January 20, 2021

Ken Ehlert, Chief Scientific Officer
UnitedHealth Group
P.O. Box 1459
Minneapolis, MN 55440-1459

Subject: UHC medical benefit specialty drug update for Remicade and Renflexis

Dear Ken Ehlert,

The National Infusion Center Association (NICA) and Infusion Access Foundation (IAF) have received reports from concerned providers and patients regarding UnitedHealthcare's decision to remove Remicade and Renflexis from the preferred agent list starting February 1, 2021. As it stands, this policy would require UHC-insured patients receiving Remicade or Renflexis treatment to change their therapy to UHC's "preferred infliximab products" (Inflectra or Avsola), regardless of how long they have been stable on their prescribed medication.[1] This dangerous practice of non-medical switching devalues member and provider choice with harmful effects. For this reason, both NICA and IAF ask UHC to reverse this decision and rely on the expertise of providers to determine the most appropriate product for their patients.

NICA is a nonprofit trade association and the nation's voice for non-hospital, community-based infusion providers that offer a safe, more efficient, and more cost-effective alternative to hospital care settings for provider-administered medications. NICA's efforts are focused on addressing and overcoming challenges and threats to the sustainability of the most affordable care setting for provider-administered medications. Our goal is to help key decision-makers understand the value of receiving provider-administered medications in non-hospital care settings and preserve this vital delivery channel.

IAF is a nonprofit advocacy community and public charity dedicated to ensuring that patients have access to provider-administered therapies for any and all complex diseases. The organization was created to serve as a supportive and inclusive community for the patients receiving these life-changing medications as they seek understanding, empowerment, and unwavering support throughout their disease management journeys. IAF believes that all patients deserve treatment that works for them.

NICA and IAF understand that payors have an ongoing need to control formularies and costs, while also providing value for their members. Biologics are some of the most innovative and life-changing medications developed in the last decade and offer tremendous value to those who need them. Consequently, they are also some of the most expensive medications and present unique challenges to manufacturers, providers, patients, and insurers.

[1] UnitedHealthcare Commercial Medical Benefit Drug Policy, UnitedHealthcare, 2021.

Consequences Associated with UHC's Proposed Infliximab Policy

Patients with chronic conditions often rely on expensive biological products to manage their disease states. Throughout the journey to clinical stability, patients are subjected to high physical, emotional, and economic burdens associated with their disease. Remicade and Renflexis treat a number of these serious and rare conditions including ankylosing spondylitis (AS), Crohn's disease, rheumatoid arthritis (RA), plaque psoriasis, psoriatic arthritis and ulcerative colitis. When patients dealing with one of the aforementioned conditions identify the right treatment plans for their health and lifestyle and are able to limit the frequency and severity of disease flares, they will actually reduce their consumption of high-cost medical services. When that clinical stability is disrupted by their insurance company's requirement to change their therapy to a "preferred product," the consequences are often severe, including disease flare, additional PCP visits, specialist visits, labs and diagnostics, trips to the emergency room, inpatient care and even highly invasive surgical intervention. **Not only do these complications place a physical and mental toll on patients, but they often lead to a higher consumption of medical services that would otherwise be avoided, meaning higher out-of-pocket costs for patients and increased cost-sharing liability for payors.**

A patient's treatment plan is deeply personal and individualized. Patients living with Crohn's, RA, psoriatic arthritis, ulcerative colitis, or any other conditions managed with Remicade and Renflexis rely on expeditious and uninterrupted access to their prescribed medications to optimize health outcomes and minimize health care consumption. When dealing with complex and chronic diseases, conventional drugs are not always effective, therefore biological products are sometimes 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 and it can take months or even years to find the right biologic that manages disease progression.

Studies have shown that investing in the right medication can actually reduce the total amount spent on hospital (e.g., ED visits, inpatient care) or other medical costs (e.g., labs/diagnostics, surgery) through effective disease management. In January 2020, Avalere conducted an analysis of cost-disparity between undermanaged rheumatoid arthritis patients (a condition treated with Remicade and Renflexis) and effectively managed RA patients. The study found that the patients with undermanaged RA had 121% higher medical costs than all other RA patients. Avalere identified greater utilization of hospital and physician services as the main driver behind these higher costs for undermanaged disease.[2] Therefore, policies that implement short-term cost containment strategies, such as switching the preferred medication on a drug formulary, can actually lead to greater annual spend on members through resulting disease flares and the costly health service implications that follow.

Patient and Provider Response to Non-Medical Switching

In the short period of time since UHC announced its decision to require patients who are currently stable on Remicade or Renflexis to switch to a preferred infliximab medication (Avsola or Inflectra) for reasons unrelated to health or safety, NICA and IAF have heard from patients and providers across the country

[2]Cole, M., Vidulich, A., Francis, M., & Amodeo, K. (2020). Patients with undermanaged RA have higher medicare costs than other RA patients. In Insights & Analysis. Avalere Health. https://avalere.com/insights/patients-with-undermanaged-ra-have-higher-medicare-costs-than-other-ra-patients

who are deeply concerned with the changing requirements for coverage. The policy lists certain criteria that must be met should a patient wish to continue treatment with Remicade and Renflexis, including either a 14-week trial on both Inflectra and Avsola and physician attestation that the patient's clinical response would be superior with their prescribed medication **or** a documented history of intolerance, contraindication or adverse event to both Inflectra and Avsola and physician attestation. In both cases, the patient is required to try both preferred medications, despite the physician's prescription.

In an online study published in March 2020, 404 specialist physicians who treat complex patients (including cardiologists, endocrinologists, gastroenterologists, oncologists and rheumatologists) were asked about their perceptions of non-medical switching and the impact on their patients. The majority of physicians surveyed reported frequent or very frequent increases in non-office visit contacts and increased calls with pharmacies following non-medical switches. In fact, 43.9% of rheumatologists noted frequent or very frequent increase in additional medications needed as a result.[3] In a separate survey of 297 physicians who prescribe biologics, 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%).[4]

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 being left out 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.[5]

There is an overwhelmingly negative association with non-medical switching within the minds of healthcare providers and patients. UnitedHealthcare is placing an additional burden upon the administrative and medical staff by requiring providers to attest "in their clinical opinion, [that] the clinical response would be expected to be superior with" the prescribed drug, despite having already made this attestation by prescribing the medication in the first place.[6] If healthcare facilities decide that treating UnitedHealthcare members is too onerous, they could decide to no longer accept patients covered by UHC, reducing access points for members to receive care and forcing them into more expensive sites of care (i.e., hospitals) counteracting any cost-savings UHC realized from consumption of medical benefit drugs in non-hospital care settings.[7]

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[3] Costa, Olivia S et al. "Specialist physician perspectives on non-medical switching of prescription medications." Journal of market access & health policy vol. 8,1 1738637. 9 Mar. 2020, doi:10.1080/20016689.2020.1738637

[4]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

[5]"A Study of the Qualitative Impact of Non-Medical Switching." Alliance for Patient Access, Alliance for Patient Access, Feb. 2019,

admin.allianceforpatientaccess.org/wp-content/uploads/2020/02/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf.

[6] UnitedHealthcare Commercial Medical Benefit Drug Policy, UnitedHealthcare, 2021.

[7] UnitedHealth Group. Administering Specialty Drugs Outside Hospitals Can Improve Care and Reduce Costs by $4 Billion Each Year , UnitedHealth Group , 2019, www.unitedhealthgroup.com.

Furthermore, patients are becoming increasingly frustrated with increasing premiums, deductibles, and out-of-pocket maximums while coverage dwindles. Patients with chronic diseases, like RA and Crohn's, rely on their insurer for coverage of the care they need to maximize quality of life. If UHC continues to ignore the needs of its members, not only will patients opt for other insurance options and providers may decline services for UHC members, but they will be reluctant to refer others to UHC.

Conclusion

There are many complex, multi-faceted challenges facing the sustainability of our healthcare system. The affordability and accessibility of drugs continue to present the most significant challenge. Utilization management strategies, like non-medical switching, are contributing to unnecessary health care spending by superseding the medical expertise of providers and undermining their ability to treat patients with the right medications at the right time. Consequently, patients and providers are finding themselves at odds with the insurance landscape, to the detriment of patients and cost-savings.

NICA and IAF agree with other patient and provider advocacy organizations that the biological therapy best suited for a particular patient should be a collaborative determination made by the healthcare provider and patient. We understand that it behooves health insurers to drive their members towards the most "cost-effective" treatment option in the immediate-term, but, as we have previously described, any cost savings realized in the short term will almost certainly be outweighed by the long-term financial implications associated with undermanaged disease. We are also deeply concerned that patients' health will be adversely affected by this policy change. Therefore, NICA and IAF strongly encourage UnitedHealthcare to reconsider its decision to supersede providers' prescribing authority and clinical expertise by dictating the course of treatment for its members. Instead, we suggest empowering your members and their providers to locate the right treatment at the right time. We hope that we can work with payors to find solutions that control costs and maximize member value without compromising patient care.

On behalf of the National Infusion Center Association, the Infusion Access Foundation, the hundreds of thousands of patients across the nation requiring provider-administered medications, and the providers who treat them, **I urge you to reverse this decision and rely on the expertise of providers to determine the most appropriate product for their patients.**

Should you have any questions or need more information, please feel free to contact Kindyl Boyer, Director of Advocacy, at kindyl.boyer@infusioncenter.org or 512-402-6955.

Sincerely,

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