AIMED ALLIANCE

March 23, 2020

Steve Connelly, M.D.
Brian Rank, M.D.
Co-Executive Medical Directors
HealthPartners
8170 33rd Avenue South
Bloomington, MN 55425

Dear Dr. Connelly and Dr. Rank:

Aimed Alliance is a 501(c)(3) nonprofit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. I am writing on behalf of the undersigned plan enrollees to request that HealthPartners not engage in nonmedical switching practices and, instead, allow stable enrollees to remain on their medications throughout the plan year.

According to a January 2020 notice to providers (the Notice), HealthPartners has changed its infliximab medical policy, ending coverage for the reference product infliximab, and instead requiring the use of infliximab-dyyb, an infliximab biosimilar. The Notice explained that plan enrollees who are currently using and stable on infliximab will be unable to continue using those treatments effective April 1, 2020 – after the plan year has already begun. These enrollees will only have access to the preferred biosimilar product, infliximab-dyyb. The Notice also explains that all infliximab use after April 1, 2020 will require a new prior authorization that contains clinical rationale outlining why the biosimilar infliximab-dyyb is not medically appropriate. As a result of this policy, stable enrollees on the reference product will be subject to nonmedical switching and will be required to obtain an exception to remain on their treatment.

HealthPartners also sent a letter dated February 20, 2020 (the Letter) to its enrollees notifying them of this policy change. The Letter states that the effective date of this change is April 1, 2021, rather than April 1, 2020. This miscommunication is causing confusion among enrollees, who are concerned that they may be forced to discontinue an effective treatment next year and have now received information that conflicts with the information that has been given to their provider.

I. Nonmedical Switching

Aimed Alliance supports policies that result in cost savings, including those that improve access to biosimilar medications. As such, we support requiring plan enrollees who are prescribed an infliximab medication for the first time (i.e., new starts) to start on an infliximab biosimilar. However, we do not support policies that result in nonmedical switching.

Nonmedical switching occurs when a health insurer requires a stable patient to switch from his or her current, effective medication to an alternative drug by excluding the original medication from coverage, elevating the drug 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 drugs 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 drug 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 force stable plan enrollees to switch to a therapeutically equivalent medication for nonmedical reasons.

II. 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 happen four months after the plan year has begun, plan enrollees could argue that HealthPartners is engaging in unfair and deceptive trade practices. By rescinding coverage of infliximab in the middle of the plan year, HealthPartners has changed its benefit design at a time when enrollees are still 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. Additionally, by including the wrong date on the Letter, plan enrollees erroneously believe they have more than a year to seek an exception to HealthPartners' new policy. To prevent potentially unfair and deceptive practices, we urge you to automatically allow enrollees who are currently stable on the reference product infliximab to remain on their medication for the remainder of the plan year.

[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

III. Retroactive Denials of Prior Authorization Policies are Harmful to Patients and Increase Costs Across the Health System

The Notice states that all infliximab use after April 1, 2020 will require a new prior authorization with clinical rationale outlining why the biosimilar infliximab-dyyb is not medically appropriate. The policy effectively cancels the remaining duration of currently approved prior authorization requests for biologic infliximab. As such, HealthPartners' policy is a retrospective denial of a previously approved prior authorization request.

Retrospective denials of prior authorizations revoke coverage of treatments that have already been approved as medically necessary. Such policies increase costs across the health system and duplicate administrative burden on health plans and providers alike by processing requests for treatments that have already been deemed to be medically necessary. They are harmful to plan enrollees, who may lose access to medically necessary treatment as they await approval of an additional prior authorization. In the case of autoimmune conditions such as rheumatoid arthritis, such delays may result in disease progression and inadequately treated flares.[3]

As retrospective denials become more commonplace, they are likewise garnering more attention from lawmakers because these policies often leave enrollees with enormous and unexpected medical bills.[4] Many states have enacted laws prohibiting retrospective denials.[5] Additionally, the Minnesota Department of Insurance has received complaints regarding retrospective denials of prior authorization approvals.[6]

As such, we ask that HealthPartners not require a new prior authorization for enrollees who have previously obtained an infliximab prior authorization. Rather, HealthPartners should allow its enrollees to remain on their medically necessary treatment throughout the plan year at a minimum.

IV. Nonmedical Switching Can Be Harmful to Stable Patients with Autoimmune Conditions

Nonmedical switching negatively impacts patients' health. For example, rheumatoid arthritis is a chronic progressive inflammatory disease that requires patient-centered, individualized therapy rather than a one-size-fits-all approach. If not properly treated, it can reduce the physical

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[3] https://onlinelibrary.wiley.com/doi/epdf/10.1002/acr.24062?referrer_access_token=bTa0-pMg_978jhhYG0sHLU4keas67K9QMdWULTWMo8OspoCCtnEg5U3KYZWx_CzUTjNILtfhn6D0MqtNwYfpuAJyWuXpBOK3QgsbuTYFJ7Q_Q0QB-tJBY-mm8OJWBJW0PcpvUwLEzQaT4_EENT4DOg%3D%3D

[4] https://jamanetwork.com/journals/jama/fullarticle/2760655; https://khn.org/news/prior-authorization-revoked-patients-stuck-with-bills-after-insurers-dont-pay-as-promised/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_source=hs_email&utm_medium=email&utm_content=83048696&_hsenc=p2ANqtz-9eyLQh-u0oouJ0VJV-qztLjKvMjMLe7IZUFRuGdsg-PneeBorIX7P6UFbtp1PPK66pHqnHVhQ1MJtGF1k7Kyw3tVT3Uw&_hsmi=83048696

[5] As of 2018, Arkansas, Alaska, Arizona, Delaware, Idaho, Illinois, New York, North Carolina, Ohio, Rhode Island, Virginia, and Washington have all enacted laws that prohibit retrospective denials. https://www.ama-assn.org/media/22571/download

[6] https://khn.org/news/prior-authorization-revoked-patients-stuck-with-bills-after-insurers-dont-pay-as-promised/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_source=hs_email&utm_medium=email&utm_content=83048696&_hsenc=p2ANqtz-9eyLQh-u0oouJ0VJV-qztLjKvMjMLe7IZUFRuGdsg-PneeBorIX7P6UFbtp1PPK66pHqnHVhQ1MJtGF1k7Kyw3tVT3Uw&_hsmi=83048696

abilities of patients and cause joint damage.[7] The progression of rheumatoid arthritis can be extremely painful as swelling and stiffness in the joints damage bone and cartilage over time.[8] Many patients with rheumatoid arthritis also have comorbid mental health symptoms, such as anxiety and depression.[9] Additionally, some patients with autoimmune diseases whose medications are switched for nonmedical reasons face an increase in side effects and greater dependence on health care utilization.[10] Other patients who do not experience immediate adverse events or drop-offs in efficacy after the switch report an increase in pain and inflammation.[11] When a plan enrollee switches off of a biologic medication like infliximab and later switches back to it, the treatment may no longer be effective due to the patient building up tolerance to the medication or developing immunogenicity.

The decision to switch biologic 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.[12] Patients with chronic conditions like rheumatoid arthritis often try and fail on a number of different medications before they find one that works for them. Once stable on a medication, it is critically important that these patients remain on the same medication to ensure that they can successfully manage their health. 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, which can contribute to negative health outcomes and increased costs for the health system.

The Alliance for Patient Access released a report in February 2019, titled *A Study of the Qualitative Impact of Non-Medical Switching*.[13] This report features the results of a national survey designed to gauge patient perspectives on nonmedical switching practices. This report revealed that after being switched, nearly 40 percent of patients indicated that the new medication was not as effective as the original medication. Furthermore, almost 60 percent of respondents indicated that they experienced a complication from taking the new medication. Almost 40 percent of respondents indicated that the experience was so frustrating that they stopped taking their medication altogether. We urge you to review this report in its entirety to fully understand how nonmedical switching can negatively impact patient health, medication adherence, and outcomes.

V. Proper Notice

At a bare minimum, HealthPartners must provide adequate notice of the proposed policy change to plan enrollees. Pursuant to the Patient Protection and Affordable Care Act (ACA) regulations, health plans must provide a minimum of 60 days' notice prior to making any material modifications.[14] A "material modification" includes a "material reduction in covered services or benefits" or more strict requirements for "receipt of benefits," including changes or modifications

[7] https://nccih.nih.gov/health/RA/getthefacts.htm#about; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847317/
[8] https://nccih.nih.gov/health/RA/getthefacts.htm#about
[9] https://nccih.nih.gov/health/RA/getthefacts.htm#about
[10] https://www.healio.com/rheumatology/psoriatic-arthritis/news/online/%7B4d3c5bb3-c81b-4f16-bf9c-6614e281f1d6%7D/non-medical-switch-of-anti-tnf-agents-may-result-in-increased-side-effects-lack-of-efficacy
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5349501/
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486595/
[13] https://afpadev.wpengine.com/wp-content/uploads/2020/01/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf
[14] 45 C.F.R. § 147.200(b)

that reduce or eliminate benefits or increase cost-sharing.[15] While HealthPartners sent plan enrollees the Letter on February 20, 2020, the Letter provided less than 60 days' notice. Additionally, the Letter contained the wrong effective date, thereby creating confusion among plan enrollees and not properly conveying the urgency in which they will need to act if they choose to request an exception to remain on their current medication. Therefore, given that HealthPartners failed to provide adequate notice to plan enrollees, HealthPartners should allow stable patients to remain on their current medication for the remainder of the plan year. Alternatively, HealthPartners should provide an additional 60 days' notice to plan enrollees.

VI. Conclusion

We strongly encourage HealthPartners to reconsider using nonmedical switching practices. Instead, it should allow stable enrollees to remain on their current medication. In doing so, HealthPartners will protect the health and continuity of care of their enrollees who are stable on their medications. By limiting adverse events and preventing related increases in health care utilization, HealthPartners can also help reduce overall health care costs.

Thank you for considering our recommendations on this matter. If you would like to discuss this issue further, please contact me at (202) 559-0380 or policy@aimedalliance.org.

Sincerely,

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[15] Employee Retirement Income Security Act of 1974, Section 102; 29 C.F.R. § 2520.104b-3; 45 C.F.R. § 147.200(b).