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PATIENT ACCESS TO CARE AND TREATMENTS IN THE COST-SHIFTING ERA:

Preserving the Patient-Provider
Decision-Making Relationship





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The Problem

The patient-provider relationship is the cornerstone of quality healthcare. A 2017 survey from the Council of Accountable Physician Practices (CAPP) found that consumers believe patient-provider relationships are the single most important factor in quality care.¹

Through shared decision-making the patient and provider will develop a plan of care which meets their needs and expectations. Care guidelines are often used to establish safe and effective therapeutic plans. However, even peer reviewed guidelines acknowledge limitations and the need to individualize treatment decisions.

Patients with rare, complex, and chronic diseases often need high-cost specialty medications to manage their conditions and maintain their health. Chronic disease management and the associated complex medication regimens account for most health insurance expenditures.

To maintain the cost-effectiveness of health insurance, many organizations, including government agencies, routinely evaluate and choose to adopt alternative treatment modalities such as utilization management.^{2,3}

If utilization and cost-saving measures are not implemented wisely, patients with more complicated conditions may be placed at risk. One example is the rising cost of deductibles. Middlemen, like pharmacy benefit managers and insurers, have been shifting more of the costs to patients, with deductibles increasing 360 percent since 2006.⁴

In 2017, 69 percent of commercially insured patients did not fill their new prescriptions when they had to pay more than \$250 out of pocket. Most patients who

abandon a prescription do not fill any prescription within three months, leading to nonadherence to the agreed treatment plan.⁵

Patients' nonadherence to prescribed medications contributes to poor health outcomes and increased health care system costs. A chronically ill patient who stops taking medication may experience disease progression, causing the patient to increase his or her number of doctor visits, hospitalizations, or emergency room visits. In addition to poorer clinical outcomes there are increased total health care system costs. A 2014 analysis by Iuga and McGuire found that between \$100 and \$300 billion of avoidable U.S. health care costs are attributed to medication nonadherence annually.⁶

¹ 2017 Consumer Healthcare Priorities Study: What Patients and Doctors Want from the Health Care System. http://accountablecaredoctors.org/wp-content/uploads/2017/11/capp-research_what-patients-and-doctors-want.pdf.

² Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion. Chronic diseases: the power to prevent, the call to control: at a glance 2009. Available at: <http://www.cdc.gov/chronicdisease/resources/publications/aag/chronic.htm>. Page last updated December 17, 2009. Accessed June 21, 2012.

³ Mueller C, Schur C, O'Connell J. Prescription drug spending: the impact of age and chronic disease status. *Am J Public Health*. 1997;87:1626-1629.

⁴ <https://www.letstalkaboutcost.org/en>

⁵ IQVIA "Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption (May 2018)

⁶ Iuga AO, McGuire MJ. Adherence and health care costs. *Risk Management and Healthcare Policy*. 2014;7:35-44. doi:10.2147/RMHP.S19801

Background

Health care spending in the United States is high and continues to increase, as does the spending for prescription drugs and medical supplies. In 2018, National Health Expenditures (NHE) grew 4.6 percent to \$3.6 trillion in 2018, or \$11,172 per person, and accounted for 17.7 percent of Gross Domestic Product (GDP), of which \$335 billion was spent on prescription drugs.⁷ Prescription drug spending increased 2.5 percent in 2018, faster than the 1.4 percent growth in 2017.⁸ Retail spending for other non-durable medical products, such as over-the-counter medicines, medical instruments, and surgical dressings, increased 3.6 percent to \$66.4 billion in 2018, compared to a rate of 2.2 percent in 2017. Ostomy prosthetic products and tube feeding supplies would fall under this growth category as well. In past years, prescription drug spending growth has generally kept pace with other medical spending but the Centers for Medicare and Medicaid Services (CMS) projects that in the future retail prescription drug spending will be the fastest growing health category and will outpace other health spending.⁹

While the provider-patient relationship is the cornerstone of patient care, there are many stakeholders in the management of prescription medications and medical products such as ostomy prosthetic products. Stakeholders include patients, prescribers, pharmaceutical companies, product and medical device manufacturers, insurance carriers and employers/ premium payers. One goal common to all of them is to control the rising costs to patients and payers while maintaining quality and access to care. According to an NHE report, out-of-pocket spending grew 2.8 percent

to \$375.6 billion in 2018, or 10 percent of total NHE. A second goal is to limit unnecessary medications.

“Factors underlying the rise in prescription drug spending from 2010 to 2014 can be roughly allocated as follows: 10 percent of that rise was due to population growth; 30 percent to an increase in prescriptions per person; 30 percent to overall, economy-wide inflation; and 30 percent to either changes in the composition of drugs prescribed toward higher price products or price increases for drugs that together drove average price increases in excess of general inflation.” Medications account for 16.7 percent of overall personal health care services.¹⁰

The IMS Institute for Healthcare Informatics estimated healthcare costs caused by improper and unnecessary use of medicines exceeded \$200 billion in 2012.¹¹ This amount was equal to 8 percent of the nation’s healthcare spending that year. This is viewed by stakeholders as an opportunity for savings.

Stakeholders have created programs designed to address these unnecessary costs as well as limit rising costs. These interventions have not been subjected to in depth studies to assess the impact on patient outcomes and quality of life or the total cost of care. A lack of transparency in the process makes investigation difficult but recent studies of broad industry data have shown negative impacts on patients when the drugs they need are subject to restriction. GoodRx found that 42 percent of drugs covered in 2019 had various restrictions on reimbursement.¹²

⁷ NHE Fact Sheet. (n.d.). Retrieved October 12, 2020, from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>.

⁸ National Health Expenditures 2018 Highlights. (n.d.). Retrieved October 13, 2020, from <https://www.cms.gov/files/document/highlights.pdf>.

⁹ American Academy of Actuaries; “Prescription Drug Spending in the U.S. Health Care System An Actuarial Perspective.” Accessed at: <https://www.actuary.org/sites/default/files/files/publications/PrescriptionDrugs.030718.pdf>.

¹⁰ U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, ASPE Issue Brief: Observations on Trends in Prescription Drug Spending, (2016). <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

¹¹ Avoidable Costs in U.S. Healthcare: The \$200 Billion Opportunity from Using Medicines More Responsibly. Report by the IMS Institute for Healthcare Informatics. June 2013.

¹² The Big Pinch: New Findings on Changing Insurance Coverage of Prescription Drugs. Tori Marsh, MPH, Amanda Brooks, MPH, Diane Li, Jeroen van Meijgaard, PhD, Amanda Nguyen, PhD, and Thomas Goetz, MA, MPH. GoodRx Research March 2020.

Common Medication and Medical Supply Utilization Programs and Cost-Shifting Tactics

Quantity Limits:

For safety and cost reasons, plans may set quantity limits on the amount of drugs they cover over a certain period of time. For example, standard dosage for a medication may be two tablets per day, or 60 tablets per month. Plans may set this as a quantity limit for that medication. These policies are generally similar across benefit plans, but implementation standards should be monitored to prevent delays in care or adverse events. Most ostomy products and tube feeding supplies have a monthly allowable limit under Medicare/Medicaid and commercial plans typically follow the same guidelines.

Those requiring more than the standard amount may need to ask their provider to apply for a quantity limit exception. In the case of ostomy supplies, adequate justification notes for the overage need to be included in the medical record; otherwise, the claim will be denied and the patient will be responsible for paying the overage.

If you need an emergency prescription refill, there are ways that a pharmacist can help handle this. Reasons you might need an emergency refill include:

- You lost your medication.
- Your medication was stolen.
- You need a backup supply of your medication.
- Your pharmacy has closed unexpectedly, and you need to pick up your medication at a different pharmacy.

Pharmacists can use their clinical judgment in accordance with state laws to dispense emergency refills of up to a 30-day supply (except for controlled substances). This emergency prescription refill law, known as Kevin's Law, allows pharmacists to authorize an emergency fill of certain chronic medications if a doctor cannot be reached to authorize a prescription. Each state's law may differ on:

- The specific medications allowed
- How much of the medication can be dispensed
- How often you can get an emergency refill

- If the medication will be covered by insurance

Step Therapy:

Fail First policies, also known as Step Therapy, are insurance policies which require a certain drug to be used first without success before other drugs in the sequence can be prescribed without consideration of the treatment rationale. In theory, step therapy makes perfect sense—from a health plan's point of view. A physician starts a patient on the lowest-cost medication for the condition in question, and if the patient fails on that drug, the doctor tries the next most-expensive medication. If health plans insist on physicians using older, lower-cost drugs first, the burden should be on the health plan to respond to physicians' requests for different medications quickly, nimbly, and appropriately.

Characteristics of an ideal Step Therapy protocol:

- Conceived and implemented intelligently
- Uses evidence-based criteria
- Clinically reasonable provisions for exceptions
- Encourages more rational prescribing
- Helps control medication costs
- Patients receive the most data-driven regimens

Step Therapy Failures:

- Based on poor evidence of efficacy or cost
- Inflexible implementation
- Patients forced to return to prior ineffective medications
- Formulary changes within a plan force change in stable patients
- Changes in employer or plans force change in stable patients
- Medication costs are in a different silo from decisions, outcomes and costs for which a physician is responsible (e.g. Medicare Part D carve out)

Step Therapy Patient Stories



Patient (initial “J”) had a very serious case of ulcerative colitis in March 2017. J’s specialist wanted her to start on Entyvio due to the other diseases she has. The insurance refused to pay for it and wanted J to try Mesalamine, then Humira, then Stelara, before going on Entyvio. J’s gastroenterologist wrote several appeal letters to her prior insurance company explaining that it was too risky for J to try the other medication. J came down with c diff from the antibiotics they were using trying to heal J’s colon. As a result of delaying treatment, J came within 24 hours of losing her entire colon if last ditch steroids did not kick in. (Being diabetic, they did not want to use steroids until they had no choice). The steroids caused psychosis, which required benzodiazepines. The whole situation was a three week inpatient nightmare. It took approximately six months and several letters from different specialists in order to get the medication J needed approved. It worked by the way, J had infusions for a year, and has been in remission since.



In 2019, **patient (initial “R”)** was diagnosed with Psoriatic Arthritis by his specialist and prescribed a medication that would not conflict with his asthma medication nor exacerbate his respiratory problem. The insurance company required that R take a cheaper drug which would cause or conflict with his Asthma and prescribed medications. Therefore, R had to have his specialist mediate the situation by providing documentation to the insurance company. It took several months before the original prescribed medication was approved. In the mean time R could not afford the prescribed medication nor take the ones mandated by the insurance company resulting in his arthritis becoming so severe that it was difficult to work or use his hands, as R’s fingers became permanently deformed and painful.”



Patient (initial “B”) has needed Nexium since she was a teenager. She is now 49. As she has grown and switched providers, jobs, and insurance companies, she has repeatedly had to “fail” on several (three or four) other medications before she can get insurance coverage for Nexium. The other medications have never worked for her. The last time her doctors discussed this with her, she decided not to go through the trials again. B has some Nexium saved up, and takes it only when she needs it direly. She says her condition would be better managed if she were able to take Nexium regularly. Note that one time, her doctors pulled one of the “step” drugs she was trialing because they were worried it was pulling calcium out of her bones.

Evidence shows, however, that impeding the doctor-patient relationship and delaying access to essential treatments can increase costs in the long run for all stakeholders, especially patients.¹³

Medication Tiers:

Under a healthcare plan, the list of covered prescription drugs is called a formulary. The formulary is usually divided into tiers or levels of coverage based on the type or usage of the medication. Each tier will have a defined out-of-pocket cost that the patient must pay before receiving the drug. Common tiers descriptions include:

- **Generic drugs:** Drugs product that are no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.
- **Brand-name drugs:** Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Cross-licensing occasionally occurs, allowing an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.
- **Preferred drugs:** Drugs included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute.
- **Nonpreferred drugs:** Drugs not included on a formulary or preferred drug list; for example, a brand-name drug with a generic substitute.
- **Fourth-tier drugs:** New types of cost-sharing arrangements that typically build additional layers of higher copayments or coinsurance for specifically identified types of drugs, such as lifestyle drugs or biologics.
- **Specialty Tiers:** Specialty drugs such as biologics may be used to treat chronic conditions and often require special handling and administration and are typically high cost.

The use of medication tiers is expanding. In 2004, only 3 percent of covered employees were in plans with four or more tiers. By 2012, the figure was 14 percent, and in 2016, 32 percent of employees were in such plans. Coinsurance is more common on higher tiers. About one-quarter of covered workers in employer-sponsored plans face coinsurance for drugs on the second and third tiers, and 46 percent have coinsurance for fourth-tier drugs. In plans with a specialty drug tier, 46 percent also used coinsurance on that tier. Coinsurance rates for fourth-tier drugs average 29 percent. For specialty drugs, they average 26 percent. This means that on average a patient would pay about \$1,000 for a specialty prescription of about \$3,500.¹⁴

Medication Tiers Patient Story



Patient (initial “B”)'s doctor has been able to get the insurance company to move a more expensive drug to a lower tier because the comparable drug from the lower tier has something in it that she can't have. Her GI wrote to the insurance company and negotiated this exception, but it took a lot of his time and a lot of effort. She feels fortunate he did this for her.

Non-Medical Switching for Drug Treatments:

“Non-medical switching” broadly refers to a change in a stable patient's medication for non-medical reasons, including a change in the patient's insurance plan or the availability of a less expensive but therapeutically equivalent drug. Non-medical switching may also be called “formulary-driven switching,” “therapeutic switching,” or just “switching.”

¹³ Carlton, R. I., PharmD, Bramley, T. J., PhD, Nightingale, B., PhD, Conner, T. M., PhD, & Zacker, C., PhD. Review of Outcomes Associated With Formulary Restrictions: Focus on Step Therapy.

¹⁴ <https://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/>.

Non-medical switching requires a stable patient to switch from his or her current, effective medication to a cheaper, alternative drug. An insurer effectuates nonmedical switching by moving a drug to a higher cost tier, increasing the out-of-pocket costs owed after the plan year has begun, or dropping a medication from the formulary altogether. Nonmedical switching does not involve switching a patient from a brand-name drug to a generic drug, but instead, from one drug to an entirely different, therapeutic equivalent. Nonmedical switching is done without consideration of the medical repercussions or reasoning behind the prescriber's selection of the original medication, and often without the prescriber's or patient's knowledge.¹⁵

It can take patients and their doctors years to find the right therapy to manage their chronic conditions, often through an exhaustive process of trial and error. In an effort to lower their costs, third-party payers have begun refusing to cover the treatment the patient is stable on in favor of different therapies that are cheaper or listed on a formulary. Formulary switches can be justified through clinical evidence, but they are often employed for non-medical reasons. Non-medical switching neglects the painstaking process that patients and physicians undergo to come to a preferred treatment method and often risks a patient's ability to effectively manage their disease.

While non-medical switching may decrease the cost of certain medications, some medical research indicates that it may also have unintended effects on clinical and economic outcomes, health care utilization, and patients' medication adherence. Such effects may include disease progression, adverse side effects to new medications, increased medication costs, and nonadherence to medication protocols.

A 2016 analysis by Nguyen et al. reviewed 29 existing scientific studies on non-medical switching that included 253,795 patients between 2000 and 2015. The authors found that non-medical switching was generally

associated with negative or neutral clinical and economic outcomes and not with positive outcomes.¹⁶ This was particularly true for chronically ill patients who were medically stable before the medication switch occurred.

Non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that led to subsequent treatment change as well as increases in health care utilization.¹⁷ Cost-related switching of medications in otherwise stable pts may have unintended consequences and should be avoided.

Non-Medical Switching for Medical Supplies:

Ostomy products are defined as prosthetic devices under the Social Security Act since they replace the lost functions of waste storage and elimination.¹⁸ They are prescribed by medical professionals to address ostomates' tailored medical needs. They are not a one-size-fits-all, off-the-shelf, or over-the-counter generic product nor are they easily interchangeable. Patients along with their medical team often go through a lengthy process of trial and error to find the properly fitted pouching system.

Unfortunately, patients have reported a practice by some third-party payers of refusing to cover the products that are components of these carefully designed pouching systems in favor of different products that are oftentimes less expensive. Patients living with an ostomy for example may find themselves in a healthcare facility that does not provide a person's pouching system that works for them but rather switches and provides the formulary brand that they offer, or they may experience suppliers that switch what was ordered by the medical professional and patient with a different brand. Insurers may restrict consumers to specific brands or specific suppliers, which limits patient access to the products they need, as patients often must use products from multiple manufacturers. If a patient refuses, they are expected to

¹⁵ (2016-2017) Now or Never: The Urgent Need for Action against Unfair Coverage Denials for Quality Health Care.

¹⁶ Nguyen E, E Weeda, et al. "Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: a Systematic Literature Review, *Current Medical Research and Opinion*, 32:7, 1281-1290.

¹⁷ P354 Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents D.T. Rubin, M. Skup, , S. Johnson, J. Chao, A. Gibofsky Abstracts of the 10th Congress of ECCO - European Crohn's and Colitis Organisation S255.

¹⁸ Title XVIII, §1861 (s)(8) of the Social Security Act defines prosthetics as those, which replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, and replacement of such devices.

shoulder the cost of the treatment on their own. If they can't afford to purchase the effective products, they are forced to utilize ineffective products.

This practice, "non-medical switching," removes the collaborative process between the medical professional and patient substituting a cost-cutting strategy by non-medical staff. This often results in increased MD visits, ER visits and possible rehospitalization and surgery. The consequence of this practice is that some ostomates are unable to obtain their prescribed prosthetic devices and are no longer able to effectively manage their ostomy. This negates the purpose of a prosthetic device and jeopardizes their health and well-being.

Additionally, "non-consented switching" means that patients do not receive any instruction from their

medical provider about how to use the new product. In the case of ostomy supplies, this may result in a lack of understanding in the proper technique of pouch application and improperly sized pouching systems resulting in a poor fit and seal, which can lead to leakage, effluent on skin, peristomal skin complications and increased healthcare costs.¹⁹

Although there are no studies currently, specific to the practice of the switching of ostomy products, a study was completed with asthma patients whose inhaler products were switched, and the patients experienced negative outcomes.²⁰ With ostomy patients the clinical experience is clear and some patients are found to experience peristomal skin complications following the non-medical substitution of products.

Non-Medical Switching Patient Story



Patient (initial "B") has a central line for administration of parenteral nutrition. It can be problematic when an infusion company changes a brand of medical supply without (1) notifying the patient; or (2) training the patient.

- B has had syringes delivered that do not properly connect to other parts of the PN administration set. She has had to make it work with tape and creativity; taping and jerry rigging increase the risk of catheter related bloodstream infections (CRBSI); and they only work for B because she is very experienced and understands how to make things work. (If she were new to home PN, she would not have been able to administer her PN in these circumstances.)
- Sometimes the infusion company will switch brands of dressing kits. B is allergic to chlorahexadine and has a reaction to certain dressings. She needs specific supplies in her dressing kit (*i.e.*, betadine and alcohol, with a separate tegaderm).
- Once, with a new brand of extension set and "Y" connector, B could not get the PN to flow once she was hooked up. She had to take it apart (again, increasing risk of CRBSI with additional manipulation of the line) and test each part of the system to discover that the problem was the extension set, which did not work with her clamp.

¹⁹ Steinhagen E, Colwell J, Cannon LM. Intestinal Stomas-Postoperative Stoma Care and Peristomal Skin Complications. Clin Colon Rectal Surg. 2017;30(3):184-192. doi:10.1055/s-0037-1598159.

²⁰ Doyle S, Lloyd A, Williams A, et al. What happens to patients who have their asthma device switched without their consent?. Prim Care Respir J. 2010;19(2):131-139. doi:10.4104/pcrj.2010.00009.

Further, research has also shown that non-consented switching and switching for non-medical reasons is associated with direct negative effects on many important outcomes including disease control and results in increased healthcare costs.^{21,22}

Non-Medical Switching Patient Story



Patient (initial “J”) is a veteran and cancer survivor. He worked with his ostomy specialist to find and decide on what products would be

best for him. His ostomy specialist put in an order with the VA (Veterans Affairs) Pharmacy in MN for “Brand X” products. J received 4 of the 5 components he needs for his ostomy but they were all Brand Y products, then a day later by USPS he received the Brand Y pouches. Although, they are an equivalent and the right size, he doesn’t understand why if he and his medical professional requested Brand X why he got Brand Y. If the VA won’t help him resolve this, he has to “go into my pocket” to pay for them.

Prior Authorization:

Certain drugs may require prior authorization before a health plan will pay for them. The intent is to make sure that the therapy is medically necessary, appropriate for the patient, and follows clinical guidelines. Prior

authorization programs seek to manage costs and better align care to best practices, usually by requiring justification for a therapy when a lower-cost option or preferred option is available. Prior authorization programs also seek to improve patient health by minimizing harmful drug interactions, side effects, unproven off-label uses, or overmedication. Use of prior authorizations is growing. Published estimates predict a 20 percent per year increase.

The Council for Affordable Quality Healthcare, Inc. (CAQH) reported in the 2019 CAQH Index, their 7th update, on the changes in the administrative burden in the healthcare industry. Physicians and their staff spend on average 14.6 hours per week securing 29.1 authorizations per physician each week. This amounts to as much as \$85,000 each year to support a full-time physician.²³

The cost for providers to manually generate a prior authorization increased from \$6.61 in 2018 to \$10.92 in 2019. This is a large disincentive for providers to use the prior authorization process leading to barriers to newer treatments and increases in referrals to subspecialty centers.

The policies adopted by insurance carriers are also not uniform. There is a wide variation in authorization requirements, which creates confusion which greatly increases the burden on the patient. Response times are also not regulated despite an industry standard of a 2 day response.²⁴

A study of 23 health plans conducted by McKesson counted 1,300 procedure-specific authorization policies, with only 8 percent of those policies shared in common.²⁵

This is despite a consensus statement issued by the American Medical Association, the American Hospital Association, America’s Health Insurance Plans, the

²¹ Nguyen E, Weeda ER, Sobieraj DM, Bookhart BK, Piech CT, Coleman CI. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. *Curr Med Res Opin.* 2016;32(7):1281-1290. doi:10.1185/03007995.2016.1170673.

²² Björnsdóttir US, Gizurarson S, Sabale U. Potential negative consequences of non-consented switch of inhaled medications and devices in asthma patients. *Int J Clin Pract.* 2013;67(9):904-910. doi:10.1111/ijcp.12202.

²³ 2019 CAQH INDEX® Conducting Electronic Business Transactions: Why Greater Harmonization Across the Industry is Needed. © 2020 CAQH.

²⁴ <https://www.caqh.org/about/press-release/caqh-core-approves-two-day-rule-accelerate-prior-authorization-process>.

²⁵ Rogers, Jennifer. 2017. “Tackling Prior Auth: New Solutions to Address Provider-Payer Friction.” Chilmark Research. Accessed April 23, 2018. https://www.chilmarkresearch.com/chilmark_report/tackling-priorauth-new-solutions-to-address-provider-payer-friction/.

Medical Group Management Association, the Blue Cross Blue Shield Association and the American Pharmacy Association calling for meaningful improvement in prior authorization programs and processes.²⁶

Overall industry use of electronic transactions which reduces practice costs increased only slightly from 12 percent in 2018 to 13 percent in 2019 according to the CAQH report.

Prior Authorization Patient Story



Patient (initial “B”)’s doctors wanted her to go into acute rehab after a long hospitalization; she was 44. Insurance wanted her to go to a nursing home. Her doctors felt she would not get the level of OT and PT she needed to regain her ability to walk, and, because she was on parenteral nutrition and had a central line, they were concerned about infection if she were to go into a nursing home (increased risk). She appealed the insurance decision and there was a meeting with several of B’s doctors, insurance reps, and family. It was still denied. Patient requested transcripts from the meeting and found major inaccuracies (where stenographer recorded the exact opposite of what the doctors had said—instead of she “did” need something, the record said she “did not” need it). When they saw it, the doctors all sent faxes to the company complaining; B made several calls to the insurance company, but still without success. Finally, when the only option open to B seemed to be an external review of the appeal, an insurance executive called her and said it was approved, on the condition that the external review process stop. B’s suggestion—that there be some oversight of the prior authorization review process. Note that the medical center where B had been hospitalized sent a letter of grievance to state authorities about the event.

Cost Shifting and Co-Pay Accumulator Adjustment Programs:

Cost shifting has existed for more than 20 years and occurs when a firm raises its prices to one buyer because it lowers the price to another buyer. Cost-shifting is a component of cost-sharing, which is the amount or percentage an insured person must pay toward prescription drugs that are covered by a health insurance policy.²⁷

In 2018, pharmacy benefit managers (PBMs) rolled out new copay accumulator adjustment programs. These target specialty drugs for which a manufacturer provides

copayment assistance.²⁸ Plan sponsors—employers and health plans save big money because accumulators shift a majority of drug costs to patients and manufacturers. It also prevents patients from being able to apply these payments to their deductibles and out-of-pocket maximums which forces them to take on more of the cost themselves. Accumulator adjustment programs will further lower a plan’s drug spending by discouraging the appropriate utilization of specialty therapies and reducing adherence. These programs also go by a variety of other names, including, “out of pocket accumulators,” “co-pay maximizers,” and “specialty copay card programs.”

²⁶ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

²⁷ Cost Shifting: New Myths, Old Confusion, And Enduring Reality. Michael A. Morrissey Downloaded from HealthAffairs.org on July 22, 2020.

²⁸ Copay Accumulator Adjustment: Consequences of a New Cost-Shifting Pharmacy Benefit. Adam J. Fein, PhD.

The median U.S. household income is about \$58,000. It's clear that many will struggle to pay thousands of dollars out-of-pocket in the middle of a benefit year. QVIA analyses demonstrate that this phenomenon is already occurring. More than one in four specialty brand prescriptions are abandoned during the deductible phase. That is three times the rate of prescription abandonment when there is no deductible. Higher utilization of specialty drugs is usually considered a positive trend. That is because it is well established that pharmaceutical spending reduces medical spending and improves patients' health. The massive cost-shifting to patients, however, will reduce spending by decreasing the utilization of specialty drugs but lead to poorer outcomes for the patients including health deterioration and hospitalization, as well as increased system costs.

Co-Pay Accumulator Patient Story



Patient (initial "N") takes a growth hormone via an injection pen. The pens, which are expensive, qualify for co-pay assistance

through the manufacturer. The insurance company does not count the co-pay as part of the patient's insurance deductible.

The Path to Improvement

Preventing harm to patients is an ancient core principle in the delivery of healthcare. The concept was taught by Hippocrates, often described as the father of modern medicine, and encapsulated more recently in the Latin phrase "*Primum non nocere*" or "Above all, do no harm."²⁹

Formal review of hospitals and physicians began more than one hundred years ago and expanded after reports by such notables as Florence Nightingale, Abraham Flexner and Ernest Codman documented the "deplorable state of the nations medical schools and major hospitals."^{30,31,32}

Dedicated consumer protection in the medication realm was established with the creation of the FDA. Though the FDA can trace its origins back to the Agricultural Division in the Patent Office in 1848, its origins as a federal consumer protection agency began with the passage of the 1906 Pure Food and Drugs Act. The mission statement of the FDA states that the "FDA is responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."³³ Over the last century, formal and fair processes have been established for evaluation of new medications and treatments. Post marketing surveillance and registries track patient data to ensure an ongoing safety review. The identification of new safety concerns may even result in the removal of medications from the market.

Ongoing data collection and unbiased studies and trials help us to understand the benefits as well as the side effects and adverse events from diagnosis and treatment. Change comes because of transparency, peer review and accountability. Physician professional societies guided by this information have begun establishing diagnosis and treatment guidelines to facilitate best practices in patient care.

Patient advocacy groups were created to facilitate patient education but also to bring the voice of patients and their families to the caregiving arena. Their voices firmly established the concept of informed consent in testing and treatment. Informed consent dictates that the patient must be a participant in the decision-making

²⁹ Smith C.M. Origin and uses of *primum non nocere*—Above all, do no harm!. J Clin Pharmacol. 2005; 45: 371-377.

³⁰ Nightingale, Florence. Notes on Hospitals. London: Longman, Green, Longman, Roberts and Green, 1863.

³¹ Flexner A: Medical Education in the United States and Canada: Report to the Carnegie Foundation for Advancement of Teaching. New York, NY, Merrymount Press, 1910.

³² Codman EA (1916). A study in hospital efficiency. Boston: privately printed.

³³ [https://www.fda.gov/media/93524/download#:~:text=2-.FDA percent20Mission percent20Statement.and percent20products percent20that percent20emit percent20radiation.](https://www.fda.gov/media/93524/download#:~:text=2-.FDA%20Mission%20Statement.and%20products%20that%20emit%20radiation.)

process so that a free choice is made. Continued study of the benefits of patient inclusion has identified improved outcomes and lower costs to the healthcare system so that patient engagement is now a foundational principle in healthcare policy.³⁴

More than a decade ago, The Triple Aim, which prioritizes the patient experience, became an industry recognized goal.^{35,36} This core concept is included in the Affordable Care Act of 2010 but has yet to be fully implemented.

Despite the clearly recognized advantages, health care providers and patients face significant obstacles in putting patient participation and informed consent into practice. Utilization management programs such as prior authorization and step therapy which are established by pharmacy benefit stakeholders for the purposes of cost and utilization control create significant barriers for patients that delay the start or continuation of necessary treatments and negatively impact patient health outcomes.

The Basis for Change

While such programs represent an important tool for cost and utilization management, they have been shown to negatively impact patient care and satisfaction and are a significant burden to healthcare providers such as physicians, hospitals, and pharmacies. Multi-stakeholder groups have met to develop a framework for change. The American Medical Association in conjunction with multiple national and state medical societies met to develop guiding principles for change to ensure that patients have timely access to treatment and that administrative costs to the healthcare system are reduced. More than 100 stakeholder groups have signed on to this effort. The Prior Authorization and Utilization Management Reform Principles document details 21 broad principles that address the following areas: Clinical validity, Continuity of care, Transparency and fairness, Timely access and

administrative efficiency, and Alternatives and exemptions. These principles are summarized below.³⁷ These principles apply to each of the areas detailed above.

The DDNC recognizes the significance of these and other consensus building initiatives which bring together a diverse array of the nation's health system stakeholders. The DDNC supports recommendations to ensure formularies are designed around clinical criteria, and to develop expedient appeals processes. However, recognizing the severe and irreversible health consequences that too often result from poorly implemented medical management, the DDNC opposes non-medical switching, as well as cost-shifting tactics which lead to greater patient out of pocket costs. See the DDNC's consensus statement on policy solutions for these issues linked below.³⁸

Clinical Validity:

- Programs should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to all.
- Utilization management should be flexible and include timely appeals and overrides.
- The appeal process should involve a peer reviewer with appropriate background (for example, the same specialty) with authority to override (not to merely re-state the policy).
- Ordering providers should have direct access such as a toll-free number with access to a reviewer of the same training for discussion.

Continuity of Care:

- There should be a minimum of a 60-day grace period on authorizations for those who are established and stable on therapy. Treatment should not be interrupted during the review process.

³⁴ Informed Consent: Past and Present. Nandini K. Kumar. *Perspect Clin Res*. 2013 Jan-Mar; 4(1): 21–25.

³⁵ Stiefel M, Nolan K. A Guide to Measuring the Triple Aim: Population Health, Experience of Care, and Per Capita Cost. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012.

³⁶ Donald M. Berwick, Thomas W. Nolan, and John Whittington. The Triple Aim: Care, Health, And Cost. *HEALTH AFFAIRS VOL. 27, NO. 3: HEALTH REFORM REVISITED*.

³⁷ <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>.

³⁸ <http://www.ddnc.org/third-party-payer.html>.

- Medications or services removed during an enrollment period should be covered without restrictions for the duration of the benefit year.
- A prior authorization approval should be valid for the duration of the prescribed/ordered course of treatment.
- Patients should not be required to repeat step therapy protocols or retry failed therapies before qualifying for a current effective therapy.

Transparency and Fairness:

- Review entities should publicly disclose current and timely patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services.
- Review entities should provide, and vendors should display, accurate, patient-specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing.
- Utilization review entities should make statistics regarding prior authorization approval and denial rates available. Statistics shall include the following:
 - Health care provider type/specialty;
 - Medication, diagnostic test or procedure;
 - Indication;
 - Total annual prior authorization requests, approvals and denials;
 - Reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and
 - Denials overturned upon appeal.

These data should inform efforts to refine and improve utilization management programs.

- Reviewers should provide detailed explanations for denials. All denials should include the clinical rationale for the adverse determination such as national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment and detail the provider's appeal rights.

Timely Access and Administrative Efficiency:

- Reviewers should accept and respond to override requests exclusively through secure electronic transmissions using the standard electronic transactions for pharmacy and medical services benefits.
- Eligibility and all other medical policy coverage determinations should be performed as part of the prior authorization process.
- To allow sufficient time for care delivery, a reviewer should not revoke, limit, condition or restrict coverage for 45 business days from the date of authorization.
- For non-urgent care, a determination and notification should be within 48 hours. For urgent care, the determination should be made within 24 hours.
- An expedited appeal decision should be communicated within 24 hours. Providers and patients should be notified of all other decisions within 10 calendar days. All appeal decisions should be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider and (b) was not involved in the initial adverse determination.
- Prior authorization should never be required for emergency care.
- Reviewers are encouraged to standardize criteria across the industry to promote uniformity and reduce administrative burdens.

Alternatives and Exemptions:

- Utilization management programs to “outlier” providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix and other relevant factors.
- Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, such as but not limited to “gold-card” or “preferred provider” programs or attestation of use of appropriate use criteria, clinical decision support systems or clinical pathways.
- A provider that contracts with a health plan to participate in a financial risk-sharing payment plan should be exempt from prior authorization and step-therapy requirements for services covered under the plan's benefits.

Going Forward

Stakeholder groups are making efforts to utilize these principles to define concrete changes for reform. One example is the Consensus Statement on Improving the Prior Authorization Process—created by the American Medical Association (AMA), American Hospital Association (AHA), America’s Health Insurance Plans (AHIP), American Pharmacists Association (APhA), BlueCross BlueShield Association (BCBSA) and Medical Group Management Association (MGMA).³⁹ This diverse group agreed to promote and develop specific changes to the prior authorization process with the goal of meaningful reform.

Without legislative and regulatory reform these efforts are likely to have limited impact. Patients with serious, life-threatening, chronic, complex, and disabling conditions are threatened by out-of-pocket cost shifting. Access and adherence to medically necessary treatment is limited with worsened health outcomes. Cost sharing creates a two-class system with respect to prescription medications: patients with adequate resources can access the full spectrum of health benefits from innovative advances in biotechnology and drug development while those with insufficient resources may have to settle for less-expensive treatments that may be less effective than newer options; skip doses; skip a refill; or forgo the medications and supplies altogether. People should not be prevented from accessing necessary medication and treatment if they and their provider feel it is required.⁴⁰

Advocacy and partnering with other stakeholders will be the key. It is imperative that patient engagement is achieved when devising strategies to address the critical cost sharing issues. An evidence-based approach to advocacy will be needed with the complexity of the issues at hand.⁴¹

The Coalition

The Digestive Disease National Coalition (DDNC) is an advocacy organization comprised of the major national

voluntary and professional societies concerned with digestive diseases. The DDNC focuses on improving public policy and increasing public awareness with respect to diseases of the digestive system.

Mission

The DDNC’s mission is to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients.

Digestive Diseases

Digestive diseases are disorders of the digestive tract, which includes the esophagus, stomach, small and large intestines, liver, pancreas, and the gallbladder. Some of these diseases are classified as acute, as they occur over a short period of time, while others are chronic, life-long conditions. 60 to 70 million Americans are affected by these diseases, accounting for 21.7 million hospitalizations and \$141.8 billion in health care costs.

White Paper Review Panel

- Joseph D. Feuerstein, MD, American Gastroenterology Association
- Dale Dirks, Digestive Disease National Coalition
- Nancy Ginter, Beyond Celiac
- Jeanine Gleba, United Ostomy Associations of America
- Lesia Griffin, Digestive Disease National Coalition
- Ralph McKibbin, MD, FACP, FACG, AGAF
- Lisa Metzger, The Oley Foundation
- Amy Ratner, Beyond Celiac
- Jackson Rau, Digestive Disease National Coalition
- Ceciel Rooker, International Foundation for Gastrointestinal Disorders
- Samir A. Shah, MD, FACP, FASGE, AGAF, American College of Gastroenterology

³⁹ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

⁴⁰ https://www.panfoundation.org/app/uploads/2019/12/Attachment1_PAN-Patient-Community-RFI-Letter.pdf.

⁴¹ <https://www.actuary.org/sites/default/files/files/publications/PrescriptionDrugs.030718.pdf>.

DDNC Constituent Members

- Alliance of Families Fighting Pancreatic Cancer
- American College of Gastroenterology
- American Gastroenterological Association
- American Liver Foundation
- American Neurogastroenterology and Motility Society
- American Pancreatic Association
- American Society for Gastrointestinal Endoscopy
- American Society for Parenteral and Enteral Nutrition
- Association of Gastrointestinal Motility Disorders, Inc.
- Beyond Celiac
- Community Liver Alliance
- Crohn's & Colitis Foundation
- Fight Colorectal Cancer
- Florida Gastroenterologic Society
- Global Colon Cancer Alliance
- Global Healthy Living Foundation
- Global Liver Institute
- Griffith Family Foundation
- G-PACT
- International Foundation for Functional Gastrointestinal Disorders
- Louisiana Gastroenterology Society
- Massachusetts Gastroenterology Association
- National Celiac Association
- National Pancreas Foundation
- New Jersey Gastroenterology & Endoscopy Society
- New York Society for Gastrointestinal Endoscopy
- No Stomach for Cancer
- North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
- North Carolina Society of Gastroenterology
- Ohio Gastroenterology Society
- Oley Foundation
- Pennsylvania Society of Gastroenterology
- Society of Abdominal Radiology
- Society of Gastroenterology Nurses and Associates, Inc.
- South Carolina Gastroenterology Association
- Texas Society for Gastroenterology and Endoscopy
- The MMIHS Foundation
- United Ostomy Associations of America
- VHL Alliance

DDNC Institutional Members

- AbbVie
- Allergan
- Amgen
- B. Braun Medical, Inc.
- Janssen Pharmaceutical Companies of Johnson & Johnson
- Merck & Co.
- Pfizer
- RedHill Biopharma
- Shire
- Takeda Pharmaceuticals USA, Inc.
- United Chemical Companies of Belgium

Literature Review

- Effect of 6 Managed Care Pharmacy Tools: A Review of the Literature; Abt Associates, Inc., for the Academy of Managed Care Pharmacy: Journal of Managed Care Pharmacy: July 2010 Supplement, Vol. 16, No. 6-a

Conclusions: There is strong evidence for the effectiveness of several managed care pharmacy tools for achieving intended outcomes such as increased utilization of preferred drugs, formulary compliance, and decreased prescription drug spending. Although these tools achieve reductions in utilization and expenditures, it is unclear whether patients are impacted positively or negatively. While some studies examine the effect of managed care pharmacy tools on medical utilization and costs, the results are mixed.

- Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature, Brenda R. Motheral, RPh, MBA, PhD: J Manag Care Pharm. 2011;17(2):143-55

Conclusions: The research demonstrates that ST programs for therapy classes other than antipsychotics can provide significant drug savings through the greater use of lower-cost alternatives and, to a lesser extent, reduced drug utilization. The drug savings and clinical impact of ST for antipsychotics are unclear given the research conducted to date, but ST programs for NSAIDs and PPIs can provide significant drug savings without increasing use of other medical services. The research on ST shows gaps in the breadth of evaluation and methodological quality as well as possible study bias. Further research on ST is needed for other therapy classes and for the Medicare Part D population. Recommendations for other areas of research, needed methodological improvements, and reducing the potential for study bias are provided.

- A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization. Laura E. Happe 1, Deanna Clark, Edana Holliday, Tramaine Young. J Manag Care Spec Pharm, 2014 Jul; 20(7):677-684

Conclusions: There is a strong evidence base demonstrating a negative correlation between formulary restrictions on medication adherence outcomes. Additional research on commonly used formulary restrictions, specifically prior authorization and step therapy, as well as on the association between formulary restrictions and clinical outcomes, is warranted.

- The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review. Yujin Park, PharmD; Syed Raza, MS; Aneesh George, MS; Rumjhum Agrawal, MPharm; and John Ko, PharmD, MS. J Manag Care Spec Pharm. 2017;23(8):893-901

Conclusions: Findings from this SLR suggest that formulary coverage decisions by MCOs may lead to unintended consequences on patient or payer outcomes. Although formulary restrictions reduce drug utilization and associated drug costs, resulting in pharmacy cost savings, some of these cost savings may be offset by increased health care resource utilization and medical costs. Therefore, we recommend careful evaluation of formulary restriction policies before implementation and continued reevaluation while accounting for various disease states and plan types.

- Impact of Therapeutic Switching in Long-Term Care. Bryan R Cote, MA and Elizabeth A. Petersen, MA. Am J Manag Care. 2008;14(11 Spec No.):SP23-SP28

Conclusions: Nonmedical switching in long-term care settings increased administrative time, side effects, and downstream costs to plans.

- P354. Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents, Journal of Crohn's and Colitis, Volume 9, Issue suppl_1, February 2015, Page S255

Conclusions: Non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that led to subsequent treatment change as well as increases in health care utilization.

- Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review, Elaine Nguyen, Erin R. Weeda, Diana M. Sobieraj, Brahim K. Bookhart, Catherine Tak Piech & Craig I. Coleman; Current Medical Research and Opinion, 32:7, 1281-1290

Conclusions: Non-medical switching was more often associated with negative or neutral effects than positive effects on an array of important outcomes. Among patients with stable/well controlled disease, non-medical switching was associated with mostly negative effects.

- Consequences of non-medical switch among patients with type 2 diabetes, Natalia M. Flores, Charmi A. Patel, Brahim K. Bookhart & Shaffeeulah Bacchus; Current Medical Research and Opinion, 34:8, 1475-1481

Approximately one in five patients reported a moderate/major negative impact on their blood glucose level, diabetes, mental well-being, general health and control over their health following a non-medical switch. Finding suggest that a non-medical switch may have unintended negative health consequences and results in considerable burden across multiple domains for a sizeable minority of patients with T2DM.

- Avalere, Avalere Planscape Analysis of Prescription Drug Tier Placement and Cost Sharing in Health Insurance Exchange Plans 4 (2015). http://go.avalere.com/acton/attachment/12909/f-017c1-/-/20152011_Avalere_percent20Plansscape_percent2015_Class_percent20Tiering_percent20Analysis.pdf

Half of the plans in a 2015 study revised their formularies after the plan year began.

- New Analysis: Midyear Formulary Changes in Marketplace Plans Can Significantly Reduce Access to Needed Medications for Patients. Karyn Schwartz. <https://catalyst.phrma.org/new-analysis-midyear-formulary-changes-in-marketplace-plans-can-significantly-reduce-access-to-needed-medications-for-patients>

Of the forty-one plans with revised formularies, thirty-three reduced drug coverage, twenty-seven eliminated coverage for up to seven medication across classes, and six plans removed between fifteen and fifty-seven products, reducing formulary coverage by 6 percent to 63 percent.



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