NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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October 10, 2019

Ken Ehlert
Chief Scientific Officer, UnitedHealthcare
9800 Healthcare Lane
Minnetonka, Minnesota 55343

Subject: Updating formulary to switch beneficiaries to an insurer-preferred product for reasons unrelated to health or safety

Dear Mr. Ehlert

The National Infusion Center Association (NICA) has received reports from concerned providers and patients regarding UnitedHealthcare's decision to steer members toward self-administered formulations for reasons unrelated to health or safety, independent of the prescription drug order—even for members that are clinically stable on a provider-administered formulation. This dangerous practice of non-medical switching devalues member and provider choice with significant implications.

NICA is a 501(c)(3) nonprofit patient advocacy organization formed to ensure that our nation's sickest and most vulnerable patients can access outpatient infusion and injectable medications through advocacy, education, and resource development. We represent hundreds of thousands of patients managing complex, chronic, rare, life-threatening and/or difficult-to-manage diseases—like autoimmune diseases—with medical benefit drugs, like biologics, in one of several thousand outpatient infusion facilities across the country. To improve the affordability of these drugs for patients, we work to ensure that patients can access these drugs in low-cost, non-hospital care settings.

There are many complex, multi-faceted challenges threatening the sustainability of our health care system. Specialty medications, particularly biological products, are incredibly expensive, and patients continually struggle with affordability as payers struggle to mitigate increased cost-sharing liability.

NICA understands that payors have an ongoing need to control formularies and costs related to the growing specialty medication market, while providing value for their members. Biologics are some of the most innovative and life-changing medications developed in the last decade. They bring tremendous value to those that need them. Consequently, they are some of the most expensive medications. As such, this class of medications brings unique challenges to manufacturers, providers, patients, and insurers, including escalating costs, complex administration, and a volatile reimbursement environment.

Summary of Concerns

Biological products are used to manage some of the most expensive conditions (e.g., autoimmune diseases, cancer), for which patients are subjected to extraordinarily high physical, emotional, and economic burden of disease. Many of the conditions these drugs treat are complex, difficult to treat, and life-long. When they are clinically stable, patients can minimize the frequency and severity of disease flares, reducing consumption of high-cost medical services. When clinical stability is disrupted, disease flares can result in additional PCP visits, specialist visits, labs and diagnostics, presentation to the Emergency Department, repeat labs and diagnostics, and possibly inpatient care or even highly

invasive—and expensive—surgical intervention. When undermanaged, patients consume more high-cost medical services that would otherwise have been avoided, translating to increased out-of-pocket (OOP) costs for patients and increased cost-sharing liability for payors.

Autoimmune disease manifests differently in many patients. The more complex the case, the more difficult it is to manage. A person's health care and treatment plan are deeply personal and unique to that individual. People living with autoimmune disease rely on expeditious and uninterrupted access to the *right* prescription medications at the *right* time to optimize health outcomes, maximize quality of life, and minimize the physical, emotional, and economic burden of disease. Unfortunately, conventional drugs don't work for some people, so biological products provide the only hope for achieving clinical stability. However, it can take several years to exhaust conventional treatment protocols before providers and patients consider a biologic product. Then it can take months or even years to find the right biologic for each patient.

Until patients become clinically stable on the right medication, the burdens of disease are undermanaged. Switching patients that are clinically stable on a biologic to a different biologic can carry significant financial and quality of life implications. I have heard countless horror stories from patients who were clinically stable on a product but suddenly switched to a different product by their insurance company to reduce immediate-term costs. Instead, these policies contributed to poor outcomes like hospitalization, seven days in the Intensive Care Unit, bowel resection, colon resection, joint replacement, and disability— all of which significantly and unnecessarily increased the economic burden of disease.

Studies have shown that spending money on the right medication can reduce the total amount spent on hospital-related (e.g., ED visits, inpatient care) or other medical costs (e.g., labs/diagnostics, surgery) through effective disease management. For example, a 2007 study found that a $1 increase in drug spending was associated with a $2.06 reduction in Medicare spending.[1] Due to the increased cost of medical services under a commercial plan, savings would likely be more pronounced. Additionally, a 2009 study found that outpatient prescription drug expenditures create "cost savings for Medicare beneficiaries" once hospital costs are considered.[2] Similarly, a 2011 study found that "the typical new drug slows the growth of overall medical care spending".[3] Furthermore, a 2014 study found that undermanaging autoimmune disease, like Inflammatory Bowel Disease, can double the annual per capita economic burden of disease (130 percent increase).[4] For example, if it costs $30,000 per year to effectively manage someone living with IBD, ineffective management can cost more than $69,000 per year. This increase cost-burden translates to other autoimmune diseases as well. The more frequent and more severe the disease flares, the higher the annual spend on that member.

Finding an acceptable balance between affordability, access, and cost-mitigation, particularly relating to biologics, is an incredibly complex and arduous challenge. In the meantime, disease continues to progress in the absence of appropriate and effective intervention. Patients with chronic disease need

[1] Shang B and Goldman DP. Prescription Drug Coverage and Elderly Medicare Spending. NBERWorking Paper 13358. 2007; https://nber.org/papers/w13358

[2] Stuart BC, Doshi JA, Terza JV. Assessing the Impact of Drug Use on Hospital Costs. Health Services Research. 2009; 44(1):128-144.

[3] Santerre RE. National and International Tests of the New Drug Cost Offset Theory. Southern Economic Journal. 2011; 77(4):1033-1043.

[4] Rubin DT, Mody R, Davis KL, Wang CC. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. Ailment Pharmacol Ther. 2014; 29:1143-1155.

uninterrupted access to whichever drug best manages their condition's progression to optimize health outcomes, maximize quality of life, and minimize the physical, emotional, and financial burden of disease.

Perception of Non-Medical Switching

In the short period of time since UHC announced its decision to require patients who are currently stable on an infusible medication, NICA has heard from dozens of infusion providers across the country who feel that UHC's decision supersedes their prescribing authority and clinical expertise by dictating the course of treatment for its members.

In a recent study that surveyed 297 physicians who currently prescribe biologics for their patients, 84% of respondents did not want stable patients undergoing a non-medical switch to a biosimilar. The majority of respondents also anticipated a negative impact on patient mental health (59%), treatment efficacy (57%), patient safety (53%), and physician office management (60%).[5]

Similarly, in a 2019 survey administered by the Alliance for Patient Access to patients affected by non-medical switching, 80% of patients expressed dissatisfaction with not being a part of the decision to switch medications. In addition, 86% believed that their insurer took control of a decision that rightfully belonged to their doctor, and 74% believed the switch disrespected their doctor and their doctor's expertise, and 93% of patients surveyed believed that both themselves and their doctor should have a say in the treatment plan of the patient.[6]

Healthcare providers are growing increasingly frustrated with insurers getting between them and their patients. It is an increasing prevalence of payor policies like this that are making providers rethink their payor contracting strategies.

There is an overwhelmingly negative association with non-medical switching within the minds of patients and healthcare providers. By requiring healthcare providers to constantly obtain prior authorizations for autoimmune diseases—chronic diseases that require life-long management—or submit letters of medical necessity for infusible medications, UnitedHealthcare is placing additional burden upon the administrative and clinical staff. If healthcare facilities decide that treating UnitedHealthcare's members is too onerous, they could decide to no longer accept patients covered by UnitedHealthcare, therefore reducing access points for members to receive care and forcing them into more expensive sites of care, such as a hospital.

Furthermore, patients are also becoming increasingly frustrated with increasing premiums, deductibles, and out-of-pocket maximums while coverage decreases. Patients with autoimmune disease rely on their insurer to facilitate coverage of the care they need to maximize quality of life. If UHC continues to devalue its members, not only will these members not renew their coverage, but they will be reluctant to refer others to UHC for coverage.

[5] A. Teeple, L.A. Ellis, L. Huff, C. Reynolds, S. Ginsburg, L. Howard, D. Walls & J. R. Curtis (2019) Physician attitudes about non-medical switching to biosimilars: results from an online physician survey in the United States, Current Medical Research and Opinion, 35:4, 611-617, DOI: 10.1080/03007995.2019.1571296

[6] http://allianceforpatientaccess.org/wp-content/uploads/2019/02/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf

Conclusion

There are many complex, multi-faceted challenges facing the sustainability of our health care system. The affordability and accessibility of drugs continue to present the most significant challenge. Utilization management strategies like Step Therapy and Non-Medical Switching are contributing to unnecessary consumption of high-cost medical services and unnecessary health care spending because they limit providers' autonomy to practice medicine and find the right drug for the patient. Consequently, patients and providers are expressing increasing frustration with the evolving insurance landscape.

NICA agrees with other patient and disease advocacy organizations and believes that the decision as to which biological therapy—and route of administration—is best suited for a particular patient should be a collaborative determination made by healthcare providers and patients on an individual basis, not a blanket requirement for all patients implemented by the payor. **NICA supports equal access to a healthy and competitive drug market so providers and patients can safely and more cost-efficiently find the right therapy at the right time— *the one that works*.** Therefore, NICA strongly encourages UnitedHealthcare to reconsider its decision to supersede providers' prescribing authority and clinical expertise by dictating the course of treatment for its members.

I understand that it behooves health insurers to drive its members towards the most "cost-effective" treatment option to save money and build member value. However, please understand that any cost savings realized in the immediate term are generally heavily outweighed by the long-term quality of life, health outcome, and financial implications associated with undermanaging autoimmune disease.

Altering effective treatment plans based solely on cost is not a choice that payors should make, or impose, lightly. NICA believes that empowering members and their providers to find the right medication at the right time will not only improve health and reduce cost, but also enhance the provider's role in managing their care. We are deeply concerned of the possibility that patients' health and well-being will be adversely affected by this policy change. It is our hope that, in conjunction with payors, we can find solutions that control costs and maximize member value without compromising care.

On behalf of the National Infusion Center Association (NICA), the hundreds of thousands of patients across the nation requiring provider-administered parenteral medications, and the tens of thousands of dedicated providers that treat them, I implore you to rescind this decision and rely on health care providers to reduce costs and maximize member value by determining the most appropriate product for their complex patients that are prescribed a therapeutic biological product.

Should you have any questions or need more information, please feel free to contact me at brian.nyquist@infusioncenter.org or 512-402-6955.

Sincerely,

Brian Nyquist, MPH Executive Director National Infusion Center Association

c.c. Dirk McMahon, MBA
Chief Executive Officer
UnitedHealthcare