe or irreversible consequences.** Jake, from Alaska, was diagnosed with Crohn’s disease as a young child. A year later, he experienced a severe flare and the doctors insisted he immediately be put on an anti-TNF biologic. Jake was a primary non-responder to the anti-TNF, which meant that he would not respond to any anti-TNF. His doctors then tried to put him on an alternative biologic, however, his insurance company required him to prove failure on an additional anti-TNF biologic even though it was against the clinical evidence and guidelines. This process delayed Jake’s access to appropriate treatment for several weeks. By the time Jake was granted coverage for the new biologic, his disease had progressed so much that the treatment was not as effective as it would have been if prescribed earlier. As a result, Jake lost his colon. Jake turned 13 this year.

3. **Required drug will cause harm to the patient.** Jenn, from California, was diagnosed with psoriasis and psoriatic arthritis, her doctor prescribed a treatment that would ease her arthritis pain and slow down joint degeneration. Unfortunately, Jenn’s doctor-prescribed treatment was denied by the insurance company and required her to take an alternate medication, which would have led to life-threatening side-effects on the patient’s liver. After three months of back-and-forth between the provider, patient, and the insurance company, and explaining that the insurance preferred medication would result in a “death sentence” – Jenn was asked to try a third medication which exacerbated her condition. Finally after nearly a year, Jenn was approved for her original doctor-prescribed treatment and began seeing improvements within three weeks.

4. **Required drug will prevent a patient from working.** Elliot, nicknamed Duffy, from Alaska, is an epilepsy patient and works as a ski instructor and heavy machine operator. The first medication he tried controlled his seizures, however the side-effects made him feel like he was inebriated and dizzy, making it unsafe and even dangerous to perform the tasks necessary for his jobs. Despite his inability to work on the treatment, his insurer would not cover alternative treatments, and he was faced with the option of losing his job or paying out of pocket for a different treatment, which would cost him $700 a month. Duffy opted to pay for the new treatment with no coverage. The new medication controlled his seizures with less side effects so that he could perform his occupational duties.

5. **Patient is stable on their current medication.** Katie, a psoriatic arthritis patient, has been stable on her treatment for years. Her treatment was covered by her employer’s private insurance until, in the middle of the plan year, her insurer sent her a letter stating that her current treatment would no longer be covered until she went through step therapy protocols. Within four weeks, Katie, who had been an active adult, was back in a wheelchair. Her step therapy journey lasted for ten months, leading to 14 surgeries, countless doctors’ visits, missed time from work, and ultimately health care costs that far exceeded the price of her treatment.
This bill has been endorsed by 85 organizations:

Aimed Alliance
Allergy & Asthma Network
Alliance for Patient Access
American Academy of Dermatology Association
American Academy of Neurology
American Autoimmune Related Diseases Association
American Cancer Society Cancer Action Network
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Heart Association
American Liver Foundation
American Partnership for Eosinophilic Disorders
Arthritis Foundation
Association for Clinical Oncology
Association of Gastrointestinal Motility Disorders (AGMD)
Asthma and Allergy Foundation of America
Beyond Celiac
Cancer Support Community
Caregiver Action Network
Celiac Disease Foundation
Child Neurology Foundation
Color of Crohn’s & Chronic Illness
Crazy Creole Mommy Life
Crohn’s & Colitis Foundation
CURE Epilepsy
CURED Nfp
Danny Did Foundation
Depression and Bipolar Support Alliance
Digestive Disease National Coalition
Dup15q Alliance
Dystonia Advocacy Network
Dystonia Medical Research Foundation
Epilepsy Foundation
Fabry Support & Information Group
Gastroparesis: Fighting for Change
GBS (CIDP) Foundation International
Global Healthy Living Foundation
Global Liver Institute
Hawai’i Parkinson Association
Hemophilia Federation of America
Hope Charities
IBDMoms
Infusion Access Foundation (IAF)
International Essential Tremor Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Foundation for Gastrointestinal Disorders (IFFGD)
International Myeloma Foundation
Lupus and Allied Diseases Association, Inc.
Mental Health America
METAvivor
Metro Maryland Ostomy Association
Movement Disorders Policy Coalition
Multiple Sclerosis Association of America
National Alliance on Mental Illness
National Alopecia Areata Foundation
National Ataxia Foundation
National Eczema Association
National Infusion Center Association (NICA)
National Organization for Rare Disorders
National Organization for Tardive Dyskinesia
National Pancreas Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
Patient Services, Inc.
Pennsylvania Society of Gastroenterology
Project Sleep
Pulmonary Hypertension Association
Scleroderma Foundation
Society of Gastroenterology Nurses and Associates, Inc.
Spondylitis Association of America
Susan G. Komen
The American Liver Foundation
The American Society for Parenteral and Enteral Nutrition
The Life Raft Group
The Michael J. Fox Foundation for Parkinson’s Research
The National Council for Behavioral Health
The Sturge-Weber Foundation
Tourette Association of America
Tuberous Sclerosis Alliance
U.S. Hereditary Angioedema Association
U.S. Pain Foundation
United for Charitable Assistance
United Ostomy Associations of America
VHL Alliance
The Medical Nutrition Equity Act

Co-Sponsor the Medical Nutrition Equity Act

The Crohn's & Colitis Foundation urges members of Congress to co-sponsor the Medical Nutrition Equity Act. This bill would ensure that public and private insurance covers medically necessary foods for inherited metabolic disorders and digestive diseases, including Crohn's disease and ulcerative colitis (inflammatory bowel disease or IBD).

What are medically necessary foods?
The legislation defines medically necessary foods as:

- Recommended for use by a physician
- Specially formulated for partial or exclusive feeding of an individual
- Intended to meet medically determined nutrient requirements
- Intended for use under medical supervision

How are medically necessary foods used to manage IBD?

Patients with IBD can turn to medically necessary foods to for nutritional support and to help them achieve remission.

For pediatric patients:

- The standard of care for inducing remission internationally in children with mild to moderate Crohn's disease is with orally or enterally administered formula.¹
- Using enteral formula may reduce the frequency of use of higher cost medications.²
- A diet consisting partially of formula may prolong remission without increasing the dosage of expensive therapies.
- Exclusive enteral nutrition (EEN) as a means to induce remission is safer, improves growth, and encourages healing in children over steroid therapy.³,⁴

Parenteral and Enteral Nutrition

- **Parenteral Nutrition**: Feeding intravenously, bypassing the usual process of eating and digestion.
- **Enteral Nutrition**: Liquid supplemental nutrition is either taken by mouth or is given via a feeding tube.

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What are the costs of medically necessary foods, and coverage landscape?

- Medically necessary foods can range from $10–$60 per day.
- Medically necessary foods are not typically covered by insurance unless they are delivered via a feeding tube—which is often unnecessary for IBD patients.
- Families that can’t pay for medically necessary foods out of pocket may turn to more expensive medications that are covered by insurance but may have more side effects, such as steroids or biologics.

Co-sponsor the Medical Nutrition Equity Act

This bill provides for coverage of medically necessary foods under Medicaid, CHIP, Medicare, FEHBP, and private insurance if prescribed by a patient’s provider for patients with inherited metabolic disorders, as well as digestive diseases like Crohn’s disease and ulcerative colitis.

Contact: Sarah Buchanan, Director of Advocacy at sbuchanan@crohnscolitisfoundation.org
The Crohn's and Colitis Caucus is a bipartisan group of members of Congress dedicated to educating their colleagues and the American public on Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel diseases (IBD). The Caucus works together to raise awareness, support IBD medical research, and protect patient access to care.

**Congressional Crohn’s and Colitis Caucus Members**

**Chairs: Representatives Carolyn Maloney (D-NY) and John Rutherford (R-FL)**

| Donald Beyer (D-VA) | Zoe Lofgren (D-CA) |
| Sanford Bishop (D-GA) | Barry Loudermilk (R-GA) |
| Julia Brownley (D-CA) | Carolyn Maloney (D-NY) |
| Michael Burgess (R-TX) | Sean Patrick Maloney (D-NY) |
| Cheri Bustos (D-IL) | James McGovern (D-MA) |
| David Cicilline (D-RI) | Eleanor Holmes Norton (D-DC) |
| Emanuel Cleaver (D-MO) | Donald Payne (D-NJ) |
| Steve Cohen (D-TN) | Mark Pocan (D-WI) |
| Gerald Connolly (D-VA) | Bill Posey (R-FL) |
| Rodney Davis (R-IL) | David Price (D-NC) |
| Peter DeFazio (D-OR) | Jamie Raskin (D-MD) |
| Suzan Delbene (D-WA) | Lucille Roybal-Allard (D-CA) |
| Mario Diaz-Balart (R-FL) | C.A. "Dutch" Ruppersberger (D-MD) |
| Mike Doyle (D-PA) | John Rutherford (R-FL) |
| Anna Eshoo (D-CA) | Tim Ryan (D-OH) |
| Ruben Gallego (D-AZ) | Janice Schakowsky (D-IL) |
| Garrett Graves (R-LA) | Adam Schiff (D-CA) |
| Alcee Hastings (D-FL) | Adam Smith (D-WA) |
| Hank Johnson (D-GA) | Lloyd Smucker (R-PA) |
| David Joyce (R-OH) | Jackie Speier (D-CA) |
| William Keating (D-MA) | Mike Thompson (D-CA) |
| Mike Kelly (R-PA) | Dana Titus (D-NY) |
| Derek Kilmer (D-WA) | Paul Tonko (D-NY) |
| Ann Kuster (D-NH) | Debbie Wasserman Schultz (D-FL) |
| Jim Langevin (D-RI) | Susan Wild (D-PA) |
| Andy Levin (D-MI) | Joe Wilson (R-SC) |

To join the Caucus, or if you have any questions, please reach out to Lizzie Messer in Rep. Rutherford's office at Lizzie.Messer@mail.house.gov or Danielle Sumner in Rep. Maloney's office at Danielle.Sumner@mail.house.gov
To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

IN THE SENATE OF THE UNITED STATES

February 25, 2021

Ms. Murkowski (for herself, Ms. Hassan, Mr. Cassidy, Ms. Rosen, Mrs. Hyde-Smith, Mrs. Gillibrand, Ms. Sinema, Mrs. Capito, Ms. Hirono, Mr. Tillis, Mrs. Shaheen, Mr. Cramer, Mr. Merkley, and Mr. Blumenthal) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions.

A BILL

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

1. Be it enacted by the Senate and House of Representa-
2. tives of the United States of America in Congress assembled,
3. SECTION 1. SHORT TITLE.
4. This Act may be cited as the “Safe Step Act”.

S. 464
SEC. 2. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

(a) IN GENERAL.—The Employee Retirement Income Security Act of 1974 is amended by inserting after section 713 of such Act (29 U.S.C. 1185b) the following new section:

"SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

"(a) IN GENERAL.—In the case of a group health plan or health insurance coverage offered in connection with such a plan that provides coverage of a prescription drug pursuant to a medication step therapy protocol, the plan or coverage shall—

"(1) implement a clear and transparent process for a participant or beneficiary (or the prescribing health care provider on behalf of the participant or beneficiary) to request an exception to such medication step therapy protocol, pursuant to subsection (b); and

"(2) where the participant or beneficiary or prescribing health care provider’s request for an exception to the medication step therapy protocols satisfies the criteria and requirements of subsection (b), cover the requested drug in accordance with the terms established by the health plan or coverage for patient cost-sharing rates or amounts at the time of
the participant’s or beneficiary’s enrollment in the health plan or health insurance coverage.

“(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—

The circumstances requiring an exception to a medication step therapy protocol, pursuant to a request under subsection (a), are any of the following:

“(1) Any treatments otherwise required under the protocol, or treatments in the same pharmacological class or having the same mechanism of action, have been ineffective in the treatment of the disease or condition of the participant or beneficiary, when prescribed consistent with clinical indications, clinical guidelines, or other peer-reviewed evidence.

“(2) Delay of effective treatment would lead to severe or irreversible consequences, and the treatment otherwise required under the protocol is reasonably expected to be ineffective based upon the documented physical or mental characteristics of the participant or beneficiary and the known characteristics of such treatment.

“(3) Any treatments otherwise required under the protocol are contraindicated for the participant or beneficiary or have caused, or are likely to cause, based on clinical, peer-reviewed evidence, an adverse
reaction or other physical harm to the participant or
beneficiary.

“(4) Any treatment otherwise required under
the protocol has prevented, will prevent, or is likely
to prevent a participant or beneficiary from achieving or maintaining reasonable and safe functional
ability in performing occupational responsibilities or
activities of daily living (as defined in section
441.505 of title 42, Code of Federal Regulations (or
successor regulations)).

“(5) The participant or beneficiary is stable for
his or her disease or condition on the prescription
drug or drugs selected by the prescribing health care
provider and has previously received approval for
coverage of the relevant drug or drugs for the dis-
ease or condition by any group health plan or health
insurance issuer.

“(6) Other circumstances, as determined by the
Secretary.

“(e) REQUIREMENT OF A CLEAR PROCESS.—

“(1) IN GENERAL.—The process required by
subsection (a)—

“(A) shall provide the prescribing health
care provider or beneficiary or designated third-
party advocate an opportunity to present such
provider's clinical rationale and relevant medical information for the group health plan or health insurance issuer to evaluate such request for exception;

“(B) shall clearly set forth all required information and the specific criteria that will be used to determine whether an exception is warranted, which may require disclosure of—

“(i) the medical history or other health records of the participant or beneficiary demonstrating that the participant or beneficiary seeking an exception—

“(I) has tried other drugs included in the drug therapy class without success; or

“(II) has taken the requested drug for a clinically appropriate amount of time to establish stability, in relation to the condition being treated and prescription guidelines given by the prescribing physician; or

“(ii) other clinical information that may be relevant to conducting the exception review;
“(C) may not require the submission of any information or supporting documentation beyond what is strictly necessary to determine whether any of the circumstances listed in subsection (b) exists; and

“(D) shall clearly outline conditions under which an exception request warrants expedited resolution from the group health plan or health insurance issuer, pursuant to subsection (d)(2).

“(2) AVAILABILITY OF PROCESS INFORMATION.—The group health plan or health insurance issuer shall make information regarding the process required under subsection (a) readily available on the internet website of the group health plan or health insurance issuer. Such information shall include—

“(A) the requirements for requesting an exception to a medication step therapy protocol pursuant to this section; and

“(B) any forms, supporting information, and contact information, as appropriate.

“(d) TIMING FOR DETERMINATION OF EXCEPTION.—The process required under subsection (a)(1) shall provide for the disposition of requests received under such paragraph in accordance with the following:
“(1) Subject to paragraph (2), not later than 72 hours after receiving an initial exception request, the plan or issuer shall respond to the requesting prescriber with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met. The plan or issuer shall respond to the requesting provider with a determination of exception eligibility no later than 72 hours after receipt of the additional required information.

“(2) In the case of a request under circumstances in which the applicable medication step therapy protocol may seriously jeopardize the life or health of the participant or beneficiary, the plan or issuer shall conduct a review of the request and respond to the requesting prescriber with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met, in accordance with the following:

“(A) If the plan or issuer can make a determination of exception eligibility without additional information, such determination shall be
made on an expedited basis, and no later than
24 hours after receipt of such request.

“(B) If the plan or issuer requires addi-
tional information before making a determi-
nation of exception eligibility, the plan or issuer
shall respond to the requesting provider with a
request for such information within 24 hours of
the request for a determination, and shall re-
spond with a determination of exception eligi-
bility as quickly as the condition or disease re-
quires, and no later than 24 hours after receipt
of the additional required information.

“(e) Medication Step Therapy Protocol.—In
this section, the term ‘medication step therapy protocol’
means a drug therapy utilization management protocol or
program under which a group health plan or health insur-
ance issuer offering group health insurance coverage of
prescription drugs requires a participant or beneficiary to
try an alternative preferred, prescription drug or drugs be-
fore the plan or health insurance issuer approves coverage
for the non-preferred drug therapy prescribed.

“(f) Clarification.—This section shall apply with
respect to any group health plan or health insurance cov-
erage offered in connection with such a plan that provides
coverage of a prescription drug pursuant to a policy that
meets the definition of the term ‘medication step therapy protocol’ in subsection (e), regardless of whether such policy is described by such group health plan or health insurance coverage as a step therapy protocol.”.

(b) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 713 the following new items:

“Sec. 713A. Required exceptions process for medication step therapy protocols.”.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) applies with respect to plan years beginning with the first plan year that begins at least 6 months after the date of the enactment of this Act.

(2) REGULATIONS.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Labor shall issue final regulations, through notice and comment rulemaking, to implement the provisions of section 713A of the Employee Retirement Income Security Act of 1974, as added by subsection (a).