



WHITE PAPER

Shields Health Solutions

Multiple Sclerosis Care Model and Clinical Program

How Specialty Pharmacy Can Drive Better Outcomes in Multiple Sclerosis

KEY TAKEAWAYS

- **Multiple Sclerosis (MS) is a chronic, autoimmune disease of the central nervous system, affecting communication between the brain and other parts of the body.**
- **This complex disease requires prompt initiation of therapy.**
- **Patients with MS face many barriers to medication access and achievement of therapy goals, including limited distribution drug (LDD) access, high copays, and adherence challenges.**
- **A high-touch IDN (Integrated Delivery Network) specialty pharmacy model can help MS patients overcome these barriers and achieve their therapy goals.**
- **Improved clinical and economic outcomes within our MS population are driven by ShieldsRx' ability to support faster time to therapy, high medication adherence, and low out-of-pocket costs for medication.**

A lower patient reported relapse rate, also called the annualized relapse rate (ARR), is correlated with slower disease progression and improved quality of life.

Multiple sclerosis (MS) is a chronic, inflammatory disease of the central nervous system. Characterized by demyelination and neurodegeneration that affects the communication between the brain and other parts of the body, MS leads to physical and cognitive disability.¹ The disease affects nearly 2.8 people worldwide², with almost one million people with MS in the United States alone.³ With approximately 10,000 to 20,000 new cases diagnosed each year, most often in those aged 20 to 50 years and three times as often in women than in men, MS is a cause of significant disability and medical expense to society and individuals at a very productive time in their lives.^{2,3,4}

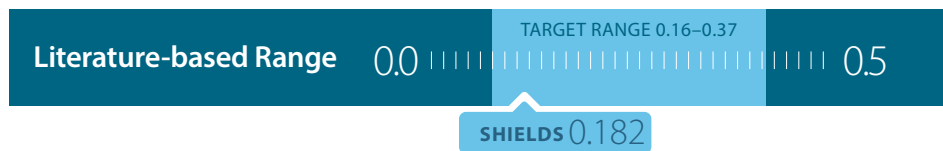
While there is currently no cure for MS, establishing and following a treatment plan is the best way to manage the disease and enhance quality of life.¹ Treatment plans for MS typically include disease modifying therapies (DMTs) to delay disease progression and to prevent relapses as well as medications to treat symptoms.¹

In recent years, there has been an increase in available DMTs, most of which are considered specialty medications, along with a robust pipeline of MS therapies that will largely be dispensed out of a specialty pharmacy. As a result, specialty pharmacy services are essential for this high-touch patient population that requires close monitoring and frequent assessments. Health system specialty pharmacies (HSSPs), which have implemented a proactive, integrated, and coordinated approach to address the needs of complex patients, can play a critical role in ensuring timely medication access and coordinating quality care for the MS population, which may drive better patient outcomes.

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MANAGEMENT OF MS AND ITS CHALLENGES

While there are multiple subtypes of MS, approximately 85% of patients are initially diagnosed with relapsing-remitting MS (RRMS), which is characterized by acute episodes of worsening symptoms followed by periods of partial or complete recovery.⁵ These episodes of neurologic dysfunction are termed relapses and alternate with remissions, during which there is no disease progression. To track the clinical efficacy of MS therapies and disease progression, the annualized relapse rate (ARR) is measured. A lower ARR is correlated with slower disease progression and improved quality of life.⁴ Reducing the number of MS relapses over time can delay the progression of disability and neurologic dysfunction caused by MS.⁶



Treatment guidelines emphasize the prompt initiation of DMT for patients with MS as an essential step to slow disability progression, reduce relapse rate, and neurodegeneration.⁷ Unfortunately, delays in treatment initiation, whether it be deferred neurology consultation or medication cost barriers, can lead to poor patient outcomes and disease progression.⁷

Non-adherence to DMTs has been linked to increased MS-related hospitalizations and increased disease relapses.¹¹

However, because MS therapies are considered specialty medications, patients may encounter challenges or delays in access. Even after patients gain access to their MS medication, they may delay initiation of therapy due to reluctance to a long-term treatment,⁸ or they may have poor adherence because of administration challenges associated with injectable medications.⁹ Literature reports of adherence to MS therapies vary widely; a systematic review of 31 studies assessing oral DMTs reported a one-year mean PDC of 76.5%.¹⁰ Furthermore, non-adherence to DMTs has been linked to increased MS-related hospitalizations and increased disease relapses.¹¹

Common Barriers to the Treatment & Management of Multiple Sclerosis

1. Timely access and/or delays to therapy
2. Lack of financial resources
3. Inadequate care coordination between multiple sclerosis care and non-integrated specialty pharmacies
4. Lack of adequate information and support for families caring for someone with multiple sclerosis

High out-of-pocket (OOP) costs are a common barrier to MS medication access. An analysis of a large, privately insured, health-care claims database of OOP drug costs for neurology patients revealed that MS medications had the highest increase in average monthly expense from 2004 to 2016 (\$15 vs. \$309, respectively).¹² The burden of financial toxicity attributed to MS therapies can delay prescription initiation or result in lower medication adherence. Access to financial assistance programs by HSSPs can alleviate this burden for MS patients.

Many MS medications are limited distribution drugs (LDDs), which can be another source of delay in time to therapy. Lack of HSSP access to limited distribution networks (LDNs) can restrict access to critical MS medications and force patients to fill through non-integrated specialty pharmacies, prolonging time to therapy initiation. A study examining time to initiation of dalfampridine, an oral LDD medication indicated for the treatment of MS walking difficulties, demonstrated a significant difference in time to drug access after a HSSP gained admission into the distribution network, compared to before LDD access (22 days (IQR: 11-45) vs. 1 day (IQR: 0-3), respectively).¹³ The results of this study suggest that expanded LDD access to MS medications through HSSP programs can reduce time to therapy initiation.

HOW THE SHIELDS CARE CONTINUUM CAN HELP

ShieldsRx proactively works with patients to provide best-in-class therapy management to elicit optimal clinical outcomes, to reduce the incidence of adverse drug events, and to prevent unnecessary health care costs. Core clinical services provided by a team of MS clinical pharmacists include patient needs assessment, comprehensive medication review, medication education, ongoing support through frequent outreach calls, and direct care coordination with the HSSP and MS center liaisons and staff.

ShieldsRx has dedicated pharmacy liaisons who are embedded within health system partner sites, many of which have nationally recognized MS Centers of Excellence. The liaisons, with the support of a centralized Patient Support Center (PSC), perform all benefits investigations, prior authorizations (PAs), and financial assistance for all specialty patients serviced by the MS centers regardless of the dispensing specialty pharmacy. The liaisons interact with patients in the clinics, providing personalized attention, and serve as a single point of contact for proactive refill management.

Clinical reassessments measure patient progress to goals of therapy progress and provide communication and follow up to the integrated care team.

As a result of the financial assistance support provided by the ShieldsRx model, liaisons within MS clinics have secured more than \$14 million in 2021, resulting in an average per script copay of \$5.

Reminder calls are made to patients at a minimum of seven days before the refill date to ensure timely prescription receipt, and liaisons communicate with the MS centers when issues with unreachable patients or those with adherence concerns arise. ShieldsRx liaisons also coordinate with the patient and provider to facilitate manufacturer hub enrollment for medication support services.

The team of Multiple Sclerosis Certified Specialists, a designation granted by the MS Consortium of Care,¹⁴ takes a proactive approach to drug therapy that includes cadenced clinical assessments based on drug-specific requirements. Pharmacist assessments include administration training, side effect counseling, disease-specific education, adherence tracking, and coordination of care with providers and nurses. The MS clinical management program includes adherence risk assessments and targeted interventions as well as patient-reported outcomes to measure treatment tolerability and quality of life.

Clinical reassessments measure patient progress to goals of therapy progress and provide communication and follow up to the integrated care team. Treatment plans are created and followed to closely monitor patients' success with a therapeutic regimen and any barriers in achieving goals of therapy, including MS relapses. In response to a patient-reported relapse, the pharmacist will evaluate the patient and EMR data to determine if the event could be due to medication-related issues, such as non-adherence. In collaboration with the prescriber, the clinical pharmacist will design interventions, tailor the care plan frequency, and outline goals of therapy, which are periodically reassessed. The clinical reassessments include adherence screening, side effect monitoring, and strategies for minimizing or managing reported events. Pharmacists execute clinical interventions based on reassessment findings.

Full access to the electronic medical record (EMR), pharmacy dispensing system, and clinical management platform by both the clinical pharmacists and liaisons is key to supporting a best-in-class, fully integrated specialty pharmacy program for MS patients. To provide a seamless continuum of care, all documentation is recorded within the EMR and in the therapy management system. Pharmacist interventions and patients' clinical questions are documented in the EMR and communicated to the prescriber in real-time, often preventing unnecessary provider office or ER visits. This integration bridges the communication and connection barriers that exist with non-integrated specialty pharmacies which could lead to delays in initiating therapy, medications being dispensed that are no longer appropriate, or confusion for the patient and their caregivers as to whom they should contact when issues or questions arise.

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PDC indicating that patients receive and take their medications on time with ShieldsRx Care Continuum.



Interventions in the enrolled MS patient population in 2021.

Clinical roles of the ACP included appeal writing and submission for denied MS medication prior authorizations (PAs) as well as peer-to-peer reviews.

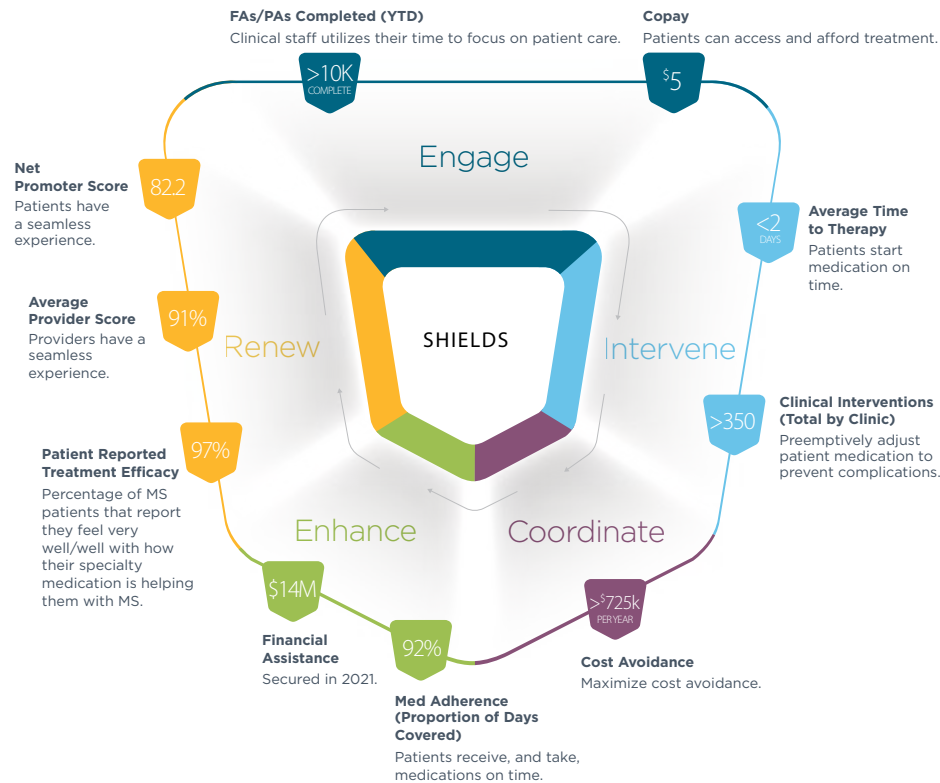
THE SHIELDSRX IMPACT

The Shields Care Continuum has resulted in industry-leading outcomes for MS. In addition to ensuring a high PDC of 92%, an indicator that patients receive and take their medications on time, the ShieldsRx MS clinical program results in timely initiation of therapy, with less than 2 days to therapy on average.

As a result of the financial assistance support provided by the ShieldsRx model, liaisons within MS clinics have secured more than \$14 million in 2021, resulting in an average per script copay of \$5. Alleviating out-of-pocket costs for MS patients reduces financial toxicity barriers for medication access, which ultimately correlates with adherence.

In 2021, the ShieldsRx MS clinical program resulted in over 7,000 pharmacist care interactions and over 10,000 liaison touchpoints, all of which drive better coordination of care, improved patient satisfaction, and enhanced treatment outcomes. Through these clinical interactions, pharmacists identified more than 350 interventions in the enrolled MS patient population in 2021, ranging from identification of drug interactions, prevention of adverse events, elimination of drug wastage, and avoidance of urgent care or ER visits, with an acceptance rate of over 98%. These clinical interventions generate medical cost avoidance of over \$725,000, calculated from literature-based values. Taken together, the MS clinical model resulted in a superior ARR of 0.182 when compared to published benchmarks in this population.⁵ This low rate of disease flares over time indicates medication efficacy and delayed progression of disability and neurologic dysfunction in MS patients.

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*Calendar Year 2021

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Furthermore, 97% of patients report that they believe their treatment is working well or very well to improve their condition, a ShieldsRx measure termed Patient Reported Treatment Efficacy (PRTE). All of the components of the ShieldsRx MS clinical program have contributed to high patient and provider satisfaction scores, 84% and 91%, when compared to industry benchmarks for these ratings.

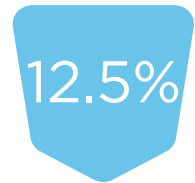


Increase in PA approval rates after introduction of an ambulatory pharmacist

THE ROLE OF AMBULATORY CARE PHARMACISTS IN MS MANAGEMENT

Ambulatory care pharmacists are directly involved in daily clinic operations and are equipped to support the intricate medication management of MS patients, as demonstrated by a retrospective review of the impact of clinical pharmacist services in a hospital-based neurology clinic.¹⁵ As an added layer of support and clinical services for this high-touch population, an ambulatory care pharmacist (ACP) was embedded at an affiliated health system partner in 2021. Clinical roles of the ACP included appeal writing and submission for denied MS medication prior authorizations (PAs) as well as peer-to-peer reviews. After implementation of the ACP within this MS clinic, PA turn-around-times (TAT), medication appeal rates, and PA approval rates were compared to a six-month period prior to service implementation and demonstrated the following impact:

- **Decrease** in PA turn-around-time of 1 day
- **Increase** in PA approval rate by 23%
- **Increase** in appeal approval rates by 12.5%



Increase in appeal approval rates after introduction of an ambulatory pharmacist

In addition to the improvements in PA turn-around-time and PA and appeal approval rates, a survey of clinic staff demonstrated overwhelmingly positive feedback to the ACP service. Survey results indicated the most impactful services offered by the ACP was PA and appeal assistance, patient counseling, drug information support, and prescription clarification. The incorporation of an ACP into a health system MS center is an additional layer of clinical care that supports medication access and increased clinic satisfaction.

CONCLUSION AND SUMMARY

Improved clinical and economic outcomes within our MS population are driven by ShieldsRx' ability to support faster time to therapy, high medication adherence, and low out-of-pocket costs for medications. Our goal of providing safe and appropriate use of prescribed therapy regimens is reinforced by a low annualized relapse rate and a high proactive clinical intervention acceptance rate.

The ShieldsRx MS clinical program and care model is designed to support the most innovative, best-in-class patient services in the industry. The program is continually evaluated to ensure services and care protocols are supported by the most recent evidence-based guidelines, stakeholder input and collaboration, patient-reported outcomes, and real-world evidence. Our objective is to consistently promote clinical and economic outcomes while improving patient quality of life.

REFERENCES

- ¹ Multiple Sclerosis FAQ. National Multiple Sclerosis Society. <https://www.nationalmssociety.org/What-is-MS> (Accessed May 23, 2022).
- ² Walton C, King R, Rechtman L, et al. Rising prevalence of multiple sclerosis worldwide: Insights from the Atlas of MS, third edition. *Mult Scler*. 2020;26(14):1816-1821.
- ³ Wallin MT, Culpepper WJ, Campbell JD, et al. The prevalence of MS in the United States: A population-based estimate using health claims data. *Neurology*. 2019;92(10):e1029-e1040.
- ⁴ Compston A and Coles Alasdair. Multiple sclerosis. *Lancet*. 2008;372(9648):1502-1517.
- ⁵ Relapsing-Remitting MS (RRMS). National Multiple Sclerosis Society. <https://www.nationalmssociety.org/What-is-MS/Types-of-MS/Relapsing-remitting-MS> (Accessed May 23, 2022).
- ⁶ Montalban X. Review of methodological issues of clinical trials in multiple sclerosis. *J Neurol Sci*. 2011; 311(Suppl. 1): S35-S42.
- ⁷ Noyes K, Weinstock-Guttman B. Impact of diagnosis and early treatment on the course of multiple sclerosis. *Am J Manag Care*. 2013 Nov;19(17 Suppl):s321-31. PMID: 24494633
- ⁸ Ross AP, Thrower BW. Recent developments in the early diagnosis and management of multiple sclerosis. *J Neurosci Nurs*. 2010;42(6):342-353.
- ⁹ Bruce JM, Lynch SG. Multiple sclerosis: MS treatment adherence--how to keep patients on medication? *Nat Rev Neurol*. 2011;7(8):421-422.
- ¹⁰ Nicholas J, Edwards N, Edwards R. Real-world adherence to, and persistence with, once- and twice-daily oral disease-modifying drugs in patients with multiple sclerosis: a systematic review and meta-analysis. *BMC Neurology*. 2020;20(281):1-15.
- ¹¹ Steinberg S, Faris R, Chang C, et al. Impact of adherence to interferons in the treatment of multiple sclerosis: a non-experimental, retrospective, cohort study. *Clin Drug Investig*. 2010;30(2):89-100.
- ¹² Callaghan BC, Reynolds E, Banerjee M, et al. Out-of-pocket costs are on the rise for commonly prescribed neurologic medications. *Neurology*. 2019;92(22):e2604-e2613.
- ¹³ Peter ME, Markley B, DeClercq J, et al. Inclusion in limited distribution drug network reduces time to dalfampridine access in patients with multiple sclerosis at a health-system specialty pharmacy. *J Manag Care Spec Pharm*. 2021;27(2):256-262.
- ¹⁴ Multiple Sclerosis Certified Specialist. The Consortium of Multiple Sclerosis Centers. <https://www.msca.org/page/MSCS#> (Accessed June 3, 2022).
- ¹⁵ May A, Morgan O, Quairol K. Incorporation and Impact of a Clinical Pharmacist in a Hospital-Based Neurology Clinic Treating Patients with Multiple Sclerosis. *Int J MS Care*. 2021 Jan-Feb;23(1):16-20. doi: 10.7224/1537-2073.2019-032. Epub 2020 Feb 14. PMID: 33658901; PMCID: PMC7906034.

ABOUT SHIELDS HEALTH SOLUTIONS

Shields Health Solutions (ShieldsRx) is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system. As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 80 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 70 health systems across the country through national-scale collaboration, ShieldsRx has a vested interest in delivering measurable clinical and financial results for health systems.



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