PUTTING PATIENTS FIRST: ENSURING THE IRA DOES NOT LIMIT ACCESS TO THE BEST CLINICAL OPTIONS

JULY 2024

SUMMARY

The Inflation Reduction Act (IRA) introduces several significant changes to the Medicare Part D prescription drug benefit, including a cap on annual out-of-pocket (OOP) spending, redesign of the benefit that shifts payer liability, and the highly publicized Medicare Drug Price Negotiation Program (MDPNP). Certain IRA elements directly address existing challenges in the benefit related to access, equity, and affordability (e.g. removal of cost-sharing for vaccines covered by Part D). However, the MDPNP also has potential for unwelcome, unintended consequences that have the reverse effect and put beneficiary access to essential therapies at risk.

In particular, the MDPNP changes financial incentives for Part D plans in ways that may lead them to deter access or exclude drugs from formularies, potentially causing a reduction in drug choices to address individual therapeutic needs. This issue is particularly important when considered in the context of incentives created by the Part D redesign for plans to constrain access to medicines more broadly. The potential loss of access to clinically important treatment options represents a critical challenge as individual Medicare beneficiaries have differing treatment needs and preferences due to unique physiological, molecular, environmental, economic, social, and behavioral characteristics. These many, nuanced, clinical and non-clinical factors should be carefully considered when choosing medical interventions aimed to optimize patient-centered outcomes, and also when structuring and monitoring significant Medicare policy changes.

Using two of the most prevalent conditions among Medicare beneficiaries impacted by the MDPNP—diabetes and atrial fibrillation—we examine evidence on the importance of preserving a variety of therapeutic options addressing patient heterogeneity to optimize health outcomes, and estimate the number of beneficiaries who may be at risk for increased barriers to treatment access for these conditions as a result of the MDPNP. While the impacts of the MDPNP on patient access have yet to be fully realized, any risk of a disruption or sub-optimal care delivered to vulnerable Medicare beneficiaries with common and complex chronic conditions must be closely monitored.

Current clinical research demonstrates the importance of protecting beneficiary and clinician choice to a range of treatment options in each of these therapeutic areas. **We estimate that at least 1.5 million beneficiaries who rely on just two classes of medicines to treat diabetes and atrial fibrillation are at risk of reduced access to clinically important medications as a result of the MDPNP.** However, this approximation is likely an underestimate, as it does not capture the full range of clinical and patient factors that may necessitate patients in different subgroups having access to a wide variety of treatment options. Policymakers and researchers should carefully monitor changes in access and utilization of medicines for these and other disease states impacted by the MDPNP, and consider steps to strengthen identification of clinically important patient differences, and oversight of Part D formularies.

OPTIMAL CHRONIC DISEASE MANAGEMENT FREQUENTLY REQUIRES SEVERAL ALTERNATIVE TREATMENTS

Over 90% of U.S. health care expenditures arise from health care services aimed at managing symptoms and preventing complications of common chronic conditions, such as hypertension, diabetes, mental health disorders, and cancer.[1] Hundreds of millions of Americans are currently diagnosed with these conditions, and yet, most individuals cannot be successfully managed using a 'one size fits all' approach.

Moreover, most common chronic conditions do not have 'cures' but rather demand life-long treatment and management with the aim of minimizing symptoms, complications and slowing disease progression. Seniors and other Medicare beneficiaries have substantial clinical characteristics and social circumstances that demand tailored treatments. For example, increased prevalence in concurrent conditions, threats to financial security, or increasing risk of loneliness and self-sufficiency can demand periodic adjustments in therapeutic treatments to ensure adherence. Therefore, access to available alternative therapies that best meet an individual patient's need is critical to achieve optimal clinical, social and financial outcomes.

IMPLICATIONS OF THE PRESCRIPTION DRUG PROVISIONS OF THE INFLATION REDUCTION ACT (IRA)

Changes to public policy can greatly affect patient access to alternative therapies for Medicare beneficiaries. For nearly two decades, the implementation of the Medicare Part D prescription drug benefit has significantly improved patient access and affordability of medicines. The Inflation Reduction Act of 2022 (IRA) transforms the Part D benefit in a way that has both positive and negative implications for patients. While the IRA could reduce patient OOP costs for millions of beneficiaries through provisions such as an annual OOP cap and smoothing provisions, unintended consequences of some elements have the potential to limit beneficiary access to the treatment options they need.

Elements of the IRA expected to reduce patient out-of-pocket costs

Some of the less publicized provisions of the IRA are expected to lower patient out-of-pocket costs. For instance, as of January 2023, Medicare Part D beneficiaries no longer have cost-sharing requirements for adult vaccinations recommended by the Advisory Committee on Immunization Practices (such as the shingles vaccine), and most beneficiaries using insulin now pay no more than $35 per month for their supply. Notably, starting in 2025, the IRA also caps annual out-of-pocket spending for Medicare Part D beneficiaries to $2,000 per year and allows patients to spread their cost-sharing requirement over 12 months—both huge wins on affordability for Medicare beneficiaries. Beginning in 2025, federal reports estimate that these redesign features will reduce out-of-pocket spending by more than $7 billion annually, impacting more than a third of Medicare beneficiaries (nearly 20 million).[2] However, the IRA contains other provisions that may threaten Medicare beneficiary access to clinically relevant treatment options.

IRA MEDICARE DRUG PRICE NEGOTIATION (MDPNP) PUTS ACCESS TO CLINICALLY RELEVANT OPTIONS AT RISK

A more highly publicized provision of the Inflation Reduction Act of (IRA) establishes the "Medicare Drug Price Negotiation Program" (MDPNP), which requires that the Centers for Medicare & Medicaid Services (CMS) set a "maximum fair price" (MFP) for selected prescription drugs. The MDPNP program may be positive for some beneficiaries in cases where the OOP costs are lower for the medications that the beneficiary needs, and access to these treatments is not reduced through formulary exclusions, utilization management, or higher cost-sharing.[3] For some beneficiaries, however, this combination of circumstances is not likely to be present.

When considering potential changes in coverage and access, there are two likely scenarios resulting from the introduction of a negotiated drug on a Part D plan formulary that may impede access to treatment options. Both could be plausible based on different market dynamics and differing levels of competition within a therapeutic class.

Deterred Access to Medications Not Assigned an MFP due to Plan Preference for an MFP Drug

First, consider what could occur if CMS designates one drug (out of many therapeutic options included in published clinical guidelines) to reduce high blood sugar for individuals diagnosed with type 2 diabetes mellitus (T2DM) at an MFP that is much lower than the price of other medications used to manage blood sugar levels. In that case, insurers may have a financial incentive to put programs in place that encourage the use of the lowest-cost treatment by making it easy for clinicians to prescribe and lowering OOP costs for patients, even if it may not be the ideal therapeutic choice for an individual (i.e., patient is allergic, cannot take due to drug interactions and/or does not offer the greatest clinical benefit). Because insurers may want to advantage access to the MFP drug in this case, they might deter access to medications that were not assigned an MFP by putting more restrictions on their prescription with utilization management tools (e.g., via step-edits, prior authorization, or other cost control mechanisms), forcing patients to pay more for or refusing coverage altogether.

Deterred Access to Medications Assigned an MFP due to Plan Preference for a Non-MFP Drug

Alternatively, to avoid being disadvantaged on formulary, manufacturers of other glucose lowering drugs competing with the negotiated drug(s) may offer additional discounts or rebates to the plan to compete with the negotiated price and secure better formulary placement than the negotiated drug—meaning lower patient cost-sharing and fewer utilization management restrictions for a competitor product. CMS recently acknowledged that "Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."[4] This dynamic of insurers using discounts and rebates to

negotiate the level of access patients face is how the market plays out today and is expected to be exacerbated by the IRA.[5],[6] In this scenario, patients may find that they have more restrictions on access to the negotiated drug relative to other drugs. As a result, access to all therapeutic options will not be easy or equal, and patients could face increased costs, delays in treatment, or more obstacles to receive their preferred medication, potentially worsening their disease progression and overall health outcomes.

To prevent the policy from inadvertently worsening access, CMS should create sufficient safeguards to ensure that there is diversity of therapies available across plan formularies which continue to meet individual therapeutic needs. In practice, this calls for more robust monitoring of plan formularies that include both the selected drugs and drugs that aren't subject to government negotiation used to treat the same clinical conditions, and greater CMS transparency about its monitoring standards and the results of its oversight. Oversight of formularies must take into consideration the reality that a specific medication can offer varying levels of benefit to different patients (i.e., clinical nuance) and that often alternative agents within a class of drugs and in other drug classes are necessary to achieve desired clinical outcomes for certain patients. Therefore, one important outcome that will determine the success (or failure) of this policy when it comes to Medicare beneficiaries is whether or not the implementation of the MDPNP encourages or impedes access to the best treatment options for individual patients, including patients with the same diagnosis who may require access to different therapies. This requires that patients have access to a range of Part D plans that each offer robust coverage. Thus, the availability of Part D plan choices should be monitored over time. Unfortunately, 2024 is already demonstrating significant disruption from the IRA, with the fewest number of Part D stand-alone PDP plans since the Part D program was created.[7]

CLINICAL DIFFERENTIATION IS CRITICAL IN THERAPEUTIC AREAS IMPACTED BY DRUG NEGOTIATION

By September 2024, CMS will release negotiated prices for the first round of drugs in the MDPNP, which includes 10 drugs that treat diseases including diabetes, autoimmune diseases (RA, psoriatic arthritis, plaque psoriasis, ulcerative colitis, Crohn's disease, ankylosing spondylitis), blood cancer, heart failure, and stroke prevention. Treatment for these diseases requires consideration of highly complex and nuanced factors that reflect a wide range of differences across patients, natural history of disease, and treatment effects.

In these classes, there is no one-size-fits all treatment approach. Instead, treatment options for these conditions offer varying levels of benefit for different patients (and can be harmful in some cases) and alternative prescribed medicines within a class or different class of drugs are frequently necessary – either in addition to or substituted for – to achieve desired clinical outcomes.

While the effects of the MDPNP on patient access are not yet realized, the risk to disrupted access for Medicare beneficiaries with these common and complex conditions is concerning and should be closely monitored by CMS and researchers over the next several years.

TYPE-2 DIABETES

Today, there are roughly 13 million Medicare beneficiaries diagnosed with type-2 diabetes.[8] The extent to which the IRA leads to greater formulary restrictions will determine the degree to which the IRA results in policy that conflicts with a provider's ability both to comply with clinical practice guidelines, and to practice personalized, evidence-based medicine that tailors guideline-concordant care to the needs and circumstances of the individual patient and family caregivers. Clinical guidelines recommend a number of medications from several different classes, as well as different medications within a specific class to manage blood sugar levels over the course of the disease. For example, many Medicare beneficiaries with Type-2 diabetes are prescribed at least two different DPP-4 inhibitors within one-year, likely driven by clinical factors, patient choice, or other rationale.[8]

Access to available alternative therapies that best meet an individual patient's need is critical to achieve optimal clinical, social and financial outcomes.

Medication management for diabetes can change many times over the course of the disease to adjust for factors, such as drug side effects, new clinical comorbidity profiles, or treatment goals. **In fact, guidelines recommend that clinicians reevaluate the medication plan for patients with type-2 diabetes every 3-6 months to adjust treatments to meet diabetes management goals, as needed.**[9] Prior research shows that among adults starting non-insulin as a second-line therapy for type-2 diabetes, nearly two-thirds (64%) experienced a treatment modification, such as discontinuation (38.6%), intensification (19.8%), or medication switch (5.2%).[10]

Clinical guidelines also state that treatment decisions should depend on a combination of factors unique to each patient, including co-morbid conditions, patient education, social determinants of health, and healthy lifestyle modifications.[9] In particular, most patients with diabetes are also managing other diseases, such as chronic kidney disease, heart failure, obesity/weight management, and other cardiovascular risks which can significantly impact prescribing of medications.

For example, guidelines from the American Diabetes Association recommend that patients with diabetes and co-morbid chronic kidney disease, representing 5 million Medicare beneficiaries, should not be prescribed certain classes of diabetes drugs that could worsen kidney function.[11],[12] Select drugs in the sodium-glucose costransporter-2 (SGLT-2) inhibitor class are recommended for first-line treatment for these patients. However, due to differences in the potential for side effects, treatment for other co-morbid conditions, drug-interactions, and patient tolerability, a given SGLT-2 inhibitor product may not be ideal for every patient with chronic kidney disease and diabetes.[9] For this reason, even among patients taking drugs in the same class, access to all available treatments is necessary to ensure the needs of different patients can be equally met. As of 2022, roughly 550,000 Medicare beneficiaries with type-2 diabetes and co-morbid kidney disease are treated with an SGLT-2 inhibitor; these patients would face treatment disruptions if the decision for the best medicine was out of the hands of the patient and the clinical care team.

Similarly, guidelines recommend not prescribing other drugs, including sulfonylureas and insulin to patients with diabetes and co-morbid obesity due to the drugs' side effects of inducing weight gain, and instead recommend the prescription of GLP1s, which lower glucose without associated weight gain.

Given the need to continuously modify treatment regimens for diabetes due to the evolving nature of the disease and patients' clinical circumstances, CMS should protect access to all available treatment options for all 13 million Medicare beneficiaries diagnosed with Type-2 diabetes.

Beyond clinical co-morbidities, doctors may also prescribe one medicine over another to optimize clinical outcomes to promote better adherence. For example, certain patients with diabetes fear injections and prefer oral medicines over injectables.[13] On the other hand, 10%-30% of older adults have difficulty swallowing and may require injectable options.[14] Due to the unique clinical picture of each patient and the potential for multiple diabetes treatment modifications over the course of the disease, all 13 million Medicare beneficiaries with type-2 diabetes need access to every diabetes medicine.[8]

ATRIAL FIBRILLATION

Today, over 5 million Medicare beneficiaries have non-valvular atrial fibrillation, a condition characterized by irregular heartbeats (not caused by the heart valves) that leads to increased risk of blood clots and strokes.[8] People with untreated atrial fibrillation (AFib) are at twice the risk for cardiovascular death and five times the risk for stroke.[15]

When clinicians choose to prescribe an anticoagulant to reduce stroke risk in patients with AFib, they consider many factors, such as current guideline recommendations, appropriate dosing, contraindications with other medications, special dietary requirements of the medications, the patient's level of liver or kidney function, allergic reactions, dosing schedules, and social determinants of health. Given the wide heterogeneity of patients' clinical profiles, preferences, and social determinants of health, physicians need access to a variety of anticoagulant medications when treating patients with AFib.

There are two major types of oral anticoagulants for patients with AFib -- vitamin K antagonists (warfarin) and direct oral anticoagulants (DOACs). Both types of medicines work by reducing the body's ability to form blood clots.

Warfarin was the only medicine available on the market for decades before DOACs were first made available in 2010. However, warfarin requires frequent laboratory monitoring to ensure that the medication's levels are within a safe and effective range so as to not risk serious bleeding events.[16] This monitoring can be challenging for patients who are also managing work, family or caregiving needs or live in areas without convenient access to appropriate facilities.

In 2019, the American Heart Association, American College of Cardiology, and the Heart Rhythm Society updated practice recommendations and called for use of DOACs over warfarin for treatment of patients with non-valvular AFib, and these recommendations are still in place today.[17],[18] These clinical guidelines recognized the increased efficacy of DOACs over warfarin to prevent stroke and other negative health outcomes, while avoiding the monitoring needs.[17]

Although DOACs are recommended as the preferred anticoagulant medicine for most patients with AFib, clinicians use their judgement to determine which DOAC is more appropriate for each patient. Today, nearly half of the non-valvular atrial fibrillation population (2.5 million patients) takes a DOAC.[8] Over the lifetime of a patient's treatment of non-valvular atrial fibrillation, patients can develop different co-morbidities and be prescribed medicines that can interact with the prescribed DOAC therapy. Certain DOACs interact with medicines commonly used to treat prevalent diseases; however, not all DOACs are metabolized through the same pathways and therefore do not have the same drug-drug interactions. Also, patient allergies or preferences for dosing regimens can affect choice of DOAC. Therefore, patients and their clinicians need to be able to choose from among available DOACs based on the individual patient's clinical circumstances. In addition, managing AFib over the entire course of the disease may require access to all of the available DOACs as an individual's clinical needs change.

For example, select DOACs are not recommended for patients with moderate or severe liver impairment, representing up to 400,000 Medicare beneficiaries.[8] Similarly, DOAC dosing must also be adjusted based on a patient's kidney function. Today, nearly 2.2 million Medicare beneficiaries with non-valvular atrial fibrillation have co-morbid kidney disease, and over 1 million of these patients take a DOAC.[8] Patients with non-valvular atrial fibrillation and co-morbid kidney disease, who are prescribed DOACs, can require use of different DOACs depending on how the patient responds to the specific drugs, and can also require different dosing adjustments.[19] For example, among patients with end stage renal disease (ESRD), only certain DOACs are recommended, and must be used in specific low dosages. However, clinical trial evidence is not available to determine a DOAC's safety and efficacy among patients with ESRD in all patient circumstances.[19] Therefore, it is common practice for patients and clinicians to assess the risks and benefits of anticoagulation among patients with advanced kidney disease. Patients may also have allergic reactions to a certain DOAC medication, which would prompt a clinician to recommend another DOAC or warfarin treatment.

DOACs can have different dosing schedules. For example, several DOACs are recommended to be taken twice per day, while others are taken once daily. Patients may have preferences for dosing schedules that work best with other prescribed medicines, meal routines, or assistance with daily living activities. Some DOACs can be crushed and mixed with liquids or soft foods, while other DOACs are recommended to be swallowed whole. When doctors are choosing a medication regimen for the prevention of stroke, they consider factors such as convenience, nutrition habits, mealtimes, and medication adherence.

Another challenge for doctors who treat older patients with AFib is the need to avoid drug-drug interactions. Although DOACs have fewer drug-drug interactions than

warfarin, they do vary in their interactions with other medications, which may require patients to switch medicines if they have or develop other chronic conditions.[20]

Despite the effectiveness of DOACs for stroke prevention, there are racial and ethnic disparities in the initiation of DOACs as compared to warfarin.[21] These disparities call for greater need to increase the access to DOACs.

Direct acting anticoagulants (DOACs) are recommended to reduce risk of stroke, but not all DOACs metabolize in the body the same way in the presence of other diseases or treatments. Today, over 1 million Medicare beneficiaries who use DOACs also need to manage co-morbid kidney disease—these patients could face disruptions in access if the full range of options is restricted due to the IRA.

CONCLUSION

Several elements of the IRA, including the annual OOP cap and improved affordability for vaccines, are expected to improve the health of Medicare beneficiaries by lowering their OOP costs to essential medications. The IRA's highly publicized MDPNP that grants the government authority to set prices for medicines in Medicare has, on the surface, potential to enhance access for certain beneficiaries. However, the law also creates financial incentives for Part D plans that may lead to greater use of formulary restrictions, step-therapy, and prior authorization that may make it more difficult for patients and their clinicians to access certain medications to treat a specific condition.[22]

Another possible concerning impact of the MDPNP is that some patients could be subjected to "non-medical switching" following restrictions on formulary access once a drug is assigned a government price. Non-medical switching refers to a practice in which health plans switch stable patients from their current medication and onto an insurer-preferred drug.[23] A 2019 literature review of studies (2015-2018) demonstrated that non-medical switching is commonly associated with a negative impact on clinical (26.9%), economic (41.7%), health-care utilization (30.3%), and medication-taking behavior (75.0%); with a positive effect seen in 3.0% (resource utilization) to 14.0% (clinical) endpoints.[24] Although strategies to limit patients' access to essential care long precede the IRA, the trend toward increased access restrictions may be exacerbated by the IRA, and the negative effects disproportionally borne by sicker patients with chronic conditions. As illustrated here with diabetes and atrial fibrillation, various equivalent treatments have different safety profiles and yield markedly varied outcomes in different patient types. Thus, clinicians and their patients should not have their choices constrained, but instead have multiple therapeutic options available to them.

The IRA makes several consequential changes to Medicare Part D, the aims of which were to improve patients' access to essential medications, ultimately leading to better patient-centered outcomes and reduced health care disparities. Policymakers and researchers should carefully monitor changes in access and utilization of medicines for disease states impacted by the MDPNP (present and future), and consider steps to strengthen CMS oversight of Part D formularies, focusing on the various drug classes used to manage those clinical conditions treated by one or more MFP-selected medicines.

REFERENCES

1. Fast Facts: Health and Economic Costs of Chronic Conditions. Centers for Disease Control and Prevention. May 2024.
2. Sayed BA, Finegold K, Olsen TA, et al. Inflation Reduction Act Research Series – Medicare Part D Enrollee Out-of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act. ASPE. July 2023.
3. Kirsten Axelsen, Rachel Portman, Sam Tyner-Monroe, Angela Zheng. Medicare drug price negotiation: Saving money for Medicare, but what about patients? DLA Piper. March 2024.
4. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf
5. IRA: Revisiting Price Negotiations. Hayden. January 2024.
6. Surprise! Thanks to the IRA, Part D Plans Will Prefer High-List, High-Rebate Drugs. Drug Channels. February 2024.
7. An Overview of the Medicare Part D Prescription Drug Benefit. Kaiser Family Foundation. October 2023.
8. Medicare FFS beneficiary counts in 2022 were calculated using the Center for Medicare and Medicaid Services' Medicare administrative data. Medicare Advantage beneficiary counts were estimated by applying the percentage of Medicare FFS beneficiaries in each disease area to the total number of beneficiaries enrolled in Medicare Advantage in 2022 as report in the Medicare Enrollment Dashboard. Analyses were performed by Magnolia Market Access.
9. American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024. Diabetes Care 1 January 2024; 47 (Supplement_1): S158–S178.
10. Liss DT, Cherupally M, O'Brien MJ, et al. Treatment Modification After Initiating Second-Line Medication for Type 2 Diabetes. AJMC. 2023; 29 (12).
11. El Sayed NA, Aleppo G, Aroda VR, et al. Chronic kidney disease and risk management: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S191–S202.
12. de Boer IH, Khunti K, Sadusky T, et al. Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). Diabetes Care 2022;45:3075–3090.
13. Spain CV, Wright JJ, Hahn RM, Wivel A, Martin AA. Self-reported barriers to adherence and persistence to treatment with injectable medications for type 2 diabetes. Clin Ther. 2016;38(7):1653-1664. e1651.
14. Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in Older Adults. Mayo Clin Proc. 2021;96(2):488-497. doi:10.1016/j.mayocp.2020.08.001
15. American Heart Association. What is Atrial Fibrillation? Accessed May 6, 2024.

REFERENCES CONT.

16. Coumadin (Warfarin Sodium Tablets) Package Insert. Accessed May 7, 2024.
17. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons [published correction appears in Circulation. 2019 Aug 6;140(6):e285]. Circulation. 2019;140(2):e125-e151. doi:10.1161/CIR.0000000000000665
18. Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2024 Jan 2;149(1):e167] [published correction appears in Circulation. 2024 Feb 27;149(9):e936]. Circulation. 2024;149(1):e1-e156. doi:10.1161/CIR.0000000000001193
19. Micromedex. Assessed May 2024.
20. Julia S, James U. Direct Oral Anticoagulants: A Quick Guide. Eur Cardiol. 2017;12(1):40-45. doi:10.15420/ecr.2017:11:2.
21. Boursiquot BC, Jackson LR, Essien UR. Advancing Pharmacoequity in Atrial Fibrillation—The Case for Direct Oral Anticoagulants. JAMA Netw Open. 2024;7(5):e249403. doi:10.1001/jamanetworkopen
22. Step Therapy (Fail First). National Organization for Rare Diseases. 2024.
23. What is Non-Medical Switching. National Infusion Center Association. 2024.
24. Weeda ER, Nguyen E, Martin S, et al. The impact of non-medical switching among ambulatory patients: an updated systematic literature review. J Mark Access Health Policy. 2019;7(1):1678563. doi: 10.1080/20016689.2019.1678563