AIMED ALLIANCE

April 15, 2019

Thomas L. Simmer, M.D.
Chief Medical Officer
Blue Care Network of Michigan
600 E. Lafayette Blvd.
Detroit, MI 48226

Re: Non-medical switching of biosimilars for branded infliximab

Dear Dr. Simmer,

Aimed Alliance is a 501(c)(3) nonprofit organization that seeks to protect and enhance the rights of health care consumers and providers. I am writing on behalf of the undersigned organizations, representing health care providers and patient advocates. We request that the Blue Care Network of Michigan (BCN) allow stable patients to remain on their medications throughout the plan year.

According to a February 22, 2019 letter issued to health care providers (the "Letter"), BCN ended coverage of the reference product infliximab and biosimilar infliximab-abda after the plan year had begun. Furthermore, the Letter noted that enrollees who are currently using and stable on infliximab and infliximab-abda will be unable to continue using those treatments past May 1, 2019. These enrollees will only have access to the preferred biosimilar product, infliximab-dyyb, from May 1, 2019 to May 1, 2020. As a result of this new policy, stable patients on infliximab and infliximab-abda will be subject to non-medical switching.

I. What Is Non-Medical Switching?

Non-medical switching occurs when an 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 increasing the patient's out-of-pocket costs. The patient is, therefore, forced to switch to a "therapeutically equivalent" medication. Therapeutically equivalent drugs do not need to be chemically equivalent, bioequivalent, or generically equivalent.[1] They can be entirely different medications. BCN's decision to require individuals who achieved clinical stability to alter their treatment regimens to a therapeutically equivalent treatment is particularly illustrative of the problems associated with non-medical switching. We do not oppose switching a plan enrollee from a brand medication to a generic version that exhibits the same level of safety and effectiveness. However, we are opposed to policies that force stable plan enrollees to switch to a therapeutically equivalent medication for non-medical reasons.

II. Non-Medical Switching Can Be Harmful to Stable Patients with Autoimmune Conditions

Non-medical 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 abilities of patients

[1] http://www.gabionline.net/Biosimilars/General/Glossary-of-key-terms.

and cause joint damage.[2] The progression of rheumatoid arthritis can be extremely painful as swelling and stiffness in the joints damage bone and cartilage over time.[3] Many patients with rheumatoid arthritis also have comorbid mental health symptoms, such as anxiety and depression.[4] Additionally, some patients with autoimmune diseases whose medications are switched for non-medical reasons face an increase in side effects and greater dependence on health care utilization.[5] Other patients who do not experience immediate adverse events or drop-offs in efficacy after the switch report an increase in pain and inflammation.[6] 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.

We believe that 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.[7] Patients with chronic conditions like rheumatoid arthritis and ankylosing spondylitis 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 are able to 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*.[8] This report features the results of a national survey designed to gauge patient perspectives on non-medical 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 non-medical switching can negatively impact patient health, medication adherence, and outcomes.

III. Non-Medical Switching Policies May Violate State Consumer Protection Laws

Non-medical switching policies may violate consumer protection laws. Current Michigan law protects consumers against unfair and deceptive trade practices. Such practices include actions "representing or implying that the subject of a consumer transaction will be provided promptly, or at a specified time, or within a reasonable time, if the merchant knows or has reason to know it will not be so provided."[9] When a medication appears on a formulary during open enrollment and it is removed shortly afterward, an argument could be made that the administrators of the health plan knew they would not be providing access to that medication in a timely manner.

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[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847317/
[3] https://nccih.nih.gov/health/RA/getthefacts.htm#about
[4] https://nccih.nih.gov/health/RA/getthefacts.htm#about
[5] 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
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5349501/
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486595/
[8] http://allianceforpatientaccess.org/wp-content/uploads/2019/02/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf
[9] http://legislature.mi.gov/doc.aspx?mcl-445-903

Here, given that the switch happened in the first months of the plan year, enrollees could argue that BCN engaged in unfair and deceptive trade practices. By rescinding coverage of infliximab in the middle of the plan year, BCN changed its benefit design at a time when participants were still locked into their plan for the rest of the plan year. These individuals were unable to enroll in different health plans, which may have been the only way that stable patients could affordably access their current, effective medication within a reasonable time. Moreover, while the Letter indicates that an enrollee can request an exemption from the formulary change if the prescribing physician can document that the medication is medically necessary, exemptions processes are not well understood by patients, and they require additional time and resources from the patient and prescriber to complete. Such processes are often overly burdensome, leaving many to simply abandon their attempts. To reduce your exposure to legal risk, we recommend that you allow all patients who are currently stable on infliximab and infliximab-abda to remain on their current medications for the duration of the plan year without requiring them to undergo a burdensome exemption process.

IV. Conclusion

We strongly encourage BCN to reconsider using non-medical switching practices. In doing so, BCN will protect the health and continuity of care of their beneficiaries who are stable on their medications. By limiting adverse events and preventing related increases in health care utilization, BCN 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 jwylam@aimedalliance.org.

Sincerely,

Aimed Alliance
American Autoimmune Related Diseases Association
Coalition of State Rheumatology Organizations
HIV/AIDS Alliance of Michigan
Lupus and Allied Diseases Association, Inc.
Michigan Disability Rights Coalition
Michigan Rheumatism Society
National Infusion Center Association
National Organization of Rheumatology Managers
Patients Rising Now
Practicing Physicians of America
U.S. Pain Foundation