Mitigating the Negative Impact of Step Therapy Policies and Nonmedical Switching of Prescription Drugs on Patient Safety

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A Position Paper of the American College of Physicians

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I. Abstract

In 2020, the U.S. will spend roughly $358.7 billion on prescription drugs, nearly 9% of national health expenditures. Growth on prescription drug spending is projected to accelerate in the coming years—5.4% annually in 2021–2023 and nearly 6% annually 2024–2028—making it one of the fastest growing health care spending categories. This rapid growth is largely attributed to anticipated higher prices, new available drugs, and fewer available rebates.[1] Pharmacy benefit managers (PBMs) have developed a series of price management tactics to curb the rising cost of prescription drugs. Among these, step therapy policies, commonly called "fail-first"[2] policies, require patients to be initiated on lower-priced medications before being approved for originally prescribed medications.[3] Carriers can also change coverage in an attempt to force patients off their current therapies for cost reasons, a practice known as nonmedical drug switching.[4] In 2017, 14% of treatment denials for insured Americans were based on step therapy or nonmedical drug switching policies.[5]

Evidence concerning the effectiveness of these tactics is mixed. Some studies have found they can successfully drive cost savings without negatively impacting patient care.[6] Others have found overall health spending actually increased due to an uptick in hospitalizations and other services resulting from new symptoms or complications.[7] Meanwhile, these policies have drawn scrutiny for restricting patient access to effective treatments, putting patient health and safety in jeopardy by subjecting patients to potential adverse effects, interfering with the patient–physician relationship, and absorbing practice resources with burdensome approvals and documentation requirements. With the increasing prevalence and potential patient safety concerns related to step therapy and nonmedical drug switching programs, the MPQC of the ACP developed the following set of recommendations for PBMs and prescription drug plans to help mitigate unintended consequences. The recommendations are based on a robust analysis of academic research and policy interventions.

II. Methods

ACP's MPQC drafted these recommendations. The Committee's charge is to address national, state, or local policies related to improving access, payment, coverage, coding, documentation, and medical review, as well as develop programs to support the quality, safety, and affordability of patient care. The authors reviewed relevant studies, reports, and surveys from medical journals, academic institutions, industry nonprofits, research organizations, and other reputable sources related to the effectiveness and potential patient consequences associated with step therapy and nonmedical drug switching protocols. These recommendations include input from ACP's Board of Governors, Board of Regents, Council of Subspecialty Societies, Council of Early Career Physicians, Council of Resident/Fellow Members, and Council of Student Members. The policy paper and related recommendations were reviewed and approved by the ACP Board of Regents on July 25, 2020.

III. Summarized Recommendations

Recommendation 1: The ACP recommends all step therapy and medication switching policies should aim to minimize care disruption, harm, side effects, and risks to the patient.

a. Patients should never be asked to return to a medication that previously proved ineffective or harmful, had adverse side effects, or was poorly tolerated, including if they switch plans or clinicians.
b. Patients should be closely monitored for biological or physiologic symptom changes. Those that experience "failure" on a particular medication should be able to obtain a different medication as quickly as possible, preferably within 24 hours.

c. Plans and PBMs should avoid applying step therapy and nonmedical drug switching policies to patients, conditions, or classes of drugs classified high risk.
d. Step therapy and nonmedical drug switching programs should not require patients to try more than two drugs before being able to take a medication originally prescribed by their doctor. This originally prescribed medication should then be fully covered by the plan, including all standard cost sharing commensurate with the pricing tier of the preferred alternative.
e. Policies should be grounded in conclusive evidence that the less expensive drug is, at a minimum, equally as clinically effective and safe. This should be publicly posted and regularly reassessed to ensure consistency with the latest clinical evidence-based standards of safety and effectiveness.

Recommendation 2: The ACP recommends all step therapy and nonmedical drug switching policies be designed with patients at the center, taking into account unique needs and preferences.

a. PBMs should make a reasonable effort to keep patients on their current medication if they are stable, including if a patient switches plans.
b. Factors that should be considered include, but are not limited to, medical history, patient cognition, comorbid conditions, concurrent prescriptions, demographic factors, and medication history.
c. Patient ability to pay should be taken into account to prevent disproportionately limited access to lifesaving medications for lower-income or other at-risk patient populations.
d. Any formulary restrictions should be transparent; clearly articulated to the patient regardless of their education or health literacy level; and proactively communicated to the patient, prescribing clinician, and pharmacist well in advance of, not fewer than 90 days before, the change implementation, with evidence-based support substantiating the change. Supplemental educational materials should be available upon request.

Recommendation 3: The ACP recommends all step therapy and nonmedical drug switching protocols be designed with input from frontline physicians and community pharmacists; feature transparent, minimally burdensome processes that consider the expertise of a patient's physician; and include a timely appeals process.

a. Input from physicians who regularly prescribe those medications should be considered *at the onset* when designing step therapy or nonmedical drug switching protocols. Physician-to-physician consults during the appeals process do *not* suffice.
b. "Failure" on a less expensive medication should be clearly defined, including maximum durations for testing each drug based on clinical evidence base, acuity of the condition, and input from physicians and pharmacists.
c. Physicians and pharmacists should be proactively informed of changes to the formulary or coverage policies and provided with evidence-based justification for the change as well as a list of medication alternatives specific to that drug. Physicians should have the ability to request exemptions or appeal medication changes through clearly defined, streamlined, and timely processes that are ideally automated and in real time. Plans should respond within 36 hours, 24 hours for emergency cases.
d. Step therapy and nonmedical drug switching policies should avoid being combined with additional formulary restrictions, such as prior authorization requests, which create undue burden.

Recommendation 4: The ACP recommends that data concerning the effectiveness and potential adverse consequences of step therapy and nonmedical drug switching programs should be made transparent to the public and studied by policymakers. Alternative strategies to address the rising cost of prescription drugs that do not inhibit patient access to medications should be explored.

a. Health plans, PBMs, and pharmaceutical manufacturers should be required to report information on drug pricing and coverage policies to support enhanced public transparency and research efforts, ideally reporting standardized information to an easily accessible, public database.
b. Tools that help patients and clinicians work together to select cost-effective medications without restricting their access to others warrant further exploring, including formulary decision-support tools, patient educational materials, physician education programs, lower copay options, rebates, and in-kind medical services.
c. Policymakers should explore separate, complementary efforts to address the root causes of excessive and unreasonable price hikes for pharmaceuticals, which ACP explored in a 2019 position paper series.[8, 9, 10]
d. The long-term effects of step therapy and nonmedical drug switching policies on patient safety and total costs, including any added costs that result from adverse health events, should be a topic of future study.

IV. Definitions

Step therapy, also known as fail-first, sequencing, and tiering,[11] requires patients to be initiated on lower-priced medications before being approved for originally prescribed medications.[12]

Nonmedical drug switching occurs when insurance coverage changes force patients off their current therapies for no reason other than to save money. Tactics include increasing out-of-pocket costs, moving treatments to higher cost tiers, or terminating coverage of a particular drug.[13]

V. Background

Rising Cost of Prescription Drugs

In 2020, the U.S. will spend roughly $358.7 billion on prescription drugs, nearly 9% of national health expenditures. Growth on prescription drug spending is projected to accelerate in the coming years: 5.4% annually in 2021–2023 and nearly 6% annually 2024–2028, making it one of the fastest growing health care spending categories. This rapid growth is largely attributed to anticipated higher prices, new available drugs, and fewer available rebates.[14] Per capita prescription drug spending in the U.S. far exceeds other countries. In 2015, U.S. spending on pharmaceuticals exceeded $1,000 per person and was 30% to 190% higher than nine comparable countries.[15] As a result, Americans have trouble affording their medications. Eight percent do not take their medicines as prescribed because they cannot afford them. Low-income Americans are even more vulnerable; 14% did not take medications as prescribed to save money,[16] which can lead to adverse health events, including death.

The Commonwealth Fund attributes approximately one third of the rise in prescription drug spending to price increases or shifts to costlier products.[17] Specialty drugs, pharmaceuticals classified as high cost and high complexity, or both, are one of the fastest growing cost areas of pharmaceutical spending.[18] A 20% spike in U.S. prescription drug spending over a 2-year period (2014–2015) has been largely attributed to the introduction of several expensive new specialty drugs to treat hepatitis C, cystic fibrosis, and other conditions.[19] Chimeric antigen receptor T-cell therapy approved drugs, a form of immunotherapy aimed at certain cancer treatments, range from $475,000 to $1.5 million per patient.[20]

Market exclusivity protections, biologics, and other new classes of highly expensive drugs and "product hopping" are all increasingly common contributors to this problematic rise in spending for specialty drugs. Market exclusivity protections were created so drug manufacturers could recoup some of the research and testing costs that go into developing a new drug. However, they also give drug manufacturers a monopoly on pricing for several years, which can lead to significant, unexplained price increases, particularly when there is no competitor. In 2015, the price of Daraprim (Vyera Pharmaceuticals) famously increased by 5,000%.[21] Biologics, drugs derived from living cells, are a subset of specialty drugs that make up an increasing proportion of the research and development that have also made headlines for their blockbuster price tags.[22] Newer antirheumatic drugs can cost over $20,000 annually.[23] Another cost cutting tactic known as Product hopping occurs when a drug manufacturer makes modest reformulations to existing drugs that offer little to no therapeutic advantages but allow the manufacturer to relabel drugs as "new" and therefore set new, higher prices.[24]

Branded specialty drugs comprise 1% of prescription drugs but are responsible for roughly one third of total drug spending. In contrast, generics account for 39% of prescriptions but only 26% of total drug costs in the U.S.[25] However, generics are also not immune to predatory price hikes. In 1996, insulin had a list price of $21 for a 10-mL vial, the price of which today is $275.[26]

Increasing Prevalence of Step Therapy and Nonmedical Drug Switching as Cost Controls

Step therapy was first introduced by managed care organizations in the 1980s as a way to control the rising costs of prescription drugs.[27] Since then, step therapy, nonmedical drug switching, and other cost-curbing tactics have become increasingly prevalent across public and private payers in the wake of rising drug costs. A 2016 poll found that more than two thirds of patients with chronic disease in Tennessee were forced to change medications because of coverage or formulary changes.[28] By 2017, 14% of total treatment denials for insured Americans were based on step therapy or nonmedical drug switching policies (9% and 5%, respectively). Up to 14 million Americans could be subject to step therapy when they try to access a medication prescribed to treat a chronic illness.[29] Step therapy and nonmedical drug switching are particularly prevalent among high-cost drugs, including biologics and specialty drugs for autoimmune conditions, which can cost thousands of dollars per month.[30]

In 2013, two thirds of employer-sponsored health insurance plans had implemented step therapy policies.[31] The incidence of step therapy policies among large commercial plans varied widely, from 2% to 49%.[32] As of January 2019, the Centers for Medicare & Medicaid Services (CMS) authorized[33] Medicare Advantage plans to deploy step therapy for Part B drugs for new patients. Under a separate rule, CMS allowed Part D sponsors to exclude certain types of drugs under specific circumstances and implement prior authorization and step therapy protocols for protected class Part D drugs starting in 2020. However, this rule applies only to enrollees initiating therapy and precludes antiretrovirals.[34]

Benefits

Some consider step therapy and nonmedical drug switching a reasonable solution to skyrocketing drug prices. In many cases, less expensive generic prescriptions can be just as effective[35] and may have been on the market longer and therefore are considered safer.[36] Generics account for 39% of prescriptions by only 26% of total drug costs in the U.S. and were estimated to save the U.S. $253 billion in 2016, $77 billion for Medicare alone.[37] They are also less frequently subject to sudden, sharp price increases. Directing patients to try certain drugs first can increase a plan's ability to negotiate drug prices with PBMs and manufacturers, further lowering costs for patients.[38]

Concerns

However, Step therapy, nonmedical drug switching, and other cost-curbing formulary designs can also undermine the medical expertise of physicians and fail to adequately account for the individual characteristics and needs of patients, including comorbid conditions, concurrent medications, and demographic factors, all of which can impact a medication's effectiveness and side effects. Step therapy and nonmedical drug switching have been shown to delay or inhibit access to effective treatments and put patient safety at risk by increasing the risk for hospitalizations and other adverse health events.[39] Sixty percent of patients experienced side effects, 72% experienced reemerging symptoms, and nearly 10% were hospitalized as a result of nonmedical drug switching, while 40% stopped taking their medication altogether.[40] In a study of rheumatology patients who tried a nonpreferred drug in the formulary, 11% never obtained treatment.[41] Formulary restrictions like these can also disproportionately limit access to medications for low-income patients and underserved communities, such as communities of color, individuals with disabilities, and individuals with limited English proficiency, putting them at a higher risk for adverse health events.[42]

Several studies have found that adverse health events that result from switching medications can lead to higher long-term health costs. For patients with rheumatoid arthritis who switched to a less expensive drug, additional yearly medical payments increased from $6,254 to $14,127 compared with only $239 on average for those who switched to more expensive drugs (i.e., switches that were not cost-driven).[43] Georgia Medicaid's step therapy program for schizophrenia medications saved $20 per member per month but ended up costing $32 per member per month in additional outpatient services.[44]

Step therapy and nonmedical drug switching policies can also monopolize time and practice resources with winding appeal and exception request policies that can further delay patients receiving effective medications. The administrative burden of maintaining insurer preferred drug lists and time spent requesting prior authorizations is estimated to cost $1,569 per physician per year for statins and antihypertensives.[45] More than half of clinicians report difficulty obtaining approval for prescriptions on a quarter or more of their requests. Most report having to wait several days for approval.[46]

The increasing prevalence of biologics and other breakthrough medicines that can save lives, but often come at exorbitant prices, raise larger questions about the benefits versus costs for new treatments, as well as who pays for it. Covering expensive innovative therapies adds to the rising cost of insurance premiums for all policyholders. On the other hand, excluding or subjecting certain drugs to price control measures raises ethical questions about a patient's ability to access lifesaving treatments.

The evidence that step therapy or nonmedical drug switching policies reduce long-term health costs is also inconclusive. Some studies suggest that step therapy policies reduce initial drug costs without increasing the use of other medical services,[47, 48] whereas others have found that step therapy policies increase total costs in the long run due to increased inpatient and outpatient services.[49, 50, 51, 52] According to a 2016 Arthritis Foundation survey, step therapy was stopped in 39% of cases because the drugs were ineffective and 20% of the time due to worsening conditions.[53]

Legislative Efforts

Nearly two dozen states have laws that protect patients from the potential harms of step therapy and nonmedical drug switching.[54] Many prevent patients from medication disruptions if they switch insurance plans. Indiana passed one of the more stringent step therapy laws in the country, which prohibits insurers from requiring a patient to retry a drug that had previously proven ineffective and requires insurers to review appeals within 3 days. At a national level, the Safe Step Act (H.R. 2279; S 2546) was introduced to the

U.S. House of Representatives in April 2019 and to the Senate in September 2019. The bill would establish a "clear and transparent" appeals process, lays out evidence-based criteria for types of medications that would be excluded from step therapy protocols, and provides specific windows within which the plan or issuer would be expected to respond to exception requests.[55] However, no further actions have been taken to date.

VI. Detailed Recommendations

With the increasing prevalence of step therapy and nonmedical drug switching programs across public and private payers, ACP's MPQC has developed the following set of principles for consideration by PBMs and prescription drug plans that help to mitigate possible adverse consequences on patient safety, downstream health costs, and administrative burden.

Recommendation 1: The ACP recommends all step therapy and medication switching policies should aim to minimize care disruption, harm, side effects, and risks to the patient.

a. ***Patients should never be asked to return to a medication that previously proved ineffective or harmful, had adverse side effects, or was poorly tolerated, including if they switch plans or clinicians.*** According to an Arthritis Foundation survey, nearly one out of every four patients who switched insurance providers were required to repeat step therapy with their new carrier.[56] Forcing patients to return to medications that they have already tried and that failed asks for complications and risks patient safety, as well as additional costs. This should not be subject to time limitations.

b. ***Patients should be closely monitored for biologic or physiologic symptom changes. Those who experience "failure" on a particular medication should be able to obtain a different medication as quickly as possible, preferably within 24 hours.*** Vital signs that should be monitored closely include blood pressure and blood glucose/A1c. More than two thirds of patients in one study who had their initial prescriptions rejected because they did not meet the insurer's step therapy requirement had to wait more than a month before receiving an alternative treatment.[57]

c. ***Plans and PBMs should avoid applying step therapy and nonmedical drug switching policies to patients, conditions, or classes of drugs classified as high risk.*** CMS exempts several protected classes of Part D drugs from step therapy and prior authorization due to high risk, including immunosuppressants, antidepressants, and antipsychotics.[58] Narrow therapeutic index drugs, where small differences in dose or blood concentration may lead to serious therapeutic failures and adverse drug reactions that are life-threatening or result in persistent or significant disability or incapacity,[59] are another prime example of drugs that present an elevated risk to patient safety and should be considered high-risk. Patients with certain medical conditions are also at a higher risk for complication. The Epilepsy Foundation warned denying access to medications can be "extremely dangerous," put patients at high risk for preventable seizures and complications, and lead to significantly increased medical costs.[60] Plans and PBMs should work closely with patient advocate organizations, clinicians, and other disease experts to determine classes of conditions and drugs that qualify as high risk. Preferably, the government could develop a formal classification of drugs and conditions considered high risk that are universally immune from step therapy and nonmedical drug switching policies.

d. ***Step therapy and nonmedical drug switching programs should not require patients to try more than two drugs before being able to take a medication originally prescribed by their doctor.*** This originally prescribed medication should then be fully covered by the plan, including all standard cost sharing commensurate with the pricing tier of the preferred alternative. Among step therapy plans, 37% require trying multiple therapies, 15% require three or more, and some require up to five.[61] Every additional medication a patient is required to test before advancing to the originally prescribed medication can further delay proper treatment and increase the risk for adverse health events. One reasonable way to limit patient safety risks is to limit the number of drugs a patient is required before they can advance to the prescription that their doctor originally recommended. ACP believes a limit of two test drugs would be reasonable and appropriately balance potential adverse patient consequences and undue administrative burden for the practice with potential cost savings and a reasonable expectation of compliance for plans. Of existing step therapy plans, 85% are already compliant with this standard.[62]

e. ***Step therapy and nonmedical drug switching policies should be grounded in conclusive evidence that the less expensive drug is, at a minimum, equally as clinically effective and safe. This should be publicly posted and regularly reassessed to ensure consistency with the latest evidence-based standards of safety and effectiveness.*** ACP opposes any formulary change that operates to the detriment of patient care. Decisions about which drugs are chosen for formulary inclusions should be based on the drug's effectiveness, safety, and ease of administration. Cost should only be a determinant when safety and efficacy are equal among two comparable drug choices.[63] Treatment delays that result from step therapy and nonmedical drug switching protocols can increase symptom severity and lead to worse outcomes, including death. Twenty-nine percent of chronically ill patients whose insurance provider initially did not report treatment coverage reported that their condition worsened.[64] In 2009, 95% of Tennesseans reported that they had symptoms worsen when they were forced to switch medication due to cost; 68% of them had to try multiple treatments before they found an alternative that worked.[65] Patients with rheumatoid arthritis who incurred nonmedical switching experienced 42% more emergency department visits and 12% more outpatient visits in the first 6 months after a medication switch.[66] The government should consider dedicated funding to research and publish standard of care comparisons for similar medications. The College supports maintaining an adequately funded, independent entity to sponsor and/or produce trusted research on the comparative effectiveness of health care services, a role that is currently filled by the Patient-Centered Outcomes Research Institute. The College believes that the federal government should have a significant role in the funding, implementation, and maintenance of this entity, but takes no formal position on its organizational structure (e.g., government or joint public/private).[67]

Recommendation 2: The ACP recommends all step therapy and nonmedical drug switching policies be designed with patients at the center, taking into account unique needs and preferences.

a. ***PBMs should make a reasonable effort to keep patients on their current medication if they are stable, including if a patient switches plans.*** Keeping patients on their medication reduces the risk for possible adverse side effects, which puts patient safety at risk and can end up costing more money, even if the medication itself is less expensive. It also reduces administrative burden for practices. Medicare patients with rheumatoid arthritis who are stable on a therapy have lower costs than those who switch.[68]

b. ***Factors that should be considered include, but are not limited to, medical history, patient cognition, comorbid conditions, concurrent prescriptions, demographic factors, and medication history.*** The one-size-fits-all nature of step therapy and nonmedical drug switching programs defies the widely accepted importance that patient demographic and sociodemographic factors play in the effectiveness of various treatment options. One French study found that numerous sociodemographic factors were "significantly associated with poor [medication] adherence" including age, non-European geographic origin, financial difficulties, and "being professionally active." The study identified many other therapy-related and health care–related factors, including existing diabetes complications; difficulties taking medication alone, lack of family or social support, and follow-up by a specialist physician.[69]

c. ***Patient ability to pay should be taken into account to prevent disproportionately limited access to lifesaving medications for lower-income or other at-risk patient populations.*** Step therapy and nonmedical drug switching policies can disproportionately limit access to medications for low-income patients who are less able to pay out of pocket for drugs when their insurance does not cover them, putting them at a higher risk for adverse health risks. Low-income Americans are twice as likely not to take medications as prescribed because they cannot afford it.[70] ACP strongly opposes restrictive drug formularies that impose substantial economic barriers to obtaining needed medications, particularly for low-income enrollees.[71] The College supports policies that help low-income individuals maintain access to their prescription medications, including waiving cost sharing for generic drugs for Part D low-income subsidy enrollees and capping annual out-of-pocket spending.[72]

d. ***Any formulary restrictions should be transparent; clearly articulated to the patient regardless of their education or health literacy level; and proactively communicated to the patient, prescribing clinician, and pharmacist well in advance of, not fewer than 90 days before the change implementation, with evidence-based support substantiating the change. Supplemental educational materials should be available upon request.*** Ideally, the U.S. Department of Health and Human Services could develop an online portal where insurers would post and update formulary information on a regular basis. ACP has long underscored the importance of patient information and education, including understanding how out-of-pocket costs may affect the pharmacy benefit.[73] Patients who lose access to their preferred medication often take it intermittently or stop taking it altogether, which can have dangerous consequences.[74] In one study, 40% of patients stopped taking their medication due to nonmedical drug switching.[75] In another study of rheumatology patients who tried a nonpreferred drug, 11% never obtained treatment.[76] Certain patient populations, including those who are elderly, have low levels of education, and for whom English is not their first language, are particularly vulnerable. Plans should make a concerted effort to ensure all step therapy or drug switching requirements are communicated in such a way that is understandable and easily accessible to all patients regardless of primary language, education level, or technological access or ability. Plans should confirm with each individual patient and their physician a complete understanding of policies relevant to them.

Recommendation 3: The ACP recommends all step therapy and nonmedical drug switching protocols be designed with input from frontline physicians and community pharmacists; feature transparent, minimally burdensome processes that consider the expertise of a patient's physician; and include a timely appeals process.

a. ***Input from physicians who regularly prescribe those medications should be considered at the onset when designing step therapy or nonmedical drug switching protocols. Physician-to-physician consults during the appeals process does not suffice.*** This may take the form of electronic surveys, having clinician representatives at formulary decision meetings, or soliciting feedback from physician professional societies, particularly those representing medical specialties significantly affected by formulary changes involving a particular drug. Aside from physician-to-physician consults during the appeals process, physician input is rarely sought in step therapy and nonmedical drug switching protocols. In one 2017 survey, 91% of patients felt insurers should not have the final say in treatment decisions.[77]

b. ***"Failure" on a less expensive medication should be clearly defined, including maximum durations for testing each drug based on clinical evidence base, acuity of the condition, and input from physicians and pharmacists.*** The minimum duration required for patients to test the same step-therapy drugs varies widely by payer and plan. For the asthma-controlling drug omalizumab, some plans require a 3-month trial of a corticosteroid and a long-acting β-agonist, whereas others require a minimum of 6 months.[78] Payers and PBMs should look to align definitions for "failure" where possible based on clinical evidence base and physician expertise from physicians who frequently prescribe those medications.

c. ***Physicians and pharmacists should be proactively informed of changes to the formulary or coverage policies and provided with evidence-based justification for the change and a list of medication alternatives specific to that drug. Physicians should have the ability to request exemptions or appeal medication changes through clearly defined, streamlined, and timely processes that are ideally automated and in real time. Plans should respond within 36 hours, or 24 hours for emergency cases.*** In many cases, clinicians are not actively informed of medication changes. Generic notices about general formulary updates are insufficient and can often be difficult to access and interpret. After having a prescription rejected, clinicians must often try multiple substitute medications before finding one considered preferred by the formulary. If they want to appeal a decision, they must often endure many rounds of documentation and authorization hurdles that are further drawn out by processing delays due to the lack of adoption of electronic prior authorizations. Of payers and PBMs that had electronic preauthorization systems available in early 2013, only 18% were submitted via web-based preauthorization systems. Only 1% of pharmaceutical preauthorization requests were submitted electronically.[79] More than half of clinicians report experiencing difficulty obtaining approval for prescriptions on 25% or more of their requests and most report having to wait several days to receive approval.[80] Taken together, these administrative barriers can lead to substantial delays in patients accessing lifesaving medications. In addition to wasting time and delaying patient treatment, jumping through administrative hurdles to receive approval for a particular drug can be costly. Maintaining preferred drug lists and requesting prior authorization or other approvals for a particular statin or antihypertensive is estimated to cost $1,569 per physician per year.[81]

d. ***PBMs should avoid combining step therapy and nonmedical drug switching policies with additional formulary restrictions, such as prior authorization requests, which create undue burden.*** Prior authorization requests presents their own challenges when it comes to patient outcomes, burden, and cost. One *Health Affairs* study found that practices spend an estimated 20.4 hours per physician per week obtaining authorization, more than any other administrative activity aside from billing.[82] In a 2017 American Medical Association survey, 92% of physician respondents reported that prior authorizations lead to care delays that negatively affect patients and lead them to abandon treatment. The combination of prior authorization requirements with step therapy and other cost-controlling prescription drug mechanisms has been associated with adverse events, including hospitalizations and higher inpatient spending.[83]

Recommendation 4: The ACP recommends that data concerning the effectiveness and potential adverse consequences of step therapy and nonmedical drug switching programs should be made transparent to the public and studied by policymakers. Alternative strategies to address the rising cost of prescription drugs that do not inhibit patient access to medications should be explored.

a. ***Health plans, PBMs, and pharmaceutical manufacturers should be required to report information on drug pricing and coverage policies to support enhanced public transparency and research efforts, ideally reporting standardized information to an easily accessible, public database***.[84] Government entities and independent research organizations should use these data to study the effect of formulary restrictions on patient outcomes. Evidence regarding the effectiveness of step therapy, nonmedical drug switching, and other cost-curbing interventions has been inconclusive. CMS and others should closely study which interventions are most effective on different classes of drugs, medical conditions, and patient traits, as well as the potential risks and unintended consequences associated with specific step therapy or nonmedical drug switching protocols. Reporting formulary information, pricing, and coverage policies would help to support these research efforts and also address the lack of transparency and accountability surrounding step therapy and nonmedical drug switching policies and help patients and their care teams stay better informed.

b. ***Tools that help patients and clinicians work together to select cost-effective medications without restricting their access to others warrant further exploring, including formulary decision-support tools, patient educational materials, physician education programs, lower copay options, rebates, and in-kind medical services.*** ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication and urges health plans to make this information available to physicians and patients at the point of prescribing to facilitate informed decision making about clinically appropriate and cost-conscious care.[85] Improving the functionality of government and private payer websites to make it easier to compare prices across plans. Increasing funding for Local Seniors' Health Insurance Assistance Programs could go a long way in providing patients with the tools they need to select plans most tailored to their individual needs, understand coverage limitations and restrictions, and even help appeal coverage determinations.

   Lower prices incentivize patients to seek cost-effective alternatives without forcing them off their existing medication by artificially inflating prices for existing drugs. According to the Association for Accessible Medicines, 87% of patients save money when they switch to a generic alternative drug. More than half experiencing savings of $25 or more. Ninety percent of generic copays are under $20, compared with just 39% of branded drugs in the commercial and Part D markets.[86] Studies

show that patient abandonment rates are three times greater for branded drugs than for generics.[87] ACP strongly supports patient education to promote the safe integration of biosimilar use into clinical practice. However, not all biosimilars are interchangeable with the originator product. Any patient who takes a biosimilar should be closely monitored for adverse side effects.[88]

Physician education programs and formulary decision-support tools, including solutions as simple as a list of generic alternatives available at the point of care, can help physicians prescribe mediations that are safe, effective, and affordable. In one study, generic drug prescribing increased by 3.3% after physicians were given a color-coded breakdown of a preferred formulary list. The increase translated to a savings of $845,000.[89] Several payers have had success financially rewarding physicians for prescribing generic or other cost-effective drugs. In 2007, Michigan's Blue Care Network offered physicians $100 for every patient switched from a brand-name to a generic cholesterol-lowering medication. As a result, the company saved $5 million in drug costs and $1 million in patient copays over just 5 months.[90] New York's Excellus BlueCross BlueShield increased office visit rates for practices that increased generic fill rates by 5% or greater and estimated that this pilot reduced patient out-of-pocket costs by 10% to 12%.[91] A national survey of pay-for-performance programs found that bonuses for generic prescribing were common among them.[92] However, such incentive programs must be carefully designed with robust patient protections in place to ensure patients continue to have access to lifesaving medications.

c. ***Policymakers should explore separate, complementary efforts to address the root causes of excessive and unreasonable price hikes for pharmaceuticals, which ACP explored in a 2019 position paper series.*** ACP recommended[93, 94, 95] several policy solutions for addressing the rising costs of prescription drugs, including increased price transparency, a ban on gag clauses, modified cost sharing for Medicare Part D to encourage generics, Part D price negotiation, and further study of alternative payment models that incorporate drug costs. The College has also written to Congress[96] recommending improved access to generics, increased marketplace transparency, and enhanced market competition, specifically by improving access to single source drugs, increasing oversight of companies that engage in "product-hopping" or "evergreening," and enforcing restrictions against pay-for-delay practices. In our response to the Department of Health and Humans Services' Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, ACP warned against the harm of direct patient drug advertising and emphasized the importance of patient education for biosimilars.[97] There has been some progress on this front. In 2018, CMS began issuing unique Healthcare Common Procedure Coding System codes to each individual biosimilar product, rather than grouping together all biosimilar products with the same reference product to calculate a single average sales price.[98] This is expected to encourage development of biosimilars and ensure a more robust, competitive biosimilar market with more competitive pricing.

d. ***The long-term effects of step therapy and nonmedical drug switching policies on patient safety and total costs, including any added costs that result from adverse health events, should be a topic of future study.*** Some drugs are inexpensive initially, but increase the number of complications and inpatient visits in the long-term and end up increasing costs overall. Formulary restrictions, such as nonmedical drug switching, have been correlated with higher drug costs, more office visits, and more frequent hospitalizations among patients with chronic disease.[99] An *American Journal of Managed Care* study found that while step therapy caused an initial 3.1% drop in costs for antihypertensive medications, patients had more emergency department visits and inpatient hospital admissions, resulting in an increase of $99 more per user in quarterly expenditures compared with the control group.[100]

VI. Conclusion

Price-based step therapy and drug switching protocols can save costs by encouraging the use of cost-effective biosimilars, generics, or other drugs. However, stringent one-size-fits-all policies that fail to take into account a physician's clinical expertise and patient's unique medical history can be ineffective and irresponsible because they can restrict patient access to lifesaving treatments, increase the likelihood of adverse health effects, and end up costing more in the long-term as a result. As these cost-cutting policies are increasingly implemented by public and private insurers, ACP recommends insurers, PBMs, and policymakers implement the recommendations put forth in this paper to ensure reasonable guardrails are in place to help protect patient safety while minimizing unnecessary burden and costs on physician practices.

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