HOW UTILIZATION MANAGEMENT PROTOCOLS CAN BLOCK ACCESS TO LIFE-SAVING TREATMENTS
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INTRODUCTION

Over the past few decades, health insurance companies and their pharmacy benefit managers (PBMs) have increasingly employed “utilization management” (UM) protocols and other cost-saving strategies that, while sometimes necessary to limit side effects or manage costs, can often restrict patient access to certain providers, treatments and medications. These protocols have affected nearly every aspect of health insurance coverage – from prescribed diagnostic tests and medical procedures, to prescription drug benefits and physician reimbursements. In some cases, aggressive application of unnecessary or burdensome protocols has denied patients access to treatments prescribed by their doctors.

In the 2017 report Not What the Doctor Ordered: Barriers to Healthcare Access for Patients, the Doctor-Patient Rights Project (DPRP) released findings from our nationwide survey of insured Americans. We found that health insurance providers may have denied coverage for nearly one-quarter of the claims of those surveyed for treatment of chronic or persistent illnesses or conditions. These findings suggest that up to 53 million Americans may lack access to prescribed treatments for chronic or persistent illnesses because their insurer would not cover the cost.

In another recent poll of insured Americans by the Partnership to Fight Chronic Disease, 77 percent of respondents reported “difficulty using their insurance” – or knew someone who had difficulty – due to a number of insurance company barriers to access.1

Figure 1: Have you or someone you know had difficulty using your health insurance in any of the following ways? (Partnership to Fight Chronic Disease Poll, 2016)2

<table>
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<tr>
<th>Reason for Difficulty</th>
<th>I had difficulty</th>
<th>Someone I know had difficulty</th>
<th>Both</th>
<th>None of the Above</th>
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<td>Needed a specific type of provider not available in the health insurance network</td>
<td>14</td>
<td>18</td>
<td>8</td>
<td>60</td>
</tr>
<tr>
<td>Doctor’s recommended treatment not covered by insurance</td>
<td>19</td>
<td>21</td>
<td>9</td>
<td>50</td>
</tr>
<tr>
<td>Out-of-pocket costs for a prescription were too high to purchase</td>
<td>21</td>
<td>21</td>
<td>9</td>
<td>49</td>
</tr>
<tr>
<td>Health insurance covered less than I expected</td>
<td>24</td>
<td>22</td>
<td>12</td>
<td>42</td>
</tr>
<tr>
<td>Had trouble getting approval or payment for care from insurance co.</td>
<td>18</td>
<td>22</td>
<td>9</td>
<td>51</td>
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</table>
Of the insured Americans the Partnership polled, 40 percent said they, or someone they know, needed a “specific type of provider” that was not covered under the payer’s network, while 50 percent said they, or someone they know, were denied coverage by their insurance provider for a treatment their doctor recommended. Another 51 percent said they, or someone they know, could not have a prescription filled because the out-of-pocket costs were too high, while 49 percent said they, or someone they know, “had trouble getting health insurance company approval or payment for a needed treatment or service.”

This report attempts to answer why so many Americans who have purchased health insurance say they have difficulty accessing prescribed medications, therapies and procedures. Additionally, it seeks to identify the insurance company practices that patients tell us unnecessarily delay or deny treatments their doctors have determined are medically necessary.
EXECUTIVE SUMMARY

Through a comprehensive review of the academic literature on utilization management techniques, primary source materials (including prior authorization and other forms from insurance companies and our own nationwide survey of insured Americans) and news reports, DPRP identified five prominent utilization management (UM) methods that can deny patients access to potentially lifesaving treatments when insurers employ them in an overly aggressive or burdensome manner.

These five, in particular, have been cited as potentially blocking access to vital treatments for many insured Americans, especially those treating chronic or persistent illnesses or conditions. Among the patients in DPRP’s survey who report being denied coverage for a chronic illness, 63% indicated the denial was on the basis of one the following UM methods:

1. **Overly Burdensome Prior Authorization Requirements:** Insurance companies increasingly require physicians to obtain prior authorization (PA) before the insurer will cover a specific medication or procedure. Under many PA policies, physicians agree not to even prescribe a medication without approval from the patient’s insurer. Although PA requirements can help insurers save money by addressing “waste, error and unnecessary prescription drug use and cost,” according to the Academy of Managed Care Pharmacy (AMCP), overly burdensome PA policies that are inconsistent with medical standards of care can unnecessarily delay treatment and increase the cost burden on nurses and physicians.

2. **Overly Restrictive Step Therapy Programs:** Step therapy, also known as “fail first” policy, requires patients to take the insurer’s preferred treatment before using a “more complex and often more expensive medication,” that has been prescribed by a doctor. Insurers will only cover the cost of the more expensive drug if the patient’s doctor can document that a series of preferred (and
cheaper) medications did not achieve the intended therapeutic outcome. While payers use step therapy to avoid costs, this UM method can lead to slow and ineffective treatment for patients and ultimately can create “higher medical utilization,” which increases the total cost of patient care.\textsuperscript{14,15,16}

3. **Overly Expansive Formulary Exclusions:** Each year, insurers and their pharmaceutical benefit managers (PBMs) release lists – known as formulary exclusion lists – of specific treatments they will not cover. In some states, insurance providers will only cover the excluded treatments if a patient specifically requests an exception and a doctor can sufficiently justify that the prescribed treatment is medically necessary. Many insurers adjust their lists in the middle of the coverage year. Since their inception in 2011, formulary exclusion lists have expanded dramatically. For example, the number of medications on CVS’s formulary exclusion list more than doubled since 2014.\textsuperscript{17,18,19}

4. **Overly Aggressive Non-Medical Switching:** Non-medical switching is a process by which insurers force stable patients—directly or indirectly—to switch their medication to a “chemically distinct” treatment in the same therapeutic class for reasons other than lack of clinical efficacy, potential side effects or poor adherence.\textsuperscript{20} Therapeutically “equivalent” drugs commonly have a different chemical composition than the medication the doctor originally prescribed.\textsuperscript{21} In some stable patients, switching therapies can reduce treatment effectiveness or increase the risk of adverse reactions and additional complications.\textsuperscript{22,23,24,25}

5. **Overly Inclusive Adverse Tiering:** Through adverse tiering, insurers place all or most medications used to treat a particular ailment (e.g., HIV/AIDS or hepatitis C) on their most expensive formulary tiers, which require higher co-payments or cost-sharing levels.\textsuperscript{26} These plans can place heavy financial burdens on patients and deter patients with specific diseases from selecting some insurance plans. As a result, patients with more expensive care tend to cluster in plans without adverse tiering protocols, but with less appropriate treatment coverage.\textsuperscript{26,27}

Insurers argue that these UM protocols cut treatment costs and limit the overuse of certain procedures and medicines. PBMs say they are necessary to reduce the use of inappropriate drugs.\textsuperscript{28}

This report examines these claims and highlights some specific cases where aggressive application of these protocols has created barriers for patients and doctors trying to access medically necessary treatments.
METHOD 1: PRIOR AUTHORIZATION

“The decision from my insurer should have been an easy one. Upon first receiving these new drugs... my day-to-day experience immediately improved. I was able to continue working and was relieved to know there was a solution. But my insurer denied the prescription due to the higher price tag. My insurer would only approve coverage for the medication that I could not tolerate, because it was cheaper for them.

– George Acker, Albany, NY (Patient)29

ISSUE OVERVIEW

Prior authorization (PA) requires physicians to obtain authorization from a patient’s insurer before prescribing a specific medication or treatment process.30 Insurers use the tactic to reduce their expenses, since denying an authorization permits them to refuse coverage for expensive treatments, restricting or delaying patients’ access to essential care.

Between 12 percent and 36 percent of patients treating a chronic condition have been delayed or denied treatment coverage by their health insurance provider on the basis of prior authorization requirements, according to DPRP’s 2017 survey.31

Even after patients receive authorization, however, their insurers may still refuse to cover treatment costs right away.32 Insurers do not approve payment for the therapy until “the conditions for approval of the drug are met and the prior authorization is entered into the system,” a process that can delay access to treatments for months.33

Among those patients initially denied PA, the median time it took to seek authorization and be denied was more than one month. For 28 percent of denied patients, however, the denial process took three months or longer. Moreover, nearly a third (29%) reported that their condition worsened while they waited for their insurer to make a decision.34

Insurers typically use PA to limit “waste, error and unnecessary prescription drug use and cost,” according to the AMCP.35 Insurers commonly base PA criteria on their own determination that the treatment is medically necessary and likely to accrue the intended therapeutic benefit.36 The process also considers the “desired outcome for the patient, the design of the drug benefit, the value to the plan sponsor, and all statutory and regulatory requirements.”37

The authorization process begins once a physician prescribes a medication or procedure.38 If the insurer requires PA, the doctor must send an authorization form to the insurer, which may also require copies of the patient’s medical records, as well as supplemental information about the patient’s health and the physician’s diagnosis. The insurer may then contact the doctor for additional information, adding weeks or months to the approval process.
If the patient is ultimately approved, the insurer will cover the cost of the prescribed treatment. Even then, however, the insurer’s authorization may be granted only for a limited time and patients may be forced to go through the entire PA process every few months to sustain treatment coverage.

Figure 3: Prior Authorization Process
(American Medical Association, 2011)

PA forms can run more than five pages and vary in complexity. Many require physicians to provide answers to complex, compound questions and including information about a patient’s medical history, personal history, general health and specific diagnosis.

A 2015 survey of employer-sponsored prescription drug benefit plans found that nearly half required PA before the insurer would cover growth hormones, a third required PA for controlled substances, about 30 percent required PA for Retin-A or treatment of sleep disorders, and 22 percent required it for weigh loss/gain medications, among others. Some plans, however required PA for treatments of life-threatening illnesses. For example, the 2015 survey found that more than 10 percent of employer-sponsored plans required PA before they would cover the cost of diabetic supplies.
Insurers have increasingly expanded the number of therapies subject to PA. For example, a review of Medicare Part D prescription drug plans found that, in 2007, insurers required PA for 8 percent of medications. By 2013, over 21 percent were subject to PA, an increase of more than 160 percent in just 6 years.\textsuperscript{40}

Several states have passed (or are considering) legislation to limit the administrative burden of PA requirements and/or limit the amount of time the requirements can delay patients from receiving treatment coverage. In 2013, for example, Texas adopted a law requiring insurers to use a standard authorization form created by the state’s insurance commissioner. Similar legislation was passed in California, Minnesota, Michigan, Iowa and Washington.\textsuperscript{41}

In 2016, Ohio not only passed legislation standardizing the state’s PA process, it created an online portal for authorization forms and now requires insurers to respond to all requests within 48 hours for urgent care services and 10-days for non-urgent services.\textsuperscript{42}
IMPAKT ON HEALTHCARE SYSTEM

Ineffective or Untimely Treatment: PA protocols can delay access to effective treatment for many patients. According to the American Medical Association (AMA) and 125 other physician groups, PA requirements can have a direct impact on patient care by delaying or altering the course of treatment. When prescription claims are rejected at the pharmacy due to unmet PA requirements, treatment may be completely abandoned. Lengthy processing times for PA can also delay necessary treatment, potentially subjecting patients to additional pain and/or creating new medical complications.

When the AMA surveyed over 2,400 physicians, 58 percent reported a “20 percent rejection rate from insurers on first-time preauthorization requests for drugs.” About 58 percent said they had difficulty getting approval on 25 percent or more PA requests for medications.

Even when treatments are eventually approved, recurring PA requirements can lead to gaps in care delivery and threaten a patient’s health. In emergency situations, delays to complete tasks related to PA can have drastic medical consequences for patients.

Patient Stress and Depression: Regardless of whether the prescribed treatment is eventually approved, the PA process itself can create negative outcomes for patients and their families. A 2017 study published in the Journal of Oncology Practice found that the high approval rate for patients seeking authorization of treatments for breast cancer meant that the PA requirement was unlikely to reduce medication utilization, but, “may impose unnecessary burdens on patient care.”

“When consumers purchase health insurance, they rightfully expect that if they are diagnosed with a serious, potentially life threatening disease like Hepatitis C, treatment will be considered ‘medically necessary’ and covered by their insurance”

— New York Attorney General Eric Schneiderman
One study of PA requirements for treatment of children with liver disease and cancer found that 98.5 percent of authorization requests were ultimately approved, with additional efforts by physicians. The authors concluded that use of PA in pediatric hematology and oncology not only failed to provide the desired benefits, the requirements had “unmeasured negative effects on timeliness of care and psychological/emotional health.”

**High Administrative Costs:** Prior authorization is costly for the U.S. healthcare system, both in money and in time better devoted to patient care. A 2010 AMA study estimated that the average physician spends 20 hours per week on PA activities, a total of more than 868 million lost hours annually.

More recent surveys indicate that the numbers have not improved since 2010. When the AMA surveyed 1,000 physicians in December 2016, nearly half reported that they or their staff spent 20 hours or more each week completing PA requests; nearly half of those reported spending more than 40 hours per week on PA activities. Regardless of the amount of time the doctors say they spent on PA requirements, however, over 90 percent agreed that the process itself delayed patient access to necessary care.

The large amount of time doctors spend battling insurers for coverage of prescribed treatments also exacts a significant financial toll on the healthcare system. A 2011 study in *Health Affairs* found that PA requirements and other administrative burdens cost the U.S healthcare system $82,975 per physician per year.

While other estimates are lower, most put the cost of PA requirements at thousands of dollars each year for every full-time physician. For example, a 2012 study in the *Journal of the American Board of Family Medicine* (ABFM) estimated that PA costs full-time physicians between $2,161 and $3,430 annually, and concluded that the requirements are, “a measurable burden on physician and staff time.”

In 2012, the Kaiser Family Foundation extrapolated per-physician time and money costs to the estimated 835,000 practicing physicians in the U.S. and determined that practicing physicians spend a total of 868.4 million hours each year seeking prior authorization from insurers. The financial burden of these lost hours contributes to the approximately $471 billion the U.S. healthcare system spends each year on billing and insurance-related costs.

“My doctor is now pursuing a third appeal... I am fortunate to have a physician who is dedicated to helping me gain access to this medication. Additionally, my doctor employs a clinical pharmacist, working behind the scenes to coordinate these time-consuming appeals.”

— George Acker, Albany, NY (Patient)
Mr. V. had changed insurance companies, and now one of his medications required a prior authorization. The last thing I wanted was for him to be turned away at his pharmacy and have his blood pressure spiral out of control, so I called right away to sort things out.

Twenty minutes of phone tree later, I discovered that the problem was that I had exceeded a pill limit for one of his medications. Mr. V. needed to take 90 of those pills each month for the high dosage that his blood pressure required. I patiently explained this to the customer-care representative . . .

. . . The representative went down her checklist. “Would taking 45 pills per month instead of 90 pills adversely affect Mr. V.’s health?” she asked.

At first, I thought she was joking. “Well,” I replied, “it would probably make his blood pressure shoot up in the second half of the month.”

She paused, then asked her next question with the encouraging uplift of suggestion. “Has Mr. V. ever tried 45 pills per month instead of 90 pills?”

Then I realized that she was not joking. “Are you out of your mind?” I hollered into the phone. “It’s taken years — years! — to find the right combination of meds to control his blood pressure without killing his kidneys or making him dizzy or nauseated or depressed or ruining his libido or running his potassium off the charts or breaking his bank account. Do you really think I’m going to randomly jiggle the dosages just for the hell of it?”
METHOD 2: STEP THERAPY

4.7 MILLION
insured Americans could be subject to step therapy when they try to access a medication prescribed to treat a chronic illness.

(DPRP’s 2017 Survey)

ISSUE OVERVIEW

The AMCP defines step therapy as a protocol whereby patients are required to try one or more cheaper treatment options “clinically recognized” as therapies for the diagnosed condition before the insurer will cover a “more complex and often more expensive medication.”

Insurers utilize step therapy as a means of managing costs or ensuring patients get the “safest, most effective and reasonably-priced drug available,” and claim that some approved drugs need research and time “to make sure that [they] will work in the way [they are] meant to.”

Although typically associated with pharmaceutical therapies, insurers also apply step therapy to non-pharmaceutical treatments, even those with a long history of safe application and which avoid risks associated with the insurer’s preferred option. For example, Aetna will not cover radiofrequency facet denervation (a medical procedure used since the 1950’s to treat chronic back pain) as “medically necessary” until the prescribing physician documents that the patient’s pain was not effectively controlled through bed rest, back supports, physiotherapy, anti-inflammatory drugs, analgesics or muscle relaxers.

Some insurers require patients to undergo multiple-step therapies even if the doctor prefers a specific treatment, and even when the insurer is confident their preferred treatment will not succeed.

A majority of insurers use some form of step therapy to manage certain conditions. A 2015 survey of 302 employer-sponsored prescription drug benefit plans found 56 percent of the plans (60 percent of the plans with 5,000 or more employees) required step therapy. Over 69 percent (209) demanded it before covering medications for rheumatoid arthritis. Moreover, 51 percent demanded step therapy before covering drugs to reduce cholesterol, 43 percent demanded it before covering ADD/ADHD drugs, 41 percent before covering narcotic pain relievers, 40 percent before covering drugs to manage high blood pressure, 30 percent before covering asthma medications and 27 percent before covering drugs to manage diabetes.

The increasing prevalence of plans requiring step therapy has prompted state legislators to begin regulating the practice. In 2016, lawmakers in five states passed legislation to reform step therapy, joining nearly a dozen states with existing laws to regulate the practice. Indiana recently passed one of the most stringent step therapy laws in the country, prohibiting insurers from requiring a patient restart step therapy if he or she had documented its ineffectiveness with another insurer. The law also requires insurers to review and rule on appeals within three days.

“When I ultimately found relief, my insurer denied that prescription and put me on another drug — one that did nothing for my pain. My insurer insisted on this medication because it was a cheaper alternative.”

– Diane Talbert, Baltimore, MD (Patient)

(ACCESS DENIED - October 2017)

The Doctor-Patient Rights Project
In New York, Governor Andrew Cuomo recently signed a bill into law that creates an appeals process for physicians who believe step therapy is harming their patients. The bill passed with support from patient groups, including those focused on psoriatic arthritis and mental health, who claim that some of the standard initial treatments required under step therapy are potentially detrimental to patient health.

IMPACT ON HEALTHCARE SYSTEM

Ineffective Treatment: The use of a step therapy protocol can impede the proper course of treatment for patients with certain ailments, forcing patients to undergo months of pain and suffering and risking that chronic conditions worsen in the meantime.

Many patients on step therapy are delayed in receiving the care they need, even after they submit requests for coverage of a treatment subject to step therapy. A 2013 study found that more than two-thirds of patients who had their initial prescriptions for a specialty medication rejected because they did not meet the insurer’s step therapy requirement had to wait more than a month before receiving an alternative treatment.

For some patients, requiring that they try a therapy that differs from the doctor’s prescribed treatment can introduce additional complications that put a patient’s health at risk, or increase the total cost of their healthcare. Mental health advocates, for example, have argued that step therapy with psychiatric drugs increases the risk of potential adverse reactions and can have severe consequences ranging from an increased risk of hospitalization, to greater risk of suicide.

Higher Cost: Insurers argue step therapy helps control costs. However, a 2009 study in the American Journal of Managed Care found that, while step therapy caused an initial 3.1 percent drop in pharmaceutical costs following its use for antihypertensive medication, patients experienced more emergency room visits and in-patient hospital admissions, resulting in an increase of “$99 more per user in quarterly expenditures than the comparison group.” The authors concluded that step therapy may create barriers that cause patients to delay or forego any treatment at all, resulting in higher medical utilization and higher costs.

“I was forced to try two other eye drops first and fail . . . Both drops caused an adverse reaction and further inflammation and things went downhill from there. Instead of covering the initial drop that my physician prescribed for less than $200, the carrier has now covered years of numerous specialty appointments, diagnostic tests, procedures, and several devices costing over $10,000 to date.”

– Kathleen Arntsen, Verona, NY (Patient)
Because of my body’s lack of response to my current regimen, my doctor recommended I begin taking a stronger medication, administered intravenously, known as a biologic therapy. Essentially, I was asked to take a drug with a risk of more side effects, but one that would more specifically target my diseased colon. The risk was greater, but the pay-off would potentially be life-saving.

Of course, I was relieved to know there was a treatment option that my doctor endorsed so confidently. After a few weeks though, I was informed that I had to try and fail on other less costly and safer medications before the insurance company would pay for the new drug my doctor suggested. This protocol is commonly referred to as step therapy, but it isn’t therapy at all. Step therapy is a practice in which patients have to fail on less costly medications before the original prescription will be covered.

Reluctantly, I tried the other medications my insurance company required even though my doctor did not think it was the best course of treatment to get me back to normal life. And since each medication takes a certain amount of time before it becomes effective, I dedicated six months of my life to trying it. That was six months of continued symptoms — urgency, bleeding, weight loss, inflammation, and ulceration — causing permanent damage to my colon. Instead of improving and getting back to normal life, I fell further down the rabbit hole of my disease, becoming a shell of my former healthy self.

In 2014, I began chemotherapy on the drug I was forced to take by my insurance company — which was not the drug my doctor had prescribed. I contracted numerous illnesses and infections from the havoc it wreaked on my already compromised immune system.

I had to leave work at least once a week because, when I was vomiting, I could not stop . . .

Working with my physician’s office, it took six anguishing months of exhausting effort to negotiate to gain access to the medicine my doctor felt I should take to improve my health. The process was so complicated that my doctor hired a staffer dedicated to claims management — because it turned out the practice had so many patients in my situation.
METHOD 3: FORMULARY EXCLUSION

ISSUE OVERVIEW

Each year, insurers—typically through their PBMs—list the medicines they will cover on annual formularies. Most, however, also release formulary exclusion lists, which outline the specific medications the insurer will not cover except when the patient has requested an exemption and their doctor has documented that it is medically necessary.

Over the past 4 years, insurers have increasingly expanded their exclusion lists. Express Scripts and CVS Caremark are the nation’s two largest PBMs, comprising more than half of the PBM market share. Between 2014 and 2017, CVS’s exclusion list more than doubled, and Express Scripts’ grew 77 percent. On its 2017 exclusion list, Express Scripts listed 85 medications, while CVS listed 130. In 2016 and 2015, Express Scripts’ formulary exclusions listed 87 medications and 66 medications, respectively, while CVS’s listed 124 medications and 95 medications, respectively. Various other insurers and their PBMs—including Optum, Aetna, Cigna and Prime Therapeutics—have begun using exclusion lists to manage costs as well.

CVS’s 2017 list includes commonly prescribed asthma inhalers, and at least one prostate cancer drug. CVS Chief Medical Officer Troyen Brennan said the PBM removed some brand-name cancer medications for the first time because of rising prices and the availability of suitable alternatives. He noted, “in situations where the medications are equivalent, from a medical point of view, it makes sense to do this in order to reduce cost.”
CVS previously added erectile dysfunction drugs, as well as one weight loss aide, to its exclusion list. Express Scripts, which has not yet placed cancer or mental health drugs on its exclusion lists, nevertheless added a popular rheumatoid arthritis therapy to its 2017 list.84 85

Formulary exclusion lists are subject to additions even after they are issued. Express Scripts, for example, announced that they were reviewing whether to include an inflammatory condition drug as well as certain hepatitis C drugs and insulins on their 2017 formulary exclusion after they had released the list.86

Insurers began using formulary exclusion lists in 2011 (with CVS’s list) to eliminate paying for costly medications by compelling patients to take cheaper, therapeutically-similar treatment options.87

They argue that exclusions save insurance companies billions of dollars, which ostensibly they pass on to patients, who avoid paying higher premiums for potentially unnecessary medications.88 Express Scripts claimed, for example, that its 2017 exclusion list would save payers $1.8 billion, and CVS claimed its exclusion lists generated more than $9 billion in patient savings from 2012 to 2017.88 89 90

Insurers also argue that they can use these exclusion lists to help negotiate discounts with pharmaceutical manufacturers, pushing them to offer larger rebates in exchange for insurers keeping the manufacturer’s drugs off the list.91

**IMPACT ON HEALTHCARE SYSTEM**

**Ineffective Treatment:** As some PBMs and payers withhold coverage for more and more medications, patients may not get the treatment they need to effectively combat an illness. As a result, the rapid expansion of formulary exclusions can block some patients from accessing the treatments their doctors feel would be most effective, and force others to switch treatment regimens they may have been following for years.
METHOD 4: NON-MEDICAL SWITCHING

ISSUE OVERVIEW

Non-medical switching occurs when a patient is forced to change to a cheaper, alternative treatment than the one prescribed by their doctor “for reasons other than lack of clinical efficacy/response, side effects or poor adherence.” Non-medical switching can directly deny coverage for treatment by directing pharmacists, for example, to dispense a medication in the same therapeutic class, but which has a different chemical composition.

Under a policy called “therapeutic substitution,” for example, insurers require physicians under contract with their health plans to permit pharmacists to substitute the insurer’s preferred drug for the medication the doctor has prescribed, provided that the alternative treatment is in the same therapeutic class. While most states permit therapeutic substitution in some form, many states have adopted laws regulating the practice.

In certain states, pharmacists are authorized to dispense an alternative to the prescribed medication unless the doctor personally indicates “dispense as written” on the prescription. Many states also require that the prescriber “must be notified” of the substitution, but several states permit pharmacists to comply by making a notation of the substitution in the patient’s electronic medical record (or any electronically-accessible pharmacy record) without actually contacting the prescribing doctor prior to making the switch.

Non-medical switching can also indirectly block access to prescribed treatments, for example when an insurer makes changes to their formularies in the middle of a coverage period that require higher co-pays, forcing patients to switch to cheaper, potentially less effective alternatives.

A 2016 poll from the Global Healthy Living Foundation and the Tennessee Patient Stability Coalition found that more than two-thirds of patients with chronic disease were forced to change medications either because of reduced insurance coverage or increased out-of-pocket costs. The poll also found that 95 percent of respondents saw their symptoms worsen when they were forced to switch medication, while 68 percent had to try multiple treatments before they found an alternative that worked.
IMPACT ON HEALTHCARE SYSTEM

Negative Patient Outcomes: In 2015, the American College of Rheumatologists issued a statement opposing therapeutic substitution unless the pharmacist and the prescribing medical professional have established a collaborative practice agreement. In justifying its opposition, the College stated that, in some situations, substitutions carry “a significant risk of disease flares, organ damage, and adverse drug reactions.”

A 2016 comprehensive review of the medical literature on non-medical switching found that the practice “was more often associated with negative or neutral effects than positive effects on an array of important outcomes. Among patients with stable/well controlled diseases, non-medical switching was associated with mostly negative effects.”

Increased Costs: According to the U.S. Pain Foundation, rheumatoid arthritis patients who incurred non-medical switching experienced 42 percent more ER visits and 12 percent more outpatient visits in the first six months following the switch.

A 2016 Institute for Patient Access study of Medicare patients with rheumatoid arthritis found that patients forced to switch to a cheaper treatment actually cost Medicare more in overall healthcare payments. Patients who did not stop treatment, but were forced to switch medications once, cost an additional $8,712 each. Patients forced to switch twice cost Medicare an additional $8,827 per patient. Conversely, patients who were allowed to continue the same course of treatment had cost increases of only $201 each.

Increased Complications Risk: Non-medical switching may place patients at greater risk for medical complications. For example, a Florida rheumatologist claims that taking her patients off existing treatment regimens increased their risk “for complications such as heart attack while also denying them basic dignities that many of us take for granted.”

For patients with mental illness, a slightly different drug or dose can have a very different effect. It often takes years for a psychiatrist and a patient to find the right balance of medications. For a patient to suddenly find his or her treatment has been altered can be disastrous.”

– Laura Young, LCSW-R, CGP
Nonmedical switching is particularly harmful to people living with complex, chronic or rare conditions such as cancer, rheumatoid arthritis, HIV/AIDS, or epilepsy.

As a practicing rheumatologist, I care for Floridians whose condition affects their mobility, quality of life and lifespan. For example, people living with rheumatoid arthritis rely on treatments to allow them to work, pick up their children, open a jar and drive a car. In addition to irreversible joint damage and deformity, uncontrolled rheumatoid arthritis is associated with increased cardiovascular risk and internal organ damage.

For these individuals, nonmedical switching can be devastating. Forcing these Floridians off their treatment regimens means increasing their risk for complications such as heart attack while also denying them basic dignities that many of us take for granted.
ISSUE OVERVIEW

Adverse tiering is when insurers place all (or practically all) medications used to treat a particular illness (for example, H.I.V. or Hepatitis C) on its most expensive formulary tier, effectively compelling patients to take the single medication that is not adversely tiered or making treatment of certain diseases completely unaffordable for many.

As of 2013, 80 percent of working Americans had private insurance plans with three or more tiers for drug prices, up from 50 percent in 2000.111,112

In 2014, Harvard researchers reviewed adverse tiering in "silver" plans offered through Affordable Care Act marketplaces. Specifically, they evaluated plans with the lowest, second-lowest, median and highest premiums in 12 states participating in the federal marketplace.113 The authors, Douglas B. Jacobs and Dr. Benjamin D. Sommers of the Harvard School of Public Health, reviewed each plan’s formulary and benefit summary to determine cost-sharing requirements for nucleoside reverse-transcriptase inhibitors (NRTIs), a common HIV medication.113

The authors focused on HIV because it “is associated with high insurance costs, requires lifelong treatment, and is treated with an expensive and disease-specific class of medications.”113 They defined adverse tiering as, “a placement of all NRTIs in tiers with a coinsurance or co-payment level of at least 30%” and estimated average annual medication costs using drug prices negotiated by Humana.

The authors found evidence of adverse tiering in 12 of the 48 plans reviewed. Moreover, they found that adverse tiering plan (ATP) enrollees had “an average annual cost per drug of more than triple that of enrollees in non-ATPs ($4,892 vs. $1,615)” and a difference of $2,000 for generics.113 Additionally, half of the adverse-tiering plans had a drug-specific deductible, while 19 percent of the regular plans did not. As a result, an individual with HIV/AIDS enrolled in an adverse-tiering plan would pay $3,000 more than an individual in another plan, even considering potential lower premiums and caps on out-of-pocket expenses.113
Adverse tiering like this has already prompted criticism and legal action from patients. In 2014, the AIDS Institute and the National Health Law Program filed a federal complaint against four Florida insurance companies – CoventryOne, Cigna, Humana and Preferred Medical – for discriminating against people with HIV/AIDS and hepatitis C by placing relevant drugs on their most expensive tiers.114 115

Additionally, after reviewing Florida’s silver-level health plans, the AIDS Institute found that four companies placed HIV and hepatitis C drugs on the highest formulary tiers and required prior authorization before they would cover treatments. For example, Humana placed all HIV and hepatitis C drugs in Tier 5 (the top tier) with a 50 percent co-insurance after the patient pays a $1,500 deductible, prompting attorneys to allege “the companies were looking for a way around the Patient Protection and Affordable Care Act’s (ACA) protections to discourage people with HIV/AIDS from enrolling in their plans.”115

Three of the four insurers ultimately settled the suit. Humana agreed to reduce cost-sharing for HIV drugs on its 2015 plans, following the leads of Cigna and Coventry, which agreed to limit cost-sharing for four HIV drugs.116 The Florida Office of Insurance Regulation fined Humana $500,000 for discriminating against HIV/AIDS patients by requiring them to pay co-pays for potentially lifesaving drugs.117 Cigna also agreed to move generic HIV drugs to a lower tier.118 119

“Health plans are designing their drug formularies to offer differentially worse coverage for classes used by the most unprofitable individuals, consistent with the hypothesis that Exchange plan formularies are designed to deter enrollment of unprofitable individuals.”

– Michael Geruso, Timothy J. Layton, Daniel Prinz (Medical Researchers)120
In November 2016, the federal Department of Health and Human Services (HHS) issued a draft letter to insurers participating in federally-facilitated ACA marketplaces announcing that it was more aggressively analyzing insurance provider cost-sharing protocols and drug benefit designs in order to “uncover plans with potentially discriminatory benefit and cost-sharing structures” in violation of the ACA’s prohibition against discouraging the enrollment of individuals with significant health needs.

It is unclear, however, if HHS intends to pursue these enforcement efforts, especially considering that the new administration has proposed changes to the rules governing insurers participating in ACA marketplaces that would permit adverse tiering in some circumstances.

**IMPACT ON HEALTHCARE SYSTEM**

**Higher Costs:** Adverse tiering places heavy financial burdens on patients who need medications that are listed only on the higher formulary tiers. The 2014 *New England Journal of Medicine* study found a patient taking the HIV treatment Atripla would pay $3,000 more in a health plan adopting adverse tiering versus a plan that did not impose adverse tiering, even after accounting for the lower premiums in the adverse-tiering plan. The study’s lead author, Douglas B. Jacobs, noted, “that’s really a large cost difference, and really is a very significant financial constraint for those with chronic conditions.”

**Clustering of Patient Groups (“Adverse Selection”):** As some insurers do not offer cost-effective plans for some patients, the patients begin to cluster within plans that do not implement adverse tiering practices. As a result, a handful of insurance providers may be faced with covering patients with the most expensive care. These patients will begin “clustering in plans that don’t use adverse tiering for their medical conditions,” according to Jacobs and Sommers. Additionally, as these plans begin to cover more and more patients excluded by adverse tiering plans, they too may become more restrictive, prompting a “race to the bottom on drug benefit designs” according to Douglas B. Jacobs.

“Adverse tiering is about using formulary copays to circumvent Obamacare’s ban on discrimination based on pre-existing conditions. Given the popularity of the ban, insurance companies were unsuccessful at getting legislation passed to overturn it. Now, they are trying quietly to circumvent the pre-existing condition rule through cost-sharing protocols.”

— Dr. Luis Scaccabarrozzi, Senior Director of Health Policy, Latino Commission on AIDS
CONCLUSION

The U.S. health insurance system began with individuals paying monthly premiums to their community hospital in exchange for guaranteed care should they be injured or suffer a serious illness. While the system has grown more complex, the purpose remains the same. Patients pay insurance premiums in exchange for guaranteed healthcare benefits, should they require them.

For a growing number of Americans, the very insurers tasked with guaranteeing access to essential healthcare often stand between them and the medical treatments their doctors have prescribed. Intending to manage costs and prevent additional healthcare expenses from over-utilization of services, insurance companies have increasingly used prior authorization requirements, step therapy, formulary exclusions, non-medical switching and adverse tiering. When these utilization management protocols are employed too widely or too aggressively, they can effectively block many patients from receiving the treatments their doctors say are medically necessary.

Even as cost-savings strategies, however, these protocols have mixed results. Prior authorization requirements that delay effective treatment of chronic conditions, for example, permit chronic diseases to develop further. Step therapy can delay some patients from receiving effective treatment for months. Non-medical switching potentially introduces complications requiring additional physician consultations or emergency room visits. Formulary exclusion and adverse tiering can lead many patients to forego treatment altogether.

When insurers employ these protocols in ways that worsen patient health, or price effective treatments beyond what many patients can afford, they can increase the total lifetime cost of a patient’s care and undermine the intended purpose for the insurer adopting the protocols in the first place.

Health insurance furnishes little piece of mind for the growing number of insured Americans who say they are worried that their insurance provider will not cover the costs of the treatments their doctors have prescribed. More and more patients fear that insurance executives and benefits managers—who have never met or examined them—have effectively become the arbiters of their care, capable of overriding the treatment decisions they have made in consultation with their doctors. Our analysis suggests their concern may be warranted.
ENDNOTES

2. Ibid.
5. Ibid.
19. Ibid.
36. Ibid.
37. Ibid.
45. Ibid.
52. Ibid.


68. Ibid.


72. Ibid.


83. Ibid.


87. Ibid.


91. Ibid.


97. Ibid.


106. Ibid.


The Doctor-Patient Rights Project is a non-profit coalition of doctors, patients, caregivers, companies and advocates fighting to restore the fundamental practice of medicine and to ensure doctors, in partnership with their patients, drive patient care decisions.