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ANALYSIS OF STEP THERAPY REFORM ON FLORIDIANS WITH AUTOIMMUNE CONDITIONS

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Step therapy is a cost-saving measure employed by insurance companies to reduce rising drug costs; however, studies have indicated this policy has neutral or negative effects on patients. Specifically, for individuals with autoimmune diseases, the delay of proper treatment, increased risk of negative, and an underdeveloped preferred drug lists harm autoimmune patients because of the disconnect between the heterogeneity of autoimmune disease and the one-size-fits-all approach of step therapy. The objective of this study is to determine the most effective policy for dealing with the harms of step therapy in Florida. Five policy options were evaluated on a ten-point scale with respect to feasibility, benefits to insurance companies, to patients, and to physicians. Complete Reform had the highest comparative advantage. Complete Reform includes clinical review reform, transparency and reporting requirements, exemptions criteria, and a streamlined appeals process. It will increase patients' access to appropriate, doctor-prescribed medication in a timely manner dramatically increasing health while preserving physician autonomy and protecting insurance companies' revenues.

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Background | Healthcare costs in the United States have steadily increased, growing 8.6% from 2017 to 2019.[1] Prescription drug spending has also been rising, 5.8% from 2017 to 2019.[2] Strikingly, but also predictably, healthcare costs per person have increased 233% from 2000 to 2019.[1] The US now spends $11,587 per person on healthcare and 10% of those costs are attributed to prescriptions.[1,2] More poignantly, prescription costs per person have increased 272% since 2000 and do not appear to be slowing.[2]

To combat high medical costs and provide low premiums for customers insurance companies introduced many cost-saving measures.[3-5] Such measures serve to decrease drug costs by diverting patients towards cheaper, older, or generic drugs first, before covering more expensive treatments.[6-8] Step Therapy is one of those: insurance companies create Preferred Drug Lists (PDL's) and categorize various drugs into a tiered system: the higher the tier, the less likely the insurance company will cover the drug.[9,10] They require patients "to fail" on "first-line treatments" before trying "second-line (or higher) treatments," even if the physician initially prescribed higher tier drugs.[11-13] Under the Affordable Care Act, all insurance companies' PDL's are required to cover at least one drug from each pharmacology category and class.[14]

Insurance companies follow a *two-pronged* method in determining the content of the PDL's. On one hand, a small group of physicians and pharmacists determine whether drugs are effective treatments for conditions.[15] On the other hand, pharmaceutical companies offer financial incentives to entice insurance companies to prioritize their brand-name drug over similar drugs. The bargaining for priority placement on PDL's occurs annually leading to different drugs being considered "the preferred brand-name treatment" for specific illnesses.[7,16] Thus, PDL's shift in response to financial and medical decisions.

Traditionally, PDL's are broken into four tiers: generic drugs, preferred brand-name drugs, non-preferred brand-name drugs, and preferred specialty drugs.[17,18]

It is important to note for generic drugs, normally the "first-line treatment," that while the active ingredients are the same, inactive ingredients (e.g. dyes, capsules, etc.) differ and can have varied effects on patients.[19,20]

Autoimmune diseases are chronic medical conditions caused by the body's immune system targeting organs

in the body.[21] The body mounts immune responses resulting in inflammation, fatigue, or fevers as well as more dire conditions like glandular disorders.[22] The American Autoimmune and Related Disease Association has identified over 100 different diseases, examples being Rheumatoid Arthritis, Psoriatic Arthritis, and Crohn's Disease.[21] Roughly 23.5 million Americans suffer from autoimmune diseases and the rates of autoimmunity are rising.[23] Due to the variable immune responses in individuals, autoimmune diseases are classified as heterogeneous where each disease can present itself differently between patients.[6,24]

The one-size-fits-all nature of step therapy clashes with the individuality of autoimmune disease treatment; this problem also harms the general public.

Despite promises of low premiums, delays in treatments, stress of the appeals process, and diminished patient-physicians relationships plague step therapy. 40% of patients exposed to step therapy stopped medication because it felt unhelpful and 36% of patients felt a decline in quality of life.[25] Among arthritis patients, 50% tried at least two drugs before reaching the prescribed one. 20% stated their condition worsened as a result of the other treatments.[26] Physicians lose medical autonomy and patient care time dealing with step therapy and the administrative process.[27,28] On top of these problems, research indicates that even when prescription costs are saved, greater medical costs arise from future medical services.[3,4,29,30]

There are FOUR problematic areas.[3,5,8,11,12,28,31]

1. Clinical Review Committee. Clinical review committee (CRC) reform is necessary to ensure patients are receiving state-of-the-art care. Currently, CRCs consist of a small number of specialists and pharmacists tasked by an insurance company (or third party) to analyze medical data to determine whether a drug is adept for treating specific ailments.[15,32] The problem is the small number of members can result in a lack of expertise across fields.[8] Moreover, with 100 different autoimmune diseases, the review committee cannot be fully knowledgeable about all, therefore it is highly likely some treatments could be outdated or ineffective. One study found 78% of physicians believed there was "poor underlying logic for the recommended choice" on PDL's.[27]

2. Reporting Criteria & Transparency. Transparency and clear reporting requirements for insurance companies serve to increase patient and provider knowledge about step therapy requirements and new information.[3] One study found 40% of patients stopped medication because of a non-medical drug switch – a change incentivized not by medical advice.[28] It is necessary ALL patients, regardless of education, understand their coverage as complicated language can negatively impact health.[28] Furthermore, transparency allows physicians to proactively prescribed covered medications and reduce complications.[3] Finally, some insurance companies do not give a rationale for appeal denial, leaving room for cost-saving, arbitrary denials.[5]

3. Exemptions Criteria. Exemption criteria provide situations for individuals to circumvent step therapy when medically appropriate based on patients' history. There are two factors when dealing with exemption criteria: the first, patient medical history, and the second, a clear definition of failure.[5,12] Having an inflexible process eliminates physician's autonomy in treating patients' unique symptoms.[8] Cross apply the inflexibility to the various symptoms of autoimmunity and step therapy stands to harm autoimmune patients more. A study of Crohn's patients found insurance companies pay 37% more in medical costs when subjecting them to step therapy because of additional medical costs due to treatment delays.[30] Lack of exemptions may save short term costs, but total medical costs actually increase overall health costs.[4,6,8,28-30] Finally, a clear definition of failure allows for decreased time on harmful drugs.[3,5]

4. Streamlined Appeals Process. A streamlined appeals process is necessary to combat long appeal return times and large amounts of administrative paperwork. One study found healthcare administrators spend 50% of their time navigating medical appeals.[8] Pharmacists indicate they spend at least 20% (and up to 80%) of their time managing denied medications.[25] Another study found physicians themselves spend 20.4 hours a week dealing with step therapy appeals.[28] For patients, one study showed 20% spent >3 hours resolving a step therapy issue.[33] Finally, 59% of physicians experienced "long delays in processing decisions or exemptions" often, thus decreasing their ability to treat patients effectively.[27]

Methods | A policy matrix was constructed to perform a relative comparative analysis of the projected policy benefits on a ten-point scale derived from their capacity to resolve the problems outlined. Each of the four criteria evaluations were averaged for a total comparative advantage of each policy with higher scores indicating a stronger policy option.

Evaluation Criteria:

1. Feasibility. This value considers the financial and enforcement resources required to enact policies. It considers the ability for the policy to pass by analyzing previous Florida bills.

2. Benefits to Insurance Company. This value considers the positive and negative impacts to the insurance company.

3. Benefits to Patients. This value considers the positive and negative impacts to patients.

4. Benefits to Physicians. This value considers the positive and negative impacts to physicians.

It is necessary to describe the omission of pharmacists and pharmaceutical drugs manufacturing companies. Pharmacists only involve the distribution of medication to patients and have little control prescription choices or costs. Drug manufacturing companies have little involvement in the prescription or the actual patient cost for medication as the insurance company is responsible for the medication coverage. However, insurance companies might see it in their interest, as a result, to demand cheaper drug prices, but consideration of drug prices is outside the analysis's scope.

Policy Options:

Policy 1: Insurance Directed Reform. Clinical Review Committee Reform requires an independent committee to make evidence-based decisions on medication coverage with the ability to address all areas of specialty with a transparent decision-making process. Furthermore, they will acknowledge the variations between autoimmune diseases and in their treatments.

Reporting Requirements require insurance companies to make their step therapy information accessible to all levels of education and languages, both patients and physicians. Furthermore, patients must be preemptively notified of changes occurring in medication or coverage with the understanding of why the change occurred.

Policy 2: Patient Directed Reform. A streamlined appeal process requires an enforced time frame for appeal responses with the typical time frame being 24 hours for emergencies and 72 hours for non-emergencies. Moreover, the appeals process will be simplified with available formats on insurance company websites with a clear list of possible exemptions.

Exemption criteria require specific universal exemptions from step therapy: including medication already shown to be ineffective, physician believes drug will be ineffective or harmful based on medical history, a specified timeframe for "failure" (normally 6-week period), and protections from non-medical switching.

Policy 3: Complete Reform. Policy 1 + Policy 2

Policy 4: Insurance Directed Reform for Autoimmune. Policy 1 only for individuals with autoimmune diseases

Policy 5: Patient Directed Reform for Autoimmune. Policy 2 only for individuals with autoimmune diseases

Results | Policy 1: Insurance Directed Reform.

Feasibility: Government involvement in private business will cause dissent; however, this policy maintains one overhaul on the insurance side with minor timely updates. The CRC reform would require a one-time reworking accompanied by smaller financial and physical inputs in subsequent years. The reporting criteria would also be a one-time update on the website and information dispersal services. However, bills containing these reforms previously failed, including SB#1290 (2021), HB#1001 (2021), SB#906 (2019), HB#559 (2019), SB#98 (2018), HB# 963 (2016). *Score-4*

Benefits to Insurance Companies: Contracting an independent CRC requires increased spending and takes autonomy from insurance companies. Additionally, an improved CRC would increase the quantity of covered medications, thus insurance companies could pay for more medications. However, more expansive lists could reduce appeals and patients' negative symptoms, thus less doctor visits and decreased future medical bills. The reporting criteria can increase patient and physician knowledge and increase efficiency during the appeals process. Finally, clear rationale for a denial could cause the insurance company to cover more drugs. *Score-4*

Benefits to Patients: The patient would have medications backed by evidence-based, independent decisions; therefore, treatment options would most likely increase health. Additionally, understanding of the appeals process would decrease stress even though unresolved long return times lead stress and increase medication discontinuation. In the instance when they cannot appeal, they required to follow step therapy protocol and could suffer negative symptoms or permanent harm. *Score-6*

Benefits to Physicians: Physicians still lack autonomy in prescribing, despite a more adept PDL. Furthermore, despite the information on the website, the appeals process would require high levels of administrative burden, reducing patient time. They

would better understand the insurance plan coverage and can avoid clashes to streamline the process, but they would be unable to effectively individualize treatment. With better patient outcomes, the patient-physician relationship could improve. *Score-4*

Policy 2: Patient Directed Reform.

Feasibility: Government involvement would experience stronger pushback because they require more overreach increasing outcry. They would require constant monitorization to enforce streamlined appeals processes and exemption criteria. Florida has previously dismissed bills containing these reforms, including SB#1290 (2021), HB#1001 (2021), SB#906 (2019), HB#559 (2019), SB#98 (2018), HB#199 (2018), SB#1084 (2016), HB#963 (2016). *Score-3*

Benefits to Insurance Companies: A streamlined appeals process and exemption criteria requires more staff and increased efficiency for the appeals process. The government involvement reduces their autonomy, but they still control PDL's. With exemptions, the insurance company would pay for more expensive medications. While it would cost more for prescriptions, more appropriate medication promotes a healthier population resulting in less doctor visits and decreased down-the-line medical expenses. However, in the short run, cost would increase which might raise premiums and decrease customers, but if applied universally, all insurance companies would need to raise premiums, thus the patient would not be incentivized to leave. *Score-2*

Benefits to Patients: The exemption criteria and streamlined appeals process would give patients increased access to appropriate medication in a timely manner, preventing unnecessary health issues. A simplified appeals process would reduce stress, but without the easily accessible information, there still is stress. The patient-physician relationship would improve. More appropriate medication would reduce doctor visits, thus less time and money. *Score-8*

Benefits to Physicians: Streamlined appeals and exemption criteria increase physician autonomy in tailoring treatments and they gain back administrative time that could be for patients, improving patient-physician relationships. Without clear reporting criteria, each patient's coverage plan might complicate the situation. There might be a drop in doctor visits, but this is a double-edged sword as people are healthier, but physicians make less money. *Score-9*

Policy 3: Complete Reform.

Feasibility: When combining the challenge of passing the previous two policies, this would be difficult to pass as it would impose the most oversite for insurance companies. However, similar bills in other states have passed, but never in Florida. *Score-2*

Benefits to Insurance Companies: This is the most restrictive policy for their autonomy. However, as shown, step therapy can increase other costs, therefore they may save money in the long run. They would have to cover more drugs and improve their appeals process and information dissemination systems. The costs are the combined version of Policy 1 and Policy 2. *Score-1*

Benefits to Patients: While still subject to step therapy, the patient has the most control over their treatment and would have leeway if the "first-line treatment" is harmful or ineffective. They would have the combined benefits from Policy 1 and Policy 2. The patient understands step therapy and has a quicker appeals process which decreases stress and promotes health. With more knowledge and autonomy, the patient fairs the best. *Score-10*

Benefits to Physicians: Physicians gain the most autonomy and understanding of step therapy and better patient-physician relationships. Additionally, the administrative burden is greatly alleviated. Despite the presence of step therapy, in important instances, it does not stand in the way. Finally, they have healthier patients. Score-9.5

Policy 4: Insurance Directed Reform only for Autoimmune.

Feasibility: The removal of the general public from the reform makes it more manageable for the insurance company. However, pushback from non-autoimmune advocacy groups introduces new conflict. Laws have never been attempted that separate the public. Finally, defining autoimmune diseases is difficult because of its heterogeneity. *Score-4*

Benefits to Insurance Companies: Supposedly, it would reduce insurance company stress; however, the ability to separate a clinical review committee and reporting criteria solely for autoimmune diseases is challenging. With autoimmune specialists added to the review committee, it would increase likelihood of benefits; however, no individual is an expert in 100 autoimmune diseases. Additionally, it would be pragmatically facetious to only use independent, evidence-based decision-making processes only for autoimmunity. *Score-5*

Benefits to Patients: Autoimmune patients would experience the same benefits as Policy 1 and the general public would receive none. Therefore, becoming diagnosed as autoimmune to gain special

coverages would be important for adequate care of gray-area patients, thereby increasing stress and decreasing health. *Score-4*

Benefits to Physicians: Physicians dealing with autoimmune patients would receive benefits of Policy 1 and others would experience no change. Additionally, the moral dilemma of misdiagnosing autoimmunity to grant patients special coverage introduces new stress. *Score-4*

Policy 5: Patient Directed Reform only for Autoimmune.

Feasibility: With the same changes as Policy 2, but only for autoimmunity, it would be easier for insurance companies to follow as well as for the government to enforce. The challenge of legally defining autoimmune diseases as well as pushback from insurance companies and general public reformer decrease the feasibility. *Score-3.5*

Benefits to Insurance Companies: Singling out autoimmunity is more manageable because each patient could be tagged with an "autoimmunity" label granting decreased appeal time and exemptions and would be less overhaul than Policy 2. However, specialty drugs are 1% of prescriptions, but 25% of the costs, thus the savings may be less than anticipated.[7] Finally, they lose autonomy. *Score-5*

Benefits to Patients: Autoimmune individuals would experience the same benefits as Policy 2 and the general public would not. Pressure would increase to be diagnosed with autoimmunity for prescriptions. The heterogeneity of autoimmunity makes diagnosis difficult for people in-between. *Score-5*

Benefits to Physicians: Physicians dealing with autoimmunity would experience the benefits as Policy 2, but general physicians would not. The pressure to diagnose with autoimmunity for a streamlined appeals process and exemption criteria would create moral stress. *Score-4*

Discussion | Based on analysis of the policies, the most favorable policy is POLICY #3 (Complete Reform) (Table 1). It includes Clinical Review Committee Reform, Reporting Criteria/Transparency, Exemption Criteria, and Streamlined Appeals Process. It benefits the patients – including those with autoimmune conditions – and physicians while allowing insurance companies to save costs in the long run.

Limitations | The limitations of the policy analysis appear in the limited number of policies and limited number of criteria as it is impossible to consider every criterion; however, the choices were made to encompass the maximum amount of information. Furthermore, the scoring of each value was derived from relative comparative analysis; however, the analysis was grounded in evidence from current programs and issues.

Implications for Public Health Practice | Thus, the comparatively better policy for individuals with autoimmune diseases in Florida is POLICY #3 (Complete Reform) to increase all patients' access to appropriate, doctor-prescribed medication in a timely manner dramatically increasing health while preserving physician autonomy and protecting insurance companies' revenue.

Table 1. Policy matrix for evaluating possible policies to address the step therapy impacts on Floridians.

	Policy 1: Insurance Company Directed Reform	**Policy 2: Patient Directed Reform**	**Policy 3: Complete Reform**	**Policy 4: (Autoimmune only) Insurance Company Directed Reform**	**Policy 5: (Autoimmune only) Patient Directed Reform**
Feasibility	- one time overhaul with subsequent minor maintenance for IC - strong opposition to past bills **score: 4**	- continual maintenance for IC - more government involvement for enforcement - strong IC pushback	- combines both the challenges of policy 1 & 2 - requires government oversite - bills containing all four have died in the past **score: 2**	- more manageable for IC - regulation on part of autoimmune diseases - laws like this have never been introduced before - difficult to separate and target autoimmune	- more manageable for IC - easier than Policy 4 to target and separate autoimmune - bills exclusive for autoimmune never been introduced before - in-between doing too much on IC side

		- stronger opposition for past bills **score: 3**		- hard to establish bright lines **score: 4**	and not enough for step therapy advocates **score: 3.5**
Benefits to Insurance Companies	- increased spending - increased government oversite -increased coverage for medications for all ailments - less appeals - need rationale for denial -relatively less involved reform **score: 4**	- increased workload - less autonomy - increase costs - still regulate prescription choices - healthier populations, less later expenses - reduced doctor visits - pay third party for CRC **score: 2**	- greater loss of autonomy - increased costs - increased workload - increased government oversite - reduced doctor visits - healthier populations - less future medical costs **score: 1**	- difficult to physically dissociate the benefits of CRCR & RC without benefiting the general public - require updating classification system - pay third party for CRC on autoimmune -lose some autonomy -increased costs -increased workload **score: 5**	- more simplistic to single out autoimmune patients - specialty drugs make up 25% of budget for only 1% of drugs, thus may not reduce as much as thought - lose some autonomy **score: 5**
Benefits to Consumers	- more adept treatments from PDL's - understand appeals process and step therapy policy and changes - less stress - must follow step therapy - slow appeals process **score: 6**	- physician prescribed treatment in timely manner - decreased health harms - less time on failing drugs - better patient-physician relationship - less doctor visits - increased premiums **score: 8**	- still subject to step therapy - more adept treatments - understanding of step therapy and changes - quick appeals process - decreased health risks - less time on failing drugs - increased premiums - better patient-physician relationship - less doctor visits **score: 10**	- definitive autoimmune patients would receive same benefits as Policy 1 - general public would receive no benefits - place increased burden on being autoimmune diagnosis - hurt general population that needs specialty drugs - diagnosis would become high in demand **score: 4**	-separate autoimmune from general public - autoimmune individuals would experience same benefit as described in Policy 2 - general public would feel no benefits - increased burden and stress on achieving an autoimmunity diagnosis **score: 5**
Benefits to Physicians	- loss of autonomy - better patient outcomes - slow appeals process - large amount of time filling out appeals - understand coverage of patients more clearly **score: 6**	- more autonomy - tailored treatment plans - decreased administrative burden - lack of knowledge of patients' policies details **score: 9**	- most autonomy - increased understanding of step therapy - better patient outcomes - less administrative burden -better patient-physician relationship **score: 9.5**	- autoimmune physicians same as Policy 1 - general physicians no change - increased pressure from physicians to diagnose autoimmune disease to given better health coverage - lengthy appeals process **score: 4**	- autoimmune physicians same as Policy 2 - moral dilemma of diagnosing autoimmune for coverage - increased stress - lack of clear understanding of step therapy protocol for patients **score: 4**
AVERAGE	**4.5**	**5.5**	**5.625**	**4.25**	**4.375**

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