AIMEDALLIANCE

January 13, 2021

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Re: Formulary Change Impacting Infliximab Products

Dear Dr. Sandy:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. It has come to our attention that UnitedHealthcare (UHC) intends to make mid-year formulary changes that can impact individuals with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis, and ulcerative colitis. We are concerned that these policy changes will result in nonmedical switching practices that may harm patients who are particularly vulnerable during the COVID-19 pandemic. ***Therefore, we respectfully request that UHC wait until the new plan year begins to make any formulary changes, at which point, patients can select a different health plan if they so choose. Alternatively, we recommend that UHC amend its prior authorization requirements to ensure that stable patients have a more realistic pathway to accessing their current medication. In particular, UHC should allow for a straightforward exception process in which the stable patient's health care practitioner can determine that the patient's current medication is medically necessary.***

A. Nonmedical Switching

Effective February 1, 2021, UHC's Medical Benefit Drug Policy will exclude two infliximab products (the reference product infliximab and infliximab-adba) from its preferred products list, and plan enrollees, including individuals who are stable on their medication, must meet new step therapy and prior authorization criteria to access the medication. UHC created a "preferred product criteria" pathway that allows patients to access infliximab and infliximab-adba; however, the requirements are overly burdensome and will likely not result in meaningful access. The process includes, among other things, a requirement to try and fail on two other infliximab biosimilar products for a minimum of 14 weeks and not experience a loss of a favorable response after established maintenance therapy with an infliximab biosimilar product. By that point, a patient is more likely to be switched to an alternative class of drugs rather than back to his or her current, effective medication. As such, UHC's new criteria will result in nonmedical switching.

Nonmedical switching occurs when a health insurer or pharmacy benefit manager (PBM) requires a stable patient to switch from his or her current, effective medication to an alternative by excluding the original medication from coverage, elevating the medication to a higher cost tier, or otherwise limiting access to a treatment or increasing the patient's out-of-pocket costs. As a result, the patient is forced to switch to a therapeutically equivalent medication. Therapeutically equivalent products do not need to be chemically equivalent, bioequivalent, or generically

equivalent, and therefore, can affect the patient differently than his or her original treatment.[1] Forcing a patient to switch to a therapeutically equivalent medication can compromise his or her clinical stability, which can expose him or her to avoidable negative health outcomes and increased costs for both the insurer and the patient. As such, we are opposed to policies that effectively force stable plan enrollees to switch to a therapeutically equivalent medication for nonmedical reasons.

B. Nonmedical Switching May Violate State Consumer Protection Laws

Nonmedical switching policies may violate consumer protection laws. Current Minnesota law protects consumers against unfair and deceptive trade practices. Such practices include actions "represent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;" "advertis[ing] goods or services with intent not to sell them as advertised;" and "engag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding."[2] When a medication appears on a formulary during open enrollment and it is removed shortly thereafter, arguments could be made that:

- The administrators of the health plan knew they would be providing access to a different "style or model" of medication than they had represented on the formulary;
- They advertised the presence of a particular medication on the formulary with the knowledge that a mid-year formulary change would remove it; and
- The removal of a medication from the formulary in the middle of the plan year was conduct that "creates a likelihood of confusion or of misunderstanding" for consumers who are enrollees of the health plan.

Here, given that the switch is scheduled to very shortly happen after the plan year has begun, plan enrollees could argue that UHC is engaging in unfair and deceptive trade practices. By negatively modifying coverage of reference product infliximab and infliximab-adba in the middle of the plan year, UHC has changed its benefit design at a time when enrollees are locked into their plan for the rest of the plan year. They are unable to enroll in different health plans, which may have been the only way that stable enrollees could affordably access their current, effective medication within a reasonable time. To prevent potentially unfair and deceptive practices, we urge you to refrain from making these negative formulary changes until the new plan year begins, at which time patients will be free to select an alternative plan.

Furthermore, other states in which UHC offers health plans have explicit laws that prohibit nonmedical switching and midyear formulary changes (e.g., California, Illinois, Louisiana, Maryland, Nevada, New Mexico, and Texas).[3] As such, UHC's proposed changes would violate the laws in these states.

C. Nonmedical Switching Can Be Harmful to Stable Patients

Nonmedical switching can negatively impact patients' health. For example, in a study of patients with various autoimmune diseases who switched anti-tumor necrosis factor-alpha (anti-

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[1] https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#T; http://www.gabionline.net/Biosimilars/General/Glossary-of-key-terms

[2] https://www.revisor.mn.gov/statutes/cite/325D.44

[3] https://codes.findlaw.com/ca/health-and-safety-code/hsc-sect-1367-22.html; https://www.ilga.gov/legislation/ilcs/documents/021501340K25.htm; http://www.legis.la.gov/legis/ViewDocument.aspx?d=762663; https://legiscan.com/MD/text/SB405/2019; https://www.leg.state.nv.us/register/2014Register/R074-14A.pdf; https://law.justia.com/codes/new-mexico/2014/chapter-59a/article-22/section-59a-22-49.4; https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1369.htm.

TNF) agents, researchers found that a cost-influenced, nonmedical switch was associated with a 62 percent increased likelihood of an additional treatment adjustment linked to side effects or lack of efficacy during a one-year follow-up period compared with a 20 percent increased likelihood in patients who remained on stable treatment.[4] The European Crohn's and Colitis Organization ("ECCO") has stated that switching a stable patient with Crohn's disease or colitis to a biosimilar simply for cost reasons is inappropriate and can be detrimental to the patient due to the inherent complexity of biologic medications.[5] Instead, ECCO recommends that "clinical decisions should always be made on an individual basis" within the confines of the patient and provider relationship.[6]

Forcing these patients to switch to another medication, which may not be effective for treating their condition and without advance notice, can disrupt the patient's continuity of care and medication adherence. These disruptions can contribute to negative health outcomes and increased costs for the health system. As such, the decision to switch treatments should remain within the discretion of the treating health care provider and be made on a case-by-case basis, with the support of scientific evidence and the patient's full consent.[7]

D. Nonmedical Switching Can Be Particularly Risky During the COVID-19 Pandemic

UHC's decision to force stable patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis, and ulcerative colitis to change their medication regime during the COVID-19 pandemic may result in increased risk to high-risk patients. The Centers for Disease Control and Prevention (CDC) has determined that patients who are on immunosuppressants may be immunocompromised, and therefore, are at high risk for severe illness from COVID-19.[8] The CDC has explicitly cautioned patients with such conditions to continue taking their medication and to not change their treatment plan unless their health care provider determines a change is appropriate.[9] A change dictated by a PBM or an insurer based solely on financial reasons during the pandemic can place high risk patients' health and lives in jeopardy. If they experience adverse events, they may need to leave the house more frequently for visits to their health care provider or to the hospital. Each occurrence of leaving the home and going to a medical facility increases their risk of exposure to the virus. Therefore, any changes to UHC's formulary impacting high risk patients should not be done until the beginning of the next plan year when patients are free to select a new health plan.

Moreover, national health experts do not predict the end of the pandemic until the end of 2021 at the earliest.[10] These predictions were made with the assumption that 75 to 85 percent of the population would be vaccinated.[11] However, vaccination roll outs have, thus far, been slower than predicted. As such, now is not the time to switch patients from their current medication to a different treatment that could be less effective in the individual patient or cause adverse events.

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[4] https://www.tandfonline.com/doi/full/10.1080/03007995.2017.1375903
[5] https://academic.oup.com/ecco-jcc/article/7/7/586/407523
[6] https://academic.oup.com/ecco-jcc/article/7/7/586/407523
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486595/
[8] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html; https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html; https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html
[9] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[10] https://news.harvard.edu/gazette/story/2020/12/anthony-fauci-offers-a-timeline-for-ending-covid-19-pandemic/#:~:text=The%20nation's%20top%20infectious%20disease,by%20the%20end%20of%202021.
[11] https://news.harvard.edu/gazette/story/2020/12/anthony-fauci-offers-a-timeline-for-ending-covid-19-pandemic/#:~:text=The%20nation's%20top%20infectious%20disease,by%20the%20end%20of%202021.

E. Conclusion

We strongly encourage UHC to reconsider using nonmedical switching practices. Instead, it should allow stable enrollees to remain on their current medication for the remainder of the plan year, or in the alternative, offer an exception process based on a medical necessity determination made by the patient's health care provider. In doing so, UHC will protect the health and continuity of care of their enrollees who are stable on their medications during the COVID-19 pandemic.

Thank you for considering our recommendations on this matter. Please contact us at (202) 559-0380 or policy@aimedalliance.org if we can be of any further assistance.

Sincerely,

Stacey L. Worthy
Counsel