A Retrospective Analysis of Insurance Policy Impact on the Choice of Multiple Sclerosis Disease Modifying Therapies
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Background
Financial limitations and insurance restrictions are frequently cited barriers to both starting and transitioning between DMTs. These factors influence the approach to selecting a DMT by both patients and providers1. The choice of DMT for MS treatment is influenced by individual patient considerations, drug-specific factors, and perceived severity of MS course. This study aimed to investigate the impact of insurance policy on the choice of DMT for MS treatment. This practice has continued largely due to the lack of data to support a specific sequencing approach to selecting a DMT by both patients and providers. Financial limitations and insurance restrictions are frequently cited barriers to both starting and transitioning between DMTs. These factors influence the choice of DMT for MS treatment, in which patients are required to fail a cheaper DMT before considering a more expensive one. This approach is often used to ensure that patients are on the most effective and least expensive treatment options. However, this approach is not always effective, as it can lead to patients being on suboptimal treatments and experiencing disease progression.

Methods and Materials
A retrospective chart review of patients seen in the multiple sclerosis (MS) specialty clinic at Alfred Taubman Health Care Center of Michigan Medicine between January 1, 2012 and February 28, 2020 was performed. Adult patients with a diagnosis of MS based on the McDonald Criteria were included in the study. Medical records were accessed electronically on the medical-records software Epic. Data was collected from results of diagnostic tests, notes from health care providers and denial letters from insurance companies. Descriptive statistics were calculated using the statistical software IBM SPSS statistics. A chi-square test was used to compare categorical data. T-tests were used to compare means and a non-parametric test was used to assess for significant differences in gender. An alpha was set at 0.05 with a significance level of p<0.05 for statistical significance testing.

Results
460 patients were evaluated in the study of which 350 (76.1%) carried a diagnosis of MS. Of these patients, 72 (20.6%) were unable to start or continue their desired DMT as agreed upon by the provider and patient, at some point during their treatment course due to financial limitations related to their insurance coverage. The most common limitation was a required step therapy approach to treatment, followed by lost or reduced insurance coverage, and high copays among others. DMTs found to be difficult to access financially were glatiramer acetate (17.7%), dimethyl fumarate (17.7%), teriflunomide (12.7%), interferon beta-1a (12.7%), natalizumab (11.4%), teefurimide (6.3%), ritanumab (6.3%), fingolimod (2.9%), and umbrutinib (2.5%). Patients found most of these insurance difficulties as the initiation of treatment with DMT (80.6%). Due to lack of insurance coverage, 46 (12.1%) patients were off DMT at some point during their MS course.

Study Aim
This study aims to evaluate the financial limitations and insurance restrictions experienced by patients pursuing disease modifying therapy for multiple sclerosis and how the approach to choosing treatment for MS is affected.

Discussion
In this study of 350 patients with multiple sclerosis, we found that although the majority benefited from health insurance (90.4%), approximately 1 in 5 experienced difficulty accessing disease modifying therapies due to insurance limitations. We also found that the financial limitations resulting from these insurance restrictions had a significant impact on the financial burden of disease for patients with MS. The majority of patients (65.8%) experienced difficulty accessing DMT at some point during their MS course.

Inability to continue on disease modifying therapies for MS due to high copays has been reported previously and continues to serve as a barrier to access. Of the 72 patients experiencing financial difficulties, 76% (56) were unable to continue on their current DMT because their copays were too high, with subjective reports of up to $3000 a month in copay requirements.

This study found that patients who experienced insurance restrictions while pursuing DMTs for MS were more likely to benefit from public insurance in the form of Medicare and Medicaid compared to MS patients who did not experience insurance restrictions.

The high prices of DMTs have forced patients and providers to abandon shared decision making based on patient preferences and clinical data for adherence to step therapy requirements enforced by drug companies. At least 16% of our patients reported an inability to access their desired DMT due to step therapy requirements. Insurance policies should eliminate step therapy requirements to further increase access to DMTs for patients with MS, while further research is needed to identify the patients that would most benefit from low-efficiency vs intermediate efficiency vs high-efficiency DMTs.

Conclusions
- This study found that patients who experienced insurance restrictions in their pursuit of MS therapeutic options were more likely to benefit from health insurance (90.4%).
- The majority of these insurance difficulties at the initiation of treatment with DMT (80.6%).
- Due to lack of insurance coverage, 46 (12.1%) patients were off DMT at some point during their MS course.
- Financial barriers to DMT use secondary to insurance restrictions experienced by patients with MS should be further elucidated and alleviated by both insurance and drug companies.

Limitations
The results of this study should be analyzed within the context of the following limitations:
- Patients who experienced insurance restrictions while pursuing disease modifying therapies for MS were identified via notes from health care providers and insurance denial letters scanned into their medical records. Given that some insurance denial letters may not have been incorporated into a patient’s medical record or a health care provider may have excluded financial barriers to access to disease modifying therapies, this study may have underestimated the number of patients who experienced insurance restrictions in their pursuit of MS treatment.
- Given that only 150 of the 350 MS patients evaluated in this study received all of their MS treatment at Michigan Medicine, the remaining 200 patients may have experienced financial difficulties accessing disease modifying therapies that were not reported in their medical record prior to transferring their care.
- Further underestimating the true impact of financial barriers on access to disease modifying therapies.
- Further, the use of free or discounted drug programs that help mitigate out-of-pocket drug expenses was not comprehensively reported in patient medical records and may have underestimated the number of patients experiencing financial difficulties.
- These limitations along with the retrospective study design may have resulted in misclassification bias.

References