

Safe Step Coalition RFI Comments to Healthy Futures Treatment Access Workgroup

#1 RFI Question: Goal 1: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid. e) Republicans laid out a plan for drug pricing with H.R. 19 Lower Costs, More Cures Act of 2021. This includes over 30 bipartisan provisions to lower drug costs for seniors. Building off of this, what other policies should we consider to lower costs while maintaining access to lifesaving cures?

OUR RESPONSE: Both Congress and the Administration have expressed interest in addressing prescription drug costs and other policies that limit patients' access to the medications they need to treat their chronic conditions. Insurer utilization management policies that limit patient access to treatment should also be addressed. Including step therapy protections for patients in future legislation will help ensure patients have timely access to the most medically appropriate treatment.

We urge Congress to include the following step therapy protections for ERISA health plans in future legislation:

1. Establish a clear exemption process for patients and providers to request an exception to a step therapy protocol
2. Outline five exceptions to fail first protocols:
 - a. Patients already tried and failed on the required drug
 - b. Delayed treatment to the initially prescribed drug would lead to severe or irreversible consequences
 - c. The required drug is contraindicated or has caused/is likely to cause an adverse reaction
 - d. The required drug will prevent a patient from working or fulfilling activities of daily living
 - e. Patient is stable on their current medication
3. Require a group health plan to respond to an exemption request within 72 hours in all circumstances, and 24 hours if the step therapy medication protocol may seriously jeopardize the patient's life or health.

These protections are clearly articulated in pending bipartisan and bicameral legislation, known as the Safe Step Act (H.R. 2163/S. 464), first introduced in 2017. Currently, over 30 states have passed patient friendly step therapy protections. These state laws apply to state regulated insurance plans such as the individual marketplace. We are asking Congress to enact these protections for federally regulated ERISA health plans, ensuring all patients, regardless of who regulates their health plan, have access to the right treatment at the right time.

In addition, curbing utilization management could reduce costs to the health system and for patients. A recent Health Affairs study estimated that utilization management, including step therapy, was associated with \$93.3 billion in costs annually (Howell). The article concludes that "All stakeholders in the US pharmaceutical system would benefit from a de-escalation of utilization management, combining lower drug prices with lower barriers to patient access."

Source: Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Scott Howell, Perry T. Yin, and James C. Robinson. Health Affairs 2021 40:8, 1206-1214.

#2 RFI Question: Goal 2: Encourage innovation and make the Medicare system more flexible to be able absorb new innovative drugs, devices, diagnostics while being good stewards of taxpayer dollars. a) What barriers to innovation in the drug, device, or diagnostic space should Congress address?

OUR RESPONSE: Insurance-mandated step therapy as a general practice impedes access to innovative therapies. An analysis of interviews, surveys, and claims data found the following:

- “89% of physicians and 78% of pharmacists believe that step-therapy requirements prevent patients with autoimmune diseases from receiving the most innovative prescription therapies.
- 87% of physicians and 56% of pharmacists surveyed also said that the UM methods prevent patients from receiving the treatments that could help them most” (Snow).

In addition, while utilization management like step therapy defines access for patients, it does not keep pace with clinical guidelines. Researchers at Tufts Medical Center recently found that step therapy was applied to 38.9% of drug coverage decisions, and more than half (55.6%) of those decisions required more steps than the clinical guidelines for diseases like multiple sclerosis, psoriasis, psoriatic arthritis, or chronic migraines (Lenahan).

Source: J. Snow MPH, et al. The Impact of Step Therapy Policies on Patients. XCenda, https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pdf?la=en&hash=A7BB3FA4DAC189D9240CF8B724B435A8942E91DF

Source: Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans. Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, and James D. Chambers. Health Affairs 2021 40:11, 1749-1757

#3 RFI Question: Miscellaneous. b) Is there anything else the Treatments Subcommittee should consider?

OUR RESPONSE: Thank you for the opportunity to provide input to the Healthy Future Task Force’s Treatment Access Workgroup. On behalf of the undersigned 84 patient and provider advocacy groups, we urge you to consider policies that support increased access to high-quality, affordable, comprehensive health care and patient protections from barriers as part of your upcoming plans. Specifically, we ask that the Task Force include guardrails on the use of insurance-mandated step therapy protocols in ERISA health plans.

As you know, step therapy is a protocol used by health insurance companies that requires patients to try and prove failure on one or more insurer-preferred medication treatments before the insurer will provide coverage for medication initially prescribed and agreed upon by the patient and their provider. Step therapy is widely used by health plans, and protocols vary greatly from plan to plan, even for the same disease or condition. Such protocols also frequently lead to delayed access to care and can result in devastating health outcomes to the patient, including many stories from our patients who have undergone preventable and irreversible surgeries, led to severe flare-ups, or even dying.

While a drug or therapy might be generally considered appropriate for a condition, individual patient issues--the presence of comorbidities, potential drug-drug interactions, or patient intolerances may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements often fail to recognize such considerations, resulting in delays in getting patients the right

treatment at the right time. A patient's health care provider is in the best position to assess their patients' medical needs.

Step therapy policies also interfere with the patient – physician relationship, often resulting in delayed treatment, increased disease activity, disability, and in some cases irreversible disease progression. Step therapy requirements can also be administratively burdensome on clinicians and staff as they help patients navigate complicated coverage determination processes. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them onerous for busy physician practices and patients awaiting treatment.

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As patient and physician advocacy organizations representing millions of beneficiaries and their health care providers, we are keenly aware of the challenges that can arise from poorly structured and implemented step therapy protocols. If you would like to discuss this important policy further or if you have any questions, please contact Alisa Vidulich, Policy Director at the Arthritis Foundation, at avidulich@arthritis.org. Thank you for your consideration of this critical patient access concern.

Sincerely,

1. ADAP Advocacy Association
2. Aimed Alliance
3. Allergy & Asthma Network
4. Alliance for Patient Access
5. Alpha-1 Foundation
6. American Academy of Dermatology Association
7. American Academy of Neurology
8. American College of Gastroenterology
9. American College of Rheumatology
10. American Gastroenterological Association
11. American Partnership for Eosinophilic Disorders
12. American Society for Gastrointestinal Endoscopy
13. American Society for Parenteral and Enteral Nutrition (ASPEN)
14. Arthritis Foundation
15. Association of Community Cancer Centers (ACCC)
16. Association of Gastrointestinal Motility Disorders (AGMD)
17. Association of Women in Rheumatology (AWIR)
18. Asthma and Allergy Foundation of America
19. Beyond Celiac
20. Cancer Support Community
21. Caregiver Action Network
22. Crohn's & Colitis Foundation
23. Chronic Disease Coalition

24. Coalition of Hematology Oncology Practices
25. Coalition of Skin Diseases
26. Coalition of State Rheumatology Organizations
27. Community Access National Network (CANN)
28. Community Liver Alliance
29. Connecting to Cure Crohn's and Colitis
30. Cure SMA
31. Derma Care Access Network
32. Digestive Disease National Coalition
33. Epilepsy Alliance America
34. Epilepsy Foundation
35. Epilepsy Services of New Jersey
36. Exon 20 Group
37. Florida Society of Rheumatology (FSR)
38. Gastroparesis: Fighting for Change
39. GBS|CIDP Foundation International
40. Gilda's Club South Florida
41. Global Healthy Living Foundation
42. Global Liver Institute
43. Hawai'i Parkinson Association
44. HealthyWomen
45. Hemophilia Federation of America
46. Hereditary Angioedema Association
47. IBDMoms
48. ICAN, International Cancer Advocacy Network
49. IFFGD
50. International Foundation for Gastrointestinal Disorders
51. International Pain Foundation
52. Large Urology Group Practice Association (LUGPA)
53. Louisiana Hemophilia Foundation
54. Lupus and Allied Diseases Association, Inc.
55. Metro Maryland Ostomy Association, Inc.
56. Multiple Sclerosis Association of America
57. Multiple Sclerosis Foundation
58. National Ataxia Foundation
59. National Council for Mental Wellbeing
60. National Eczema Association
61. National Hemophilia Foundation
62. National Organization for Rare Disorders
63. National Psoriasis Foundation
64. Nevada Chronic Care Collaborative
65. NORM
66. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
67. Ohio Association of Rheumatology
68. PlusInc
69. Prostate Conditions Education Council
70. Pulmonary Hypertension Association
71. Rheumatology Alliance of Louisiana

72. Spondylitis Association of America
73. Society of Dermatology Physician Assistants
74. Society of Gastroenterology Nurses and Associates, Inc.
75. Tennessee Rheumatology Society
76. Texas Rheumatology Care
77. The Mended Hearts, Inc
78. The Michael J. Fox Foundation for Parkinson's Research
79. The Sturge-Weber Foundation
80. Transplant Recipients International Organization (TRIO)
81. TSC Alliance
82. United Ostomy Associations of America
83. US Pain Foundation
84. VHL Alliance