Evaluation of a Quality Measure for Multiple Sclerosis Care: Disease-Modifying Therapy Initiation at the University of North Carolina's Outpatient Neurology Clinic

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ABSTRACT

BACKGROUND: Multiple sclerosis (MS) is a neurological condition leading to significant disability and challenges to quality of life. To slow progression and reduce relapses, it is critical to rapidly initiate disease-modifying therapy (DMT) after diagnosis. Patient demographics may play a role in timely DMT initiation. Financial barriers may also result in delays in DMT access.

METHODS: This retrospective, single-center, cross-sectional study included patients seen at a neurology clinic at a large academic medical center for an initial evaluation of MS between January 1, 2022, and June 30, 2022. As an indicator of the quality of care, the primary study outcome was whether patients were offered DMT initiation on their first clinic visit. Secondary outcomes evaluated the time to DMT initiation, including differences in care based on demographic factors and financial coverage.

RESULTS: Of the 49 eligible individuals studied, 45 (91.8%) were offered DMT at their initial MS visit. Descriptive statistics appeared to demonstrate that demographic factors did not impact whether DMT was offered. However, the majority of patients experienced access barriers relating to prior authorization requirements (80.0%) and/or the need for co-pay assistance (52.0%).

CONCLUSIONS: DMT was appropriately offered to a majority of patients at their initial MS visit, regardless of demographic considerations. No offer of DMT and delays in initiation were primarily due to the need for imaging and specialty referrals, as well as financial barriers. Medication assistance teams may play a crucial role in limiting delays and financial hurdles associated with insurance coverage and co-pay assistance.

Int J MS Care. 2024;26:247-253. doi:10.7224/1537-2073.2023-069

Multiple sclerosis (MS) is a disabling, immune-mediated, demyelinating disease of the central nervous system that affects more than 400,000 people in the United States and 2.3 million people worldwide.[1] It can lead to irreversible disability and complications, including visual or sensory disturbances, weakness, fatigue, tremor, spasticity, difficulties with ambulation, loss of bladder or bowel control, cognitive impairment, and depression.[1,2] Patients with MS often encounter barriers associated with complexity of care and cost, as well as challenges to quality of life, throughout the course of their disease management.

Quality measures specific to MS have been identified to assess delivery of care, gaps in MS management, and overall patient outcomes. Because DMT initiation and monitoring have been associated with improvement in MS quality of life and because DMT treatment is the mainstay to reduce relapses and new MRI activity, a DMT should be promptly initiated following diagnosis.[1,3] The Multiple Sclerosis Coalition further emphasized this point, stating that DMT should be started as soon as possible after diagnosis, regardless of the patient's age.[4]

According to 2020 American Academy of Neurology guidelines, people with a new diagnosis of MS should be counseled on specific DMT options at a dedicated treatment visit. These options include several injectable, oral, and intravenous medications with varying adverse effects, cost profiles, safety concerns, efficacy, and tolerability. The choice of an appropriate DMT is complicated and multifaceted. Clinicians should evaluate readiness or reluctance to initiate DMT, barriers to DMT adherence, and other patient-specific factors prior to initiation.[1]

Given the importance of minimizing delays in DMT initiation, the MS Brain Health organization has released strategies for primary and specialty care physicians to ensure timely referrals and prescribing. This includes awareness of

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PRACTICE POINTS

National data demonstrate that disparities exist in multiple sclerosis care based on patient demographics, particularly in regard to timely initiation of disease-modifying therapies after diagnosis.

Financial barriers also may result in delays in access to disease-modifying therapies among all patients.

Health care providers must be diligent in assessing biases and addressing access concerns to ensure equitable and high-quality care for all patients. ■

MS symptoms; rapid diagnosis; education for patients, family members or caregivers, and physicians regarding early referral to a neurologist; and improved access to MS specialists. They also recommend using updated diagnostic criteria and aligning this with prescribing guidelines, with the goal of starting treatment promptly after diagnosis. Evidence shows that starting treatment early is associated with improved long-term outcomes.[5] The Big Multiple Sclerosis Data (BMSD) Network conducted a multinational study, including more than 11,000 patients from the Danish, Swedish, Italian, and French national registries, which demonstrated improvements in outcomes among patients who began treatment within 1.2 years of disease onset.[6]

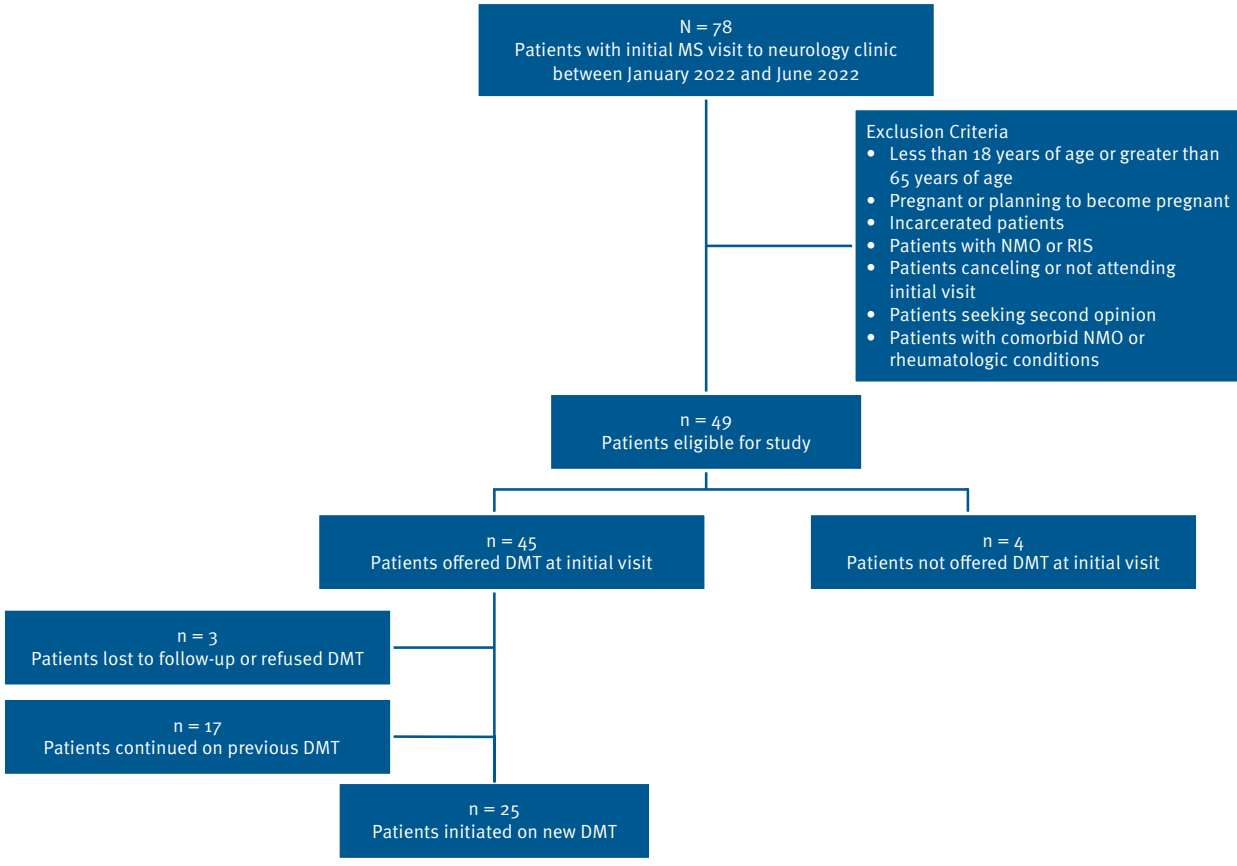
Health disparities have previously been shown to play a role in DMT initiation, disease burden, and mortality. In a retrospective chart review of the North American Registry for Care and Research in Multiple Sclerosis (NARCRMS) between December 2016 and May 2020, Hispanic patients (43%) were less likely to receive DMT compared with non-Hispanic patients (62%) and Black patients were least likely to receive treatment with DMT (26%).[7] This is especially relevant because studies have shown that outcome discrepancies, including rapid progression and disability, disproportionally affect Hispanic and Black patients compared with White patients. The causes of these discrepancies have only been hypothesized, but genetics, environment, insurance status, and cultural considerations may contribute.[8,9] Additionally, a retrospective analysis conducted by Geiger et al utilized United States Optum Market Clarity data to analyze trends among 682 patients with a new diagnosis of MS. Researchers found that non-Hispanic White patients were more likely to receive high-efficacy DMTs compared with Hispanic and Black patients, despite members of the latter groups being at higher risk for poor outcomes.[10]

Although guidelines for DMT initiation and monitoring have been developed to ensure quality care, there are limited data regarding the effect of race, ethnicity, age, and other patient demographics on MS DMT initiation and continuation, as well as limited data on the implementation and outcomes of initiation and adherence practices.[9] Given the paucity of evaluative data, our study assessed DMT initiation at the University of North Carolina (UNC) Hospitals Neurology Clinic during new patient visits, specifically to examine whether patients were offered DMT. Patient demographics, including type of MS, race, ethnicity, age, sex, sexual orientation, insurance type, and access (or lack thereof) to DMT, were included as part of the assessment.

There are also limited data on the impact of financial barriers on DMT delays. Many insurance companies require step therapy or specific trials of DMT that may differ from physician and patient preference. These requirements can result in the trial of ineffective therapies or patient nonadherence due to intolerable adverse effects, leading to disease progression and permanent loss of function. A 2018 survey of 507 patients with MS showed an average delay of 8.3 weeks from the time of prescription to when patients received the first dose of the originally prescribed DMT.[11] Past issues with DMT access were reported by 48.7% of participants, and 11.7% were experiencing a DMT access issue at the time of the survey. Of those participants reporting an access problem, 29.8% with a past issue and 48.9% with a current issue had a self-reported relapse during the delays. The most common reasons for current and past DMT access issues were insurance companies requiring authorization documentation (21.4% vs 42.9%, respectively) and high co-pay costs (31.0% vs 29.7%, respectively).

With the development of new DMTs, the financial burden for patients with and without insurance has also increased.[12] Financial burden associated with MS has also been shown to lead to financial toxicity, which includes both high monetary costs (eg, medical bills, medication costs) and higher rates of emotional distress and negative coping mechanisms, such as nonadherence and lifestyle alterations.[13] The UNC Medication Assistance Program (MAP) team assists patients with navigating payer-associated drug access requirements and works to minimize the financial toxicity associated with high-cost medications to prevent delays in treatment.[14] Many high-cost medications require prior authorization (PA). The MAP team submits PA requests for specialty medications and navigates denial appeals as needed. A follow-up on each request is conducted every 3 days to ensure timely completion. The team may also obtain co-pay cards or refer eligible patients to co-pay assistance programs. Hopefully, MAP resources improve access to and reduce delays in DMT treatment for patients with MS.The objective of this study is to identify potential barriers to the prescribing and timely

FIGURE. Study Diagram



DMT, disease-modifying therapy; MS, multiple sclerosis; NMO, neuromyelitis optica; RIS, radiologically isolated syndrome.

initiation of DMT for patients with MS at our clinic. Baseline characteristics, such as demographics, socioeconomic status, and insurance status, may play a role in disparities among this patient population.

METHODS

This single-center, retrospective, cross-sectional study evaluated patients with MS who came to the UNC Hospitals Neurology Clinic for an initial evaluation between January 1, 2022, and June 30, 2022. The study was approved by the institutional review board at the University of North Carolina Medical Center. Patients were identified through chart review of electronic health records; demographics, medication history, and insurance coverage information were collected from the same. This study included all patients with a diagnosis of MS as defined by AAN guidelines and with an associated *International Statistical Classification of Diseases, Tenth Revision,* diagnostic code. As shown in **FIGURE**, this excluded patients younger than 18 years and older than 65 years. Patients older than 65 years were excluded due to the lack of evidence regarding changes in outcomes with DMT initiation. Additional exclusion criteria included patients who were pregnant or planning to become pregnant, who were incarcerated, who did not attend the initial visit, or who were only seeking a second opinion from the clinic. Patients with rheumatologic conditions or neuromyelitis optica were also excluded due to these conditions mimicking MS and concerns relating to additional immunosuppressants influencing the decision to start DMT. Patients with radiologically isolated syndrome also were excluded due to variations in treatment that would not be consistent with our intended study population.

The primary outcome of this study was to determine whether DMT initiation was offered during the first patient visit to the neurology clinic. Each visit consisted of a 1-on-1 appointment between the patient and the neurologist. The standard for quality care was met if documentation explicitly stated that the patient was prescribed DMT during the visit and/or specific DMT agents were discussed. The quality metric was not met if a conversation regarding medications was broadly initiated but no specific DMT options were discussed. A secondary outcome was the time to DMT initiation, defined as the time from the date of the initial visit to the date the DMT prescription was written. Differences in DMT choices and potential health inequities within the MS population were evaluated by compiling information on the patient's age, race, ethnicity, sex, sexual orientation, type of insurance, type

of MS, need for insurance PA or appeal, and co-pay assistance. The cohort was divided into 2 subgroups: those who were offered a new DMT and those who continued on a previous DMT started by an outside physician. Patients who continued their previous therapy had a date to first prescription of 0 days. Due to a small sample size and to allow for lack of specificity in the initial hypothesis, descriptive statistics were utilized to determine potential relationships between variables.

RESULTS

Of the 78 patients with an initial MS visit at the neurology clinic during the study period, 49 patients were eligible for study analysis. A majority of study participants were White (57.1%) and female (79.6%), with a mean age of 41.8 years old (**TABLE 1**). The most common type of MS was relapsing-remitting (89.8%), although other forms of MS were present, including primary progressive (4.1%) and secondary progressive (6.1%). The majority of patients had commercial insurance (81.6%); 2.0% were enrolled in Medicare, 12.2% in Medicaid, and 4.1% were self-pay. Given that all patients were younger than 65 years of age, only a small proportion of patients were eligible for Medicare. Of note, 17 patients (34.7%) had previously been on DMT prior to their initial appointment at the neurology clinic, and they continued on their previous regimen.

As shown in Table 1, of the 49 patients analyzed, 45 (91.8%) were offered DMT at their initial MS visit in accordance with best practice guidelines and patient-specific criteria. This cohort included 17 patients who were previously on DMT and continued their previous regimen. Two patients were lost to follow-up prior to DMT initiation, and 1 patient refused DMT. In total, only 4 patients (8.2%) were not offered DMT at their initial visit. The most prescribed DMT was ocrelizumab (Ocrevus; 24.5%), followed by diroximel fumarate (Vumerity; 14.3%) and teriflunomide (Aubagio; 12.2%).

The individuals offered DMT were further analyzed to assess the time from their first visit to their first DMT prescription. Upon exclusion of patients who refused treatment or were lost to follow-up, there were 42 unique patients. Of these, 25 were offered a new DMT. Patients starting a new DMT frequently require baseline imaging and lab work, which delays the time to first prescription. There was a large variation in time to prescription in our study (range, 0-232 days). The subgroup of patients offered a new DMT had an average time to prescription of 55.84 days. For the combined group of those who continued on a previous DMT and those who started on a new DMT, the average time to first prescription was 33.24 days (**TABLE S1**).

In addition to analyzing the time to first DMT prescription, factors relating to time to initiation of therapy were also assessed, such as PAs. Of those patients with commercial insurance, 80% required a PA, whereas 100% of patients with Medicare required a PA. The only patient with Medicaid included in the analysis was not offered DMT, so no information regarding PA was obtained.

TABLE 1. Patient Demographics and DMT Prescribed (N = 49)

Baseline characteristics	
Age, mean + range	41.8 + 21
	n (%)
Sex (F)	39 (79.6)
Race	
Black or African American	16 (32.7)
White or Caucasian	28 (57.1)
Other	5 (10.2)
Ethnicity	
Hispanic or Latino	4 (8.2)
Not Hispanic or Latino	44 (89.8)
Other	1 (2.0)
Sexual orientation	
Heterosexual	16 (32.7)
Lesbian or gay	1 (2.0)
Do not know	1 (2.0)
Choose not to disclose	3 (6.1)
Unspecified	28 (57.1)
Insurance type	
Commercial	40 (81.6)
Medicaid	1 (2.0)
Medicare	6 (12.2)
Self-pay	2 (4.1)
Type of MS	
Primary progressive	2 (4.1)
Relapsing-remitting	44 (89.8)
Secondary progressive	3 (6.1)
DMT offered (yes)	45 (91.8)
Continued on prior DMT (yes)	17 (34.7)
Refused DMT/lost to follow-up	3 (6.1)
DMT prescribed	
ocrelizumab (Ocrevus)	12 (24.5)
diroximel fumarate (Vumerity)	7 (14.3)
teriflunomide (Aubagio)	6 (12.2)
ofatumumab (Kesimpta)	5 (10.2)
dimethyl fumarate (Tecfidera)	5 (10.2)
fingolimod (Gilenya)	4 (8.2)
glatiramer acetate (Copaxone)	2 (4.1)
natalizumab (Tysabri)	1 (2.0)
DMT not offered	4 (8.2)

DMT, disease-modifying therapy; F, female; MS, multiple sclerosis.

Time from initial PA submission to final coverage decision was also analyzed for patients receiving a new DMT. Of the 25 patients who initiated new DMT regimens, 19 were required to submit a PA; 2 patients were self-pay and 4 patients did not require a PA. Of the 19 patients with PA, 9 (47.4%) were initially denied and required an appeal letter. Upon submitting additional appeal documentation, 1 patient (11.1%) was approved, and 8 patients (88.9%) were again denied. The average and median length of time to final coverage decision was 12 days and 7 days, respectively. The range of 0 to 102 days was due to an outlier, which required 103 days to final decision. Given the significant degree of variation, a second analysis was conducted with the outlier excluded. With this data point removed, the average length of time to final decision was 7 days, with no change to the median. After

removing the outlier, the next greatest length of time to final decision was 22 days. Among those patients who required a PA, 52.0% also required co-pay assistance, regardless of the final PA decision. Of the 13 patients who utilized co-pay assistance, 3 patients (23.1%) used a co-pay card, and 10 patients (76.9%) were enrolled in manufacturer assistance (**TABLE S2**).

Further analysis was conducted for the 4 patients who were not offered DMT to determine what factors may have played a role (**TABLE S3**). All 4 were women and had relapsing-remitting MS. Sexual orientation was specified for only 1 patient, who identified as heterosexual. One patient was Black; 3 patients were White. Although all patients were actively insured, 3 patients had commercial insurance and 1 patient had Medicaid. A chart review for all 4 identified that pending MRI results appeared to be the reason treatment options were not discussed. Additionally, 2 patients required referrals to neuroimmunology specialists for further treatment discussions.

DISCUSSION

This study contributes to the literature discussing the importance of early assessment and initiation of DMT in patients with new diagnoses of MS or who have switched care providers. Although it was encouraging to see the high proportion of patients offered DMT at our clinic, it is essential to acknowledge the reasons for a lack of DMT initiation. The primary reason for delayed DMT appeared to be the need for baseline imaging and laboratory work. An additional cause of delay in initiation was a referral to neuroimmunology for patients with especially complex histories. However, even when these challenges arise, DMT selection discussions should occur as close to diagnosis as possible so time to first prescription after imaging is minimal.

Multivariate analysis of the primary outcome was unable to be conducted because of the small sample size and lack of specificity in the initial hypothesis, so statistical significance could not be determined. However, contrary to national data, type of MS, race, ethnicity, age, sex, sexual orientation, and insurance type did not appear to impact the decision to initiate DMT at the initial neurology clinic encounter. All 4 patients not offered DMT at their initial visit were women, but this was not unexpected due to MS disproportionately affecting women compared with men. Although there does not currently appear to be a concern relating to the role of demographics and baseline characteristics in standards of care for patients with MS, it is still important to consistently assess these components due to the role they have been found to play nationally. This conversation is especially crucial in academic medical centers because of the high volume of trainees caring for patients. Much like appropriate initiation of DMT, it is important that learners are trained on biases to minimize risk for their patients.

Globally, concerns relating to the availability of medical equipment for diagnostic tests and lack of health care professionals with the knowledge to make the diagnosis have also been shown to impact delays in MS diagnosis and treatment.[15] Another global barrier is lack of timely availability among health care professionals with the ability to diagnose MS, which was similarly demonstrated in this study among more complex patients who required referral to specialists.[15] However, the largest global barrier to rapid diagnosis and subsequent time to initiation of DMT is believed to be lack of awareness of MS symptoms among the general public and health care professionals.[15]

Our study also found that the requirements for baseline imaging and specialist referral played important roles in DMT initiation delays. Access and payment concerns resulted in additional delays to DMT start. Nearly all patients with a new DMT prescription required a PA, regardless of insurance type. It is especially important to note a PA was required for all Medicare patients. In addition, although most patients included in this study eventually received insurance approval, there were frequent rejections after initial appeals, resulting in further delays.

When evaluating the combined average length of time to first prescription and PA approval, it took approximately 9 weeks for most patients to gain access to DMT after their initial visit. Additionally, it is important to note that although the average time to PA decision was approximately 1 week, this statistic is likely skewed based on the resources available at the study institution. The MAP team plays a large role in facilitating conversations among insurance companies, providers, and patients to expedite the PA process. At institutions without these resources, there are likely greater challenges to access and time to treatment initiation. This is demonstrated in the Geiger et al and Margolis et al studies, in which patients had a mean time from diagnosis to initiation of DMT of 4.9 and 5.3 months, respectively.[10,16] Although these are all within the 1.2-year time frame identified by the international BMSD Network study as a marker of decreased risk for disability, researchers in each study looked at time of diagnosis rather than disease onset, as did the BMSD network.[5] Nonetheless, each reinforces the importance of minimizing delays in DMT initiation.

In addition, the MAP team also assists with financial barriers by facilitating co-pay assistance. With approximately one-fourth of patients requiring co-pay assistance, financial toxicity is another concern associated with DMT. It is likely there is a greater concern for this at other institutions without MAP resources, as patients are frequently unaware of financial assistance options. Assistance programs can be complex and difficult to navigate, which is concerning because of the impact of financial toxicity on access to appropriate treatment. Supporting medication assistance teams in as many health systems as possible will allow patients the best possible access to specialty medications such as DMT.

This study had several limitations that may have impacted the results. This was an observational study, rather than a controlled design, so confounding factors were not able to be fully accounted for. Multivariate analysis was unable to be conducted due to the small sample size and lack of specificity in the initial hypothesis and classification of demographics.

Therefore, statistical comparison could not be determined, and only descriptive statistics could be utilized. Of note, a portion of the cohort included patients with progressive MS, which swayed the mean baseline age and suitable DMT options. Also, given that being older than 65 years was a component of this study's exclusion criteria, the low number sampled in these data underestimates the true proportion of patients with Medicare seen and exposes a patient population with increased concerns relating to access and delays in care. It is likewise important to acknowledge additional institution-specific factors may have played a role in further delays in DMT initiation. For instance, baseline labs are required prior to DMT initiation and phlebotomy is not available at the UNC neurology clinic. Therefore, patients must rely on external lab draws and results must be faxed to the clinic. Although the impact of this was not captured as part of this study, it has been noted as a source of delays in DMT initiation times at the clinic in the past.

CONCLUSIONS

Further investigations regarding appropriate, timely, and cost-effective DMT initiation should be conducted at additional institutions to evaluate discrepancies and ensure equitable access to high-quality care for all patients. Social determinants of health are also an important aspect to continue to investigate when evaluating DMT decisions because they can be a large barrier to equitable health care. Finally, financial considerations contribute to delays in access to DMT, so financial assistance resources may play a pivotal role in improving access and decreasing financial toxicity. ■

ACKNOWLEDGMENTS: We would like to thank Jorge L. Almodóvar-Suárez, MD, for his expert opinion in the formulation of this project's purpose and design.

CONFLICT OF INTEREST: None of the authors or contributing members report any conflicts of interest.

FUNDING: No funding was obtained in order to conduct this study.

PRIOR PRESENTATION: Components of this study were discussed during a platform presentation at University of North Carolina Eshelman School of Pharmacy's Research in Education and Practice Symposium; May 18, 2023; Chapel Hill, NC.

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TABLE S1. Differences in Time to DMT Initiation

	Time to first prescription for new-start DMT (days)	Time to first prescription for all, including continuation DMT (days)
Mean	55.84	33.24
Mode	14	0
Range	0-232	0-232

DMT, disease-modifying therapy.

TABLE S2. Distribution of Payment Requirements Among Insured Patients (N = 25)

	Yes n (%)	No n (%)
PA required	19 (76.0)	6 (24.0)
• Commercial	16 (80.0)	4 (20.0)
• Medicare	3 (100.0)	-
• Self-pay	-	2 (100.0)
• Medicaid	-	-
PA approved	10 (52.6)	9 (47.4)
Of PAs not approved:		
• Appeal letter submitted	9 (100.0)	-
• Appeal letter approved	1 (11.1)	8 (88.9)
Co-pay assistance needed	13 (52.0)	12 (48.0)
• Co-pay card	3 (23.1)	-
• Grant	-	-
• Manufacturer assistance	10 (76.9)	-

PA, prior authorization.

TABLE S3. Demographics of Individuals Not Offered DMT

	Age (years)	Sexual orientation	Ethnicity	Race	Meds	Insurance	Insurance type	Reason DMT not offered
Patient 1	54	Unspecified	Not Hispanic or Latino	Black	23	Yes	Commercial	Doctor planned to discuss treatment following MRI results
Patient 2	58	Unspecified	Not Hispanic or Latino	White	9	Yes	Commercial	Doctor planned to discuss treatment following MRI results
Patient 3	55	Unspecified	Not Hispanic or Latino	White	13	Yes	Commercial	Doctor preferred to have MRI results and consult with neuroimmunology prior to discussing treatment options
Patient 4	37	Heterosexual	Not Hispanic or Latino	White	22	Yes	Medicaid	Doctor preferred to have MRI results and consult with neuroimmunology prior to discussing treatment options

DMT, disease-modifying therapy; Meds, number of current medications.
Note: All patients were women and had relapsing-remitting multiple sclerosis.