Non-Medical Switching & Mental Health: Ensuring Access to Appropriate Care

EXECUTIVE SUMMARY

I. Introduction

On August 31, 2021, the Alliance for Mental Health Care Access ("AMHCA") conducted its first roundtable meeting. AMHCA is a new working group that is expanding on the work of the Alliance for Depression Care Access ("ADCA"). Co-led by Aimed Alliance and the Alliance for Patient Access ("AfPA"), AMHCA works to prevent the non-medical switching of stable patients with mental health conditions. The objects of the meeting were to (1) understand the impact of non-medical switching on patients with mental health conditions; (2) consider ways to improve access to medications for stable patients with mental health conditions; and (3) gauge interest, share resources, and plan coalition activities. The following is a summary of discussions from the meeting.

II. Key Insights

A. Non-Medical Switching and the Impact on Patients with Mental Health Conditions

The meeting began with a presentation from Stacey Worthy of Aimed Alliance, in which she provided an overview of the impact of non-medical switching on patients with mental health conditions. She explained that non-medical 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 alternate drug by excluding the original medication from coverage, elevating the drug to a higher cost tier, or otherwise limiting access to treatment or increasing the patient's out-of-pocket costs. Forcing a patient to switch treatments can upset his or her stability, which can expose the patient to avoidable negative health outcomes and increase health care costs.

Non-medical switching policies are implemented by health plans and PBMs to increase health plan profits. These policies result in patients changing medications for financial rather than medical reasons. For patients with mental health conditions, this can result in a number of complications, including a lack of adherence to their treatment plan, harmful side effects, medication errors, increased office visits, and additional lab testing and medication use.[1] Lack of adherence can be especially impactful for patients with mental health conditions who may already struggle with medication adherence. Specifically, a 2020 study report that "at least 61% of patients with schizophrenia, 57% of patients with bipolar disorder, and 52% of patients with depression had problems with adherence."[2] Non-adherence can worsen symptoms and result in hospitalization or re-hospitalization, reduce effectiveness of subsequent treatments, and result in an increased risk of suicide.[3]

---

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7144249/
[2] https://www.psychiatrictimes.com/view/treatment-nonadherence-epidemic-hidden-plain-sight
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778728/

Non-medical switching is a consumer protection issue. Patients may not know their health plan permits switching until they are subjected to a change, as these policies are often buried in a plan's fine print. Additionally, these changes can occur after the plan year has begun when a patient is already locked into the plan and has no other options for coverage. These policies are also against the clinical practice recommendations. Notably, the American Medical Association ("AMA") Principle 5 on Prior Authorization and Utilization Management Reform Principles recognizes that "unanticipated changes to formularies and coverage restrictions throughout the plan year can negatively impact patients' access to needed medical care . . ."[4] Thus, AMA adopted Principle 5, which states "[a] drug or medical service that is removed from a plan's formulary or is subject to new coverage restrictions after the beneficiary enrollment period has ended should be covered without restrictions for the duration of the benefit year."[5]

For patients with mental health conditions, non-medical switching can be particularly problematic as many patients already struggle with finding a medication that works for them. Moreover, patients with mental health conditions may also experience increased anxiety and distress once they are told they will no longer be able to obtain their medication.[6] In addition, not all medications within the same class work the same for each patient.[7] Thus, a patient subject to non-medical switching may not be able to tolerate or successfully respond to the new medication.[8] For example, in the landmark STAR*D study, it was found that over a seven-year period, patients who were switched between SSRI medications had less favorable outcomes, an increase in treatment resistance, and lower rates of remission.[9]

Lastly, despite these policies being implemented to save health plans money, non-medical switching can increase health care costs. For example, one study of patients with depression found that over a three-month period, in comparison to stable patients, those who were subject to non-medical switching paid an average of $138 more in medical costs and $149 more in drug costs.[10]

B. Existing Protections

Ms. Worthy also provided an overview of current laws that are intended to address non-medical switching. For example, twelve states have enacted laws that either prohibit plans from making mid-year formulary changes or require plans to allow stable patients to remain on their current medication without additional cost-sharing.[11] Under the Patient Protection and Affordable Care Act ("ACA") guaranteed renewability provision, plans are prohibited from making mid-year formulary changes.[12] The Department of Health and Human Services ("HHS"), in its 2020 Notice of Benefit and Payment parameters also reiterated that issuers "may not make

---

[4] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf
[5] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf
[6] https://instituteforpatientaccess.org/study-non-medical-switching-reduces-quality-of-life-for-patients/
[7] https://www.webmd.com/depression/guide/untreated-depression-effects#2
[8] https://www.healthline.com/health/mdd/switching-antidepressants
[9] https://ps.psychiatryonline.org/doi/full/10.1176/ps.2009.60.11.1439
[10] https://pubmed.ncbi.nlm.nih.gov/20504111/
[11] https://aimedalliance.org/nonmedical-switching-enacted-laws/
[12] https://www.law.cornell.edu/cfr/text/45/147.106

plan design changes, other than at the time of plan renewal."[13] Medicare Part D also provides additional protections as it requires plan sponsors to cover all or substantially all drugs within the Six Protected Classes, which include antidepressants and antipsychotics.[14] However, despite these protections, non-medical switching is becoming a more prevalent practice. Specifically, a 2021 study found that "in 2019, 227 drugs from the protected classes were predominately placed on the highest tiers (non-preferred or specialty) compared to only 76 drugs (25%) in 2016."[15]

C. Practitioners Perspective

Next, David Charles, MD, Professor and Vice-Chair of Neurology at Vanderbilt University Medical Center, and the founder of AfPA, provided the clinician's perspective on non-medical switching. Speaking from his personal perspective, Dr. Charles explained to attendees that non-medical switching can be especially difficult for patients with mental health conditions. He elaborated that a patient's mental health condition may limit his or her ability to advocate for himself or herself.

In addition, Dr. Charles explained that having to appeal an insurance denial to obtain a medication can be emotionally exhausting and distressing. Dr. Charles also noted that he has observed increased anxiety when a health plan denies coverage. He added that these policies often also tax health care providers given that patients often call their health practitioner to assist in getting their medication covered. For practitioners, this results in additional administrative time spent challenging these policies, which ultimately takes away from time that could be spent treating patients. Overall, Dr. Charles provided that while utilization management may be appropriate in some instances, onerous practices such as non-medical switching are not appropriate for medications used to treat mental health conditions, and health plans should not interfere for non-medical reasons.

D. Policy Priorities, Recent Activity, and Planned Activity

Josie Cooper, Executive Director of AfPA, provided an overview of AMHCA's policy priorities, recent activities, and planned activities. She noted that the working group intends to identify and positively engage with PBMs and payers in efforts to allow appropriate access to medications for patients with mental health conditions. Additionally, the coalition will engage directly with payers and PBMs to address non-medical switching policies and support legislative and regulatory efforts to rein in switching.

Stacey Worthy then reviewed recent activity under the ADCA. For example, in 2020, CVS announced that it would end coverage of four anti-depressant medications, which would inevitably result in many patients being forced to switch medications due to a lack of coverage. In response, the ADCA sent a sign-on letter to CVS and met with CVS Chief Medical Officer Sree Chaguturu. Andrew Sperling, Director of Legislative Advocacy at the National Alliance on Mental Illness weighed in on the call. He noted that a one-size fits all approach to medication

[13] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf at p. 8.
[14] https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f
[15] http://www.partdpartnership.org/uploads/8/4/2/1/8421729/avalere_report_on_six_protected_classes_--_february_2021.pdf at p. 10.

does not work for patients with mental health conditions and that patients need access to the medications that work for them. When CVS executives indicated their intentions to move forward with its non-medical switching policy, the ADCA conducted a digital ad and letter writing campaign targeted at six CVS executives. This campaign resulted in an op-ed, 370 letters sent to executives, and nearly 100,00 digital ad impressions. Josie Cooper also noted that the AfPA has established a mental health working group, which has activated clinicians on access barriers, including non-medical switching. AfPA also leads a coalition, Keep My RX, which wages a campaign to restrict non-medical switching. Both groups can be helpful in achieving the goals of AMHCA. Josie also noted that AfPA recently released a white paper entitled "Mental Health Care Reform After the COVID-19 Pandemic."

Josie noted that AMHCA has several immediate goals, including: (1) elevating patient and health care provider stories of non-medical switching in the mental health space; (2) creating relevant materials that can inform policymaking; and (3) engaging directly with payors. She announced that next steps would include seeking alignment on the AMHCA's key message platform, placing a clinician-authored opinion piece on non-medical switching in a national health care publication, releasing a patient and provider survey, and direct engagement.

III. Roundtable Discussion

Participants engaged in a roundtable discussion. Attendees noted how non-medical switching has impacted the mental health community. Attendees stated:

- Non-medical switching has negatively impacted patients with depression, schizophrenia, and bi-polar disorder, in particular;
- Non-medical switching is an important issue that needs to be addressed;
- There are emotional and logical barriers to filing appeals for patients with mental health conditions;
- Caregivers are often disconnected from medication management and need better information on non-medical switching and how to assist patients in navigating these policies;
- Some organizations have been working to educate caregivers on non-medical switching and how they can support patients struggling with appeals and switching policies; and
- There is a need to develop more obvious ways to identify and address these policies.

Many attendee organizations also expressed interest in participating in the working group's advocacy activities to address harmful non-medical switching practices.

IV. Action Plan

To address non-medical switching practices, the AMHCA proposed both proactive and reactive activities. Proactively, they proposed identifying and highlighting payers who are preserving access to treatments and supporting relevant state and federal legislation, regulations, and policies that prohibit these policies. Reactively, it will be equally important for the working group to identify impacted patients and work with payers to change egregious policies.

V. Conclusion

In conclusion, the AMCHA will be working both proactively and reactively with partners to address harmful step-therapy practices that impair treatment for patients with mental health conditions. AMCHA will be coordinating with partners to provide key language guidance for step-therapy advocacy; a draft step-therapy survey for partner input; and a formal request to join the working group.