BRAND ACCESS MARKETPLACE DYNAMICS: MULTIPLE SCLEROSIS

Summary

A private, ongoing, multi-client study.

June 2020

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This summary provides highlights from robust longitudinal insights reports released throughout the year and available at our INTELLICENTER® portal. The Brand Access Marketplace Dynamics reports identify current and future access landscapes providing insights to support effective identification of opportunities and risks for Multiple Sclerosis (MS) brands.

Methodology

Marketplace Dynamics Multiple Sclerosis Research Methodology

Health Strategies Insights™ by EVERSANA conducts ongoing **longitudinal** research on U.S. marketplace trends, customer needs, and access barriers and opportunities for biopharmaceutical companies within the MS market

Your team will have access to our **subject matter experts** and opportunities for inquiries and input into research, as well as tailored presentations on opportunities and risks for your specific pipeline and inline MS drugs

Online surveys & follow-up interviews of **pharmacy and medical directors at health plans, IDNs, medical groups and PBMs*,** to provide quantitative benchmarking data and qualitative insights into best practices, skill sets, and future outlook

*Refer to the research agenda for sample size and detailed profile

KEY FINDINGS	IMPLICATIONS & RECOMMENDATIONS
Increased competition, high drug prices and the anticipated arrival of oral generic relief all prompt stakeholders to prioritize MS category management.	Companies should expect greater attention towards the category in 2020, and must take the threat posed by lower cost oral generics seriously; a multi-pronged approach of competitive contracting, the sharing of clinical data demonstrating superiority versus competitors, and continued investment in high value patient support programs will counter looming threats.
Stakeholders continue to be highly influenced by physician association recommendations (i.e., American Academy of Neurology (AAN)).	Aligning with the top tactics to improve MS management through 2023, stakeholders look to prioritize care coordination and implement protocols/guidelines deriving from the AAN. MS biopharmaceutical companies must include AAN engagement strategies in their launch and marketing plans to ensure protocol and/or recommendation inclusion.
Stakeholders perceive numerous unmet needs in treating MS patients in 2020; the desire for MS biomarkers has grown in recent years, with long-term reduction in disease remaining a consistent need.	Though MS biomarkers are in the infant stage of development, plans would highly value these tools when making access decisions. Development of an accurate marker will be game changing in the MS. Additionally, biopharmaceutical companies face opportunities to build brand value and loyalty with organized providers who report the need of improvements to their patient's quality of life.
Organized provider misalignment with plan formularies leaves open the possibility for biopharmaceuticals to drive utilization to their brand. In addition to formulary management, plans are most successful in driving providers to preferred MS drugs through prior authorization requirements.	Biopharmaceutical companies should continue to invest in MS services supporting organized providers in obtaining access (e.g., PA support tools) from payers, and patient support programs offsetting cost sharing requirements due to prescribing and formulary misalignment.
In order to facilitate access and provide treatment options for prescribing specialists, plans allow for preferred status for numerous MS drugs, including market-leading orals (i.e., Tecfidera, Gilenya), Avonex, Betaseron, and glatiramer acetate.	Betaseron, Tecfidera, Gilenya, and new-to-market Mayzent have experienced significant gains in preferred access status relative to 2019. The risk of future major generics will force access conversations to evolve, especially for oral brands. Focus on clinical differentiation and benefits of specific drug classes (e.g., S1Ps vs. fumarates vs. CD-20s) and brands within classes must be a priority in addition to competitive pricing and contracting agreements.
New MS brands entering the increasingly competitive market will face additional access hurdles (e.g., cost-sharing exposure from formulary management; prior authorization criteria requiring prior trials of preferred drugs) if not clinically differentiated from competitors.	Biopharmaceutical companies launching new drugs into the MS market must take a multipronged approach to clinically differentiate themselves from current market-leading brands, including real-world evidence (RWE), and head-to-head trial data against market leaders; in addition to competitive pricing strategies to gain preferred access.

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Payers target biopharmaceutical company cost-sharing support programs in an attempt to drive formulary adherence and prescribing decisions.	While current deployment of copay blocking and accumulator tools is limited, biopharmaceutical companies must not become complacent, as many plans will look to increase utilization of these tactics in the future to drive to preferred options and better predict/control costs. Biopharmaceutical companies must continue to focus primarily on achieving preferred status through clinical differentiation and contracting strategies, but they must also look for other options, such as debit cards and direct reimbursement checks, to continue their patient cost-sharing support.
Management intensity and cost-sharing exposure continue to increase for office-administered treatments under the medical benefit as payers seek to contain costs across the spectrum of care.	Rapid growth of a two-tiered medical benefit will continue, possibly driven by the large uptake in Ocrevus new starts. Companies should approach cost sharing for medical-benefit drugs as they do for pharmacy-benefit drugs, considering cost-sharing support programs, contracting for preferred status, or even partnering on disease management programs that waive copays for adherence. Companies with office-administered drugs must have discussions with both pharmacy and medical departments to determine all potential utilization tactics and access barriers their drugs will encounter.
Providers remain sensitive to payer tactics and patient out-of-pocket costs, and their own drug management tools are moderately to highly aligned with payer formularies. While specialists are comfortable advocating for patients who try and fail therapies, they are more likely to prescribe payers' preferred drugs to treatment-naïve patients.	Companies should update providers on payers' evolving policies, help them navigate access barriers, and provide resources to mitigate the administrative burden resulting from payer management tactics. Biopharmaceutical companies with new-to-market multiple sclerosis brands must take a two-pronged approach, proving superior clinical efficacy relative to market-leading legacy therapies to gain specialist support, while achieving preferred formulary access with payers and organized providers through competitive pricing strategies.
Although organized providers typically give their physicians flexibility in treatment decisions, systems in particular have lessened specialist autonomy in MS prescribing. Most organized providers require a medical rationale for going off protocol. Drug management tactics are often communicated through electronic medical records (EMRs) and their use encouraged through education from clinical pharmacists.	With most systems and groups requiring rationales from specialists prescribing off protocol, biopharmaceutical companies have partnership opportunities to ease specialists' administrative burdens through readily available data and support materials. MS companies should work to ensure inclusion of relevant data in provider EMRs and communicate key product differentiators to clinical pharmacists at provider organizations.

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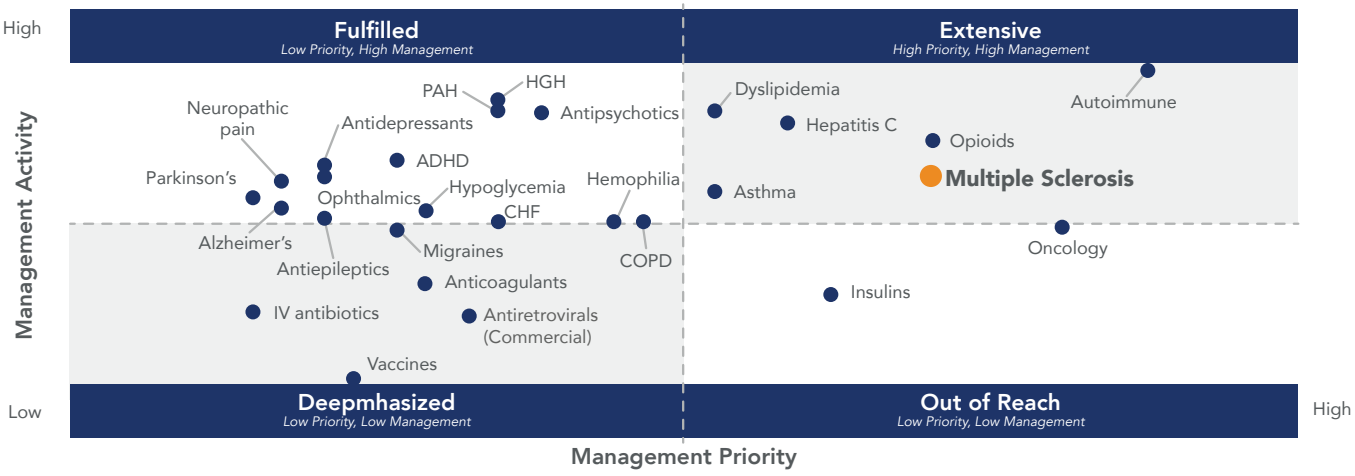
Although volume-based reimbursement will remain the prevailing model in the multiple sclerosis market, some organized providers predict a shift towards value-based reimbursement in the next few years.	Biopharmaceutical companies can provide critical assistance in this shift by offering data proving their MS drugs provide clinical benefits, improve patient adherence and satisfaction, and reduce total cost of care, all of which are related to meeting quality metrics.
Due to the high costs of relapse-related admissions/readmissions, most organized providers diligently monitor these quality metrics, as they are reflective of the care given to multiple sclerosis patients.	Brand team engagement strategies for providers must focus on helping them attain value-based goals with strong evidence that elucidates product-specific impacts on admission/readmission rates, remission duration, and patient satisfaction.

Healthcare Plan Prioritize Multiple Sclerosis Category

Plans continue to prioritize the MS category, managing access whenever possible. MS drugs face higher management priority and activity when compared to other categories.



N=40 health plans. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

With Increased Competition and Oral Generics on the Horizon, Stakeholders Prioritize MS Category Management

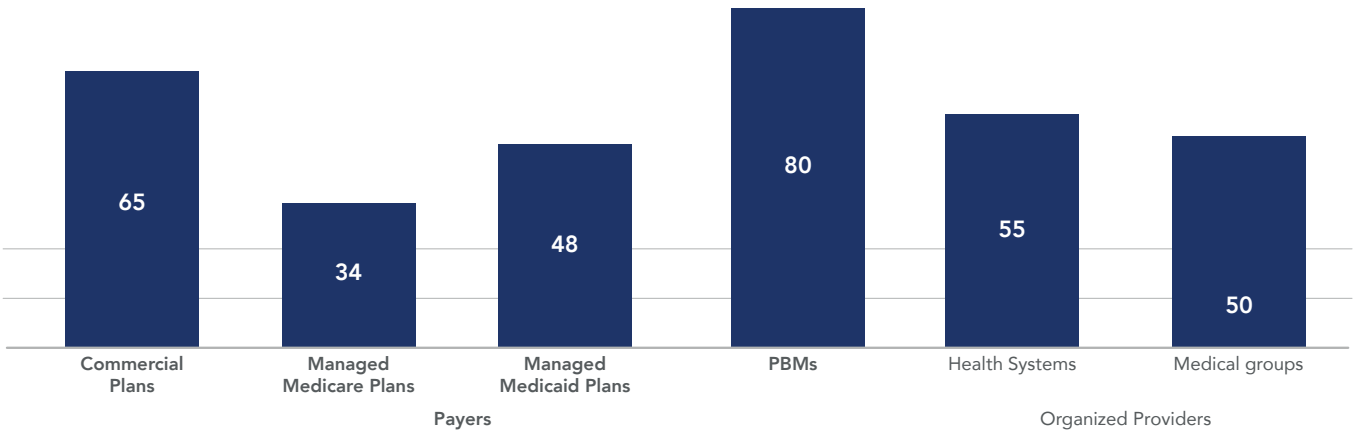
Despite increased market crowding and the looming threat of major oral generics, MS drug prices have steadily risen, prompting heightened focus from payers and organized providers. While still a priority, Medicare plans typically take on a simplified approach, putting most if not all MS drugs on a specialty tier based on sheer drug cost.

Biopharmaceutical companies should expect greater attention on the category in 2020, and must take the threat posed by lower cost oral generics seriously; a multi-pronged approach of competitive contracting, the sharing of clinical data demonstrating superiority versus competitors, and continued investment in high value patient support programs will help counter looming threats.

> **We manage more in commercial and have preferred drugs, require prior trials, but in Medicare everything is specialty tier.**
>
> *– Blues Plan Medical*

> **It's one of the top categories for us in terms of cost and focus, mainly driven by the expensive nature of the drugs... MS is on my high-cost claims list on a regular basis.**
>
> *– National Medical*

Payers and Providers Continue to Prioritize Management of MS Drugs
(Percentage rating management priority high across 30+ markets)



N=40 health plans, N=5 PBMs, N=40 health systems, N=26 medical groups. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

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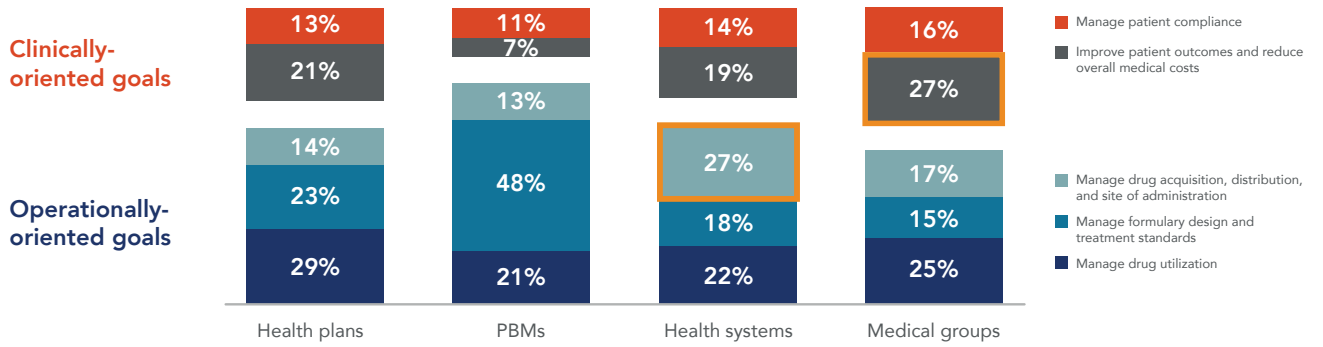
Engagement Strategies Should Focus on Provider Goals in Improving Patient Outcomes and Managing Site of Care

Payers continue to manage MS with an operational/financial focus including drug utilization tactics and formulary management. PBMs are working with large employer groups to design formularies, and seek to offer greater cost savings.

Biopharmaceutical companies should partner with organized providers, aligning outreach to their management goals; groups are increasingly held to quality goals focused on improving patient outcomes. Systems most value support with management of drug acquisition/site of care objectives.

Stakeholders Prioritize Different Goals Based on MS Business Strategies
(Average proportion across four markets, 100-point allocation)

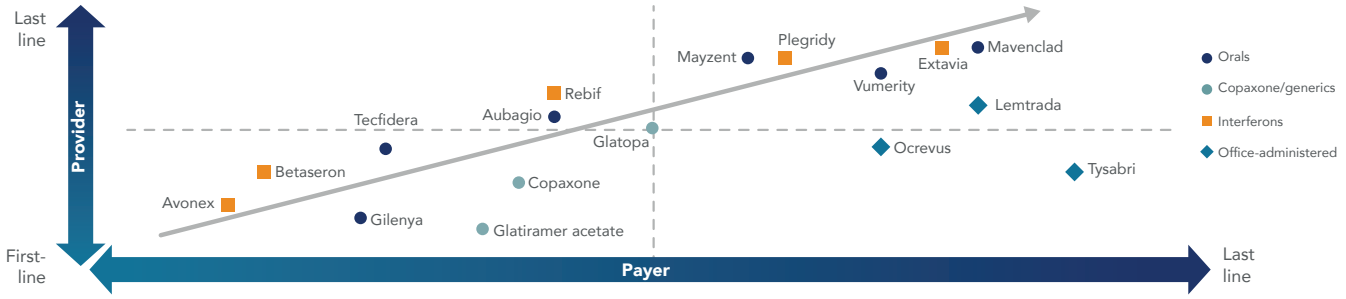


N=37 health plans, N=5 PBMs, N=40 health systems, N=26 medical groups. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

Motivated by Future Generic Drug Savings, Payers and Providers Have Increased First Line Access to Orals Gilenya and Tecfidera

Legacy ABC products (i.e., Avonex, Betaseron, Copaxone/Glatiramer acetate) continue to retain first-line status among stakeholders. 2019's Mayzent and Mavenclad have yet to gain strong first-line access, currently trailing behind preferred brands and experiencing patient cost sharing and prior trial utilization management.

Line of Therapy Assignments by Brand Align Across Payers and Providers



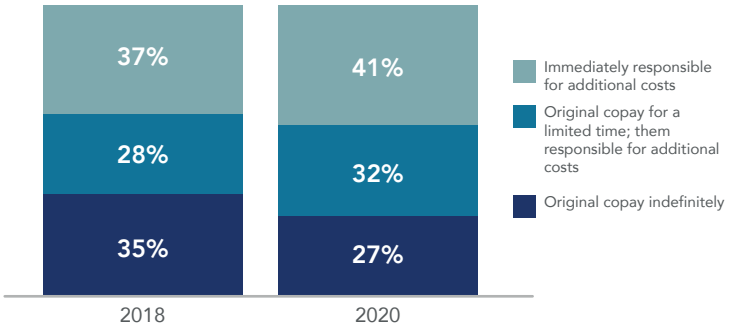
N=37 health plans, N=40 health systems. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

Pressure from Large Employers to Lower Costs Emboldens PBMs to Disallow Grandfathering in MS

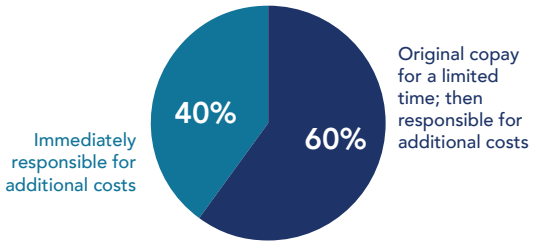
The decline of grandfathering policies creates additional opportunities for newer drugs to build market share through preferred status with payers. This increases the importance of targeted launch strategies, including demonstrated clinical benefit data and competitive pricing.

Companies should be aware of individual plans' grandfathering policies in order to better align access tactics and address potential risks to their brands' formulary status. Most plans indicate they will continue to grandfather MS patients, will also protect these patient policies in other therapeutic areas.

Nearly Half of Plans Make Patients Immediately Responsible for High Copays upon Formulary Change as Grandfathering Policies Erode
(Percentage plans)



PBMs Refrain from Grandfathering Polices in MS
(Percentage PBMs)



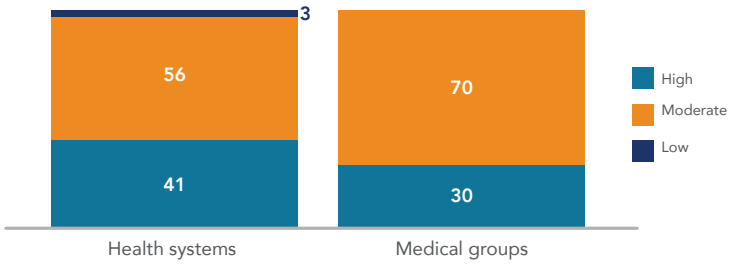
N=43.5 million managed Medicare lives; N=5 PBMs. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, March 2020

Seeking to Limit Administrative Burden and Patient Costs, Organized Providers Align to Payer Formularies as Applicable

Organized providers continue to report moderate to high alignment to payers' MS formularies as they continue to prescribe the best clinical options for patients, while balancing patient out-of-pocket costs and the administrative burden of appeals. While specialists are very familiar and comfortable with appealing payer access barriers for their patients (especially those who have failed previous therapies), they are more likely to prescribe preferred first-line options for treatment-naïve patients.

Biopharmaceutical companies with new-to-market multiple sclerosis brands must take a two-pronged approach, proving superior clinical efficacy relative to market-leading legacy therapies to gain specialist support, while simultaneously achieving preferred payer formulary access through competitive pricing strategies.

Systems Continue to Report Higher Levels of Alignment to Payer Formularies than Groups
(Percentage providers indicating level of alignment)



N=34 health systems, N=20 medical groups. Source: Health Strategies Insights by EVERSANA, Brand Access, Marketplace Dynamics - Multiple Sclerosis, May 2020.

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> **We have a whole team that's dedicated to copay assistance and affordability to try to help patients get on a product.**
>
> *– Health System Pharmacy*

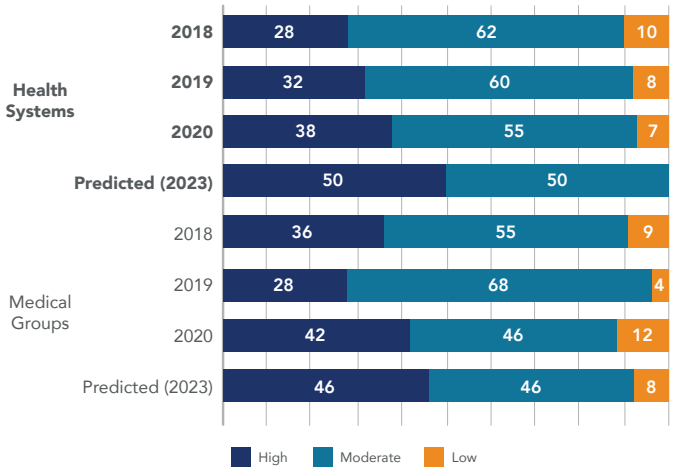
Patient Costs Increasingly Impact Prescribing Decisions, Reinforcing the Need for Preferred Payer Access and Patient Financial Support

It will be crucial for new-to-market MS brands to ensure optimal access with payers, as organized providers will be less likely to appeal against payers' access hurdles for these brands without real-world patient experience. Equally important is offering financial support programs that reduce patients' cost exposure by offering copay cards or assistance in appealing coverage denials.

However, as payers look to shift the growing cost burden to patients via copay accumulators, biopharmaceutical companies must be cognizant of each payer's policies in order to effectively tailor their engagement strategies.

Medical groups, which typically see and treat patients more often, are slightly more sensitive to patient cost exposure. Along with meeting the quality metrics of their alternative payment models (APMs), groups look to minimize disruption of therapy due to access barriers and/or high patient costs.

Patient Cost Sharing and OOP Costs Will Increasingly Impact Prescribing Decisions by 2023
(Percentage providers indicating level of impact)



N=40 health systems, N=26 medical groups. Source: Health Strategies Insights by EVERSANA, Brand Access, Marketplace Dynamics - Multiple Sclerosis, May 2020.

About EVERSANA™

EVERSANA is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.