July 24, 2020

Assemblywoman Lesley E. Cohen, Chair
Legislative Committee on Health Care
Nevada Legislature
Carson City, NV

RE: Legislative Committee on Health Care – Step Therapy

Dear Chairwoman Lesley E. Cohen:

The undersigned organizations thank you for the opportunity express the importance of access to care and difficulties patients face due to barriers from pharmacy benefit practices involving utilization management. Utilization management is a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy or efficiency of health care services, procedures or settings. Utilization management protocols include prior authorization and step therapy. We represent thousands of patients and consumers across Nevada who face serious, acute, and chronic health conditions. Below please find details about the problems experienced by patients and providers due to just one utilization management practice, step therapy. A solution put forward by our organizations highlights through legislative action the health insurers this will affect, costs associated with current step therapy protocols, and the urgency required for reforms, especially now due to added strains from the ongoing COVID-19 public health emergency.

Problem/Introduction to Step Therapy

Step therapy, or "fail first", is a practice used by insurers that requires patients to try lower-cost medications before allowing more expensive treatments, despite a physician's recommendation. As a result, drugs that are effective and more expensive can only be prescribed if the cheaper drugs prove ineffective. Under step therapy, even though a doctor recommends drug A to treat a patient's individual medical need, an insurer may require the patient to first try drugs B, C, D, and so on. Only after these drugs are shown to be ineffective can the patient receive the medicine the doctor prescribed. Under this practice, if a person changes their health insurance, or a drug they are currently taking is moved to a non-preferred status during a coverage year, the person may be put through the step therapy process again. This process forces patients to "fail-first" on alternative medications before they are permitted to obtain the medication deemed appropriate, and likely most effective, by the prescribing provider.

Importantly, step therapy is applied to prescription drugs used to treat a range of life-threatening diseases and chronic conditions, including arthritis, cancer, diabetes, HIV/AIDS, autoimmune conditions, multiple sclerosis, and mental health conditions. An analysis of 12 medications used to treat plaque psoriasis, Crohn's disease, and Colitis found that between 2015 and 2016, the use of utilization management practices on these medications in employer plans increased from 18% to 60%. This is a 42% increase.[1] In

[1] Avalere. PlanScape Review of Formulary Coverage of Selected Treatments, 2015-2017. March 2018

2010, almost 60% of commercial insurers were utilizing step therapy nationally and, in 2013, 75% of large employers reported offering employees plans that utilize step therapy.[2]

A survey of over 1,400 patients done by the Arthritis Foundation in 2016 found that over 50% of all patients reported having to try two or more different drugs prior to getting the one their doctor had initially prescribed. Yet, step therapy was stopped in 39% of cases because the drugs were ineffective, and stopped 20% of the time due to worsening conditions. A majority of respondents experienced negative health effects from delays in getting on the right treatment.

Lastly, there have been studies that have examined relative treatment effectiveness for patients with step therapy restrictions. One of those studies examined the impact of step therapy for Disease-modifying anti-rheumatic drugs (DMARDs) on the effectiveness of treatment for people with rheumatoid arthritis or psoriatic arthritis. They concluded that people with rheumatoid arthritis or psoriatic arthritis enrolled in health plans that required step therapy (with or without prior authorization) had lower odds of treatment effectiveness than people with these conditions who were enrolled in plans that did not require step therapy. These discrepancies in effectiveness have consequences for overall healthcare utilization, with the study finding that twice as many patients enrolled in plans with such access restrictions visited an emergency department, and patients were admitted to the hospital for infection three times as often.[3] [4] This is especially concerning during the current pandemic conditions, and heightens the urgency with which the issue must be addressed.

Solution

The undersigned organizations have worked together in more than 20 states to enact legislation that aims to create safeguards for all patients by guaranteeing access to a clear and expeditious prescription/prescribing/utilization management process. We would suggest that Nevada lawmakers utilize the patient protection language from these successful states as a model. Specifically, we recommend that lawmakers introduce legislation in the 2021 session that ensures insurers with step therapy protocols have standard exceptions, provide for timely determinations, and use transparent clinical review criteria.

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[2] Step therapy comeback continues." Journal of Managed Care. September 2012. http://www.managedcaremag.com/archives/1209/1209.outlook.html

[3] Boytsov N, Zhang X, Evans KA, Johnson BH. Impact of plan-level access restrictions on effectiveness of biologics among patients with rheumatoid or psoriatic arthritis. PharmacoEconomics Open. 2020;4(1):105-117.

[4] Source: Center for Biosimilars "Step Therapy in RA or PsA Leads to Worse Treatment Outcomes, Study Says" https://www.centerforbiosimilars.com/news/step-therapy-in-ra-or-psa-leads-to-worse-treatment-outcomes-study-says

First, reforms to step therapy should allow a prescribing provider, based on their professional judgment, to request a step therapy exception from an insurer on behalf of a patient. A step therapy exception should be expeditiously granted if any of the following criteria are met: (1) The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient. (2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen. (3) The patient has tried the required prescription drug, or another prescription drug in the same pharmacologic class, while covered by their current or previous health insurer, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. (4) The required prescription drug is not in the best interest of the patient based on medical necessity. (5) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration while covered by their current or previous health insurer.

It is important to note that these exceptions will not enable providers to automatically override step therapy protocols. Exceptions are not automatically granted. Like other authorization and exceptions requests, providers would be required to provide documentation making their case for an exception. The insurer would then assess that documentation and determine whether to issue an exception.

Secondly, legislation to reform step therapy protocols should include review of step therapy exception requests in a timely manner. Many states have implemented timeframes that consist of receiving a step therapy exception determination within 72 hours, or 24 hours in emergency circumstances. These timeframes are consistent with Medicare timeframes and ensure that providers, or their staff, are not having to constantly follow up with insurers over the course of several months to get an answer.

Lastly, we recommend that legislation ensures that clinical review criteria are used for step therapy protocols. It is a matter of public interest to require insurers to base step therapy protocols on appropriate clinical practice guidelines or published peer reviewed data developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when those protocols are inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent and independent process for requesting an exception to a step therapy protocol when the patients physician deems appropriate. Effective cost-control is best achieved by allowing clinical considerations and medical expertise to drive treatment decisions. This will help avoid the costly episodes of care that often arise from unnecessary delays in treatment, side effects, and/or drug abandonment.

Cost

During each discussion concerning step therapy reform, cost is justifiably at the forefront. The most common concerns a legislative body has when looking at similar reforms has been how will this impact premiums for our constituents and the state. A 2019 analysis of Silver-level plans in states where step therapy reform laws have been enacted found that there was no change in the cost of premiums in those states compared to premiums in state without such laws.[5] Further, in a study comparing spending on

[5] Source: Kaiser Family Foundation analysis of data from Healthcare.gov, state rate review websites, and state plan finder tools. https://www.kff.org/health-reform/state-indicator/marketplace-average-benchmark-premiums/. Data: Silver Plan; 40 yr old non-smokers. States with exception or override principles (implementation year): AR (2011), KY (2012), MS (2012), NH (2014), VT (2014), CT (2015), MD (2015), IN (2016), WV (2016). CA (2017), CO (2017), NY (2017), IL (2018), IA (2018), MO (2018), TX (2018), MN (2019)

schizophrenia medications in Georgia's Medicaid program, step therapy saved the state $19.62 per member per month in pharmacy benefits but these savings were accompanied by a $31.59 per member per month increase in expenditures for outpatient costs, resulting in a $11.97 per member per month increase in costs to the state[6]

The time and administrative burden associated with step therapy presents an obstacle to access that may lead to unnecessary breaks in treatment. Indeed, several studies have found that, depending on therapeutic class, 17% to 22% of patients did not submit any prescription claim to their insurance provider following a step therapy edit, instead forgoing treatment.[7] [8]

An analysis of formulary restrictions found that although these practices may decrease drug costs, total healthcare costs remained the same or increased. For example, one study examined the impact of step therapy on anti-depressants and total Medicaid costs, drug costs and drug utilization. The study found that total Medicaid costs increased by $0.32 per member per month (PMPM) while drug costs decreased by $0.26 PMPM (an overall increased spend of $.06 PMPM). The same study also found that due to step therapy requirements, more patients switched medications within 6 months and fewer patients received continuous therapy at 6 months.[9] [10] In addition, a study found that adherence to medication declined due to formulary restrictions and total costs increased with formulary restrictions due to increased inpatient and medical costs as well as increased pharmacy costs for bipolar disorder. [11]

Affected Plans

It is important to note that any legislation enacted by the Nevada Legislature will not impact Employee Retirement Income Security Act (ERISA) plans. However, efforts by states to reform step therapy have spurred Congress to introduce legislation to reform step therapy on the federal level for those plans. The House version, H.R. 2279, has more than 140 cosponsors, including Nevada Representative Mark Amodei, and the Senate version, S. 2546, has more than a dozen cosponsors, including Nevada Senator Jacky Rosen. As is the case in the many states that have passed step therapy reform, the cosponsor lists on these two bills are bi-partisan. As this legislation moves closer and closer to being enacted, it will be important for states to act to ensure similar, consistent protections are in place for their state regulated plans.

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[6] Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," Clinical Therapeutics,

[7] Delate, T., et al., Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. Am J Manag Care, 2005. 11(1): p. 29-36.

[8] Yokoyama, K., et al., Effects of a step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy.) Manag Care Pharm, 2007. 13(3): p. 235-44.

[9] Panzer PE, Regan TS, Chiao E, Sarnes MW. Implications of an SSRI generic step therapy pharmacy benefit design: an economic model in anxiety disorders. Am J Manag Care. 2005;11(12 suppl):S370-S379.

[10] Carlton, R.I.; Bramley, T.J.;Nightengale, B.;Conner, T.M. & Zacker, C. (2010) Review of outcomes associated with formulary restrictions: Focus on step therapy. The American Journal of Pharmacy Benefits 2(1). 50-58

[11] Seabury SA, Goldman DP, Kalsekar I, Sheehan J, Laubmeier K, Laubmeier K (2014). Formulary Restrictions on Atypical Antipsychotics: Impacts on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid. American Journal of Managed Care, 20(2), pages e52-e60

Prior Authorization

The focus of the undersigned is on step therapy reform, however, we acknowledge the need for a prior authorization system that works for patients and providers. Step therapy and prior authorization are sometimes tied together due to both falling under the umbrella term of utilization management. As conversations continue about reforms to step therapy, we understand that these conversations could and should include conversations about reforms to prior authorization whether in in the 2021 legislative session or a future legislative session.

Urgency

The COVID-19 pandemic has shone a light on existing issues with our current healthcare system. Throughout this pandemic, we have seen access to necessary medications in question and unnecessary hurdles to care creating barriers for patients. Patients with chronic conditions encounter these barriers regularly with improper utilization management protocols, which can lead to delays in obtaining the medications needed to manage the patients' condition. We have also seen these delays result in patients' conditions deteriorating to the point where they end up going to the emergency department. We must make every effort to keep chronic disease patients stable on their needed treatments, away from COVID-19 and out of the hospital. Accordingly, step therapy reform is necessary now more than ever.

The undersigned organizations are ready to partner with lawmakers to ensure that patients come first in regard to step therapy. We hope to work with you in the 2021 legislative session. For more information or for answers to questions, please contact me or Tom McCoy, Executive Director of the Nevada Chronic Care Collaborative at tommccoy@nvchroniccare.org.

Sincerely,

Nevada Chronic Care Collaborative

National Alliance on Mental Illness Nevada

National Hemophilia Foundation, Nevada Chapter

Nevada Cancer Coalition

Nevada Psychiatric Association

Aimed Alliance

Allergy & Asthma Network

Alliance for Patient Access

Arthritis Foundation

Chronic Care Policy Alliance

Chronic Disease Coalition

Coalition of State Rheumatology Organizations

Hemophilia Federation of America

Lupus and Allied Diseases Association, Inc.

National Alliance on Mental Illness

National Organization for Rare Disorders

National Psoriasis Foundation