In 2018, specialty medications accounted for approximately 1% of prescriptions filled in the United States, but for 45% of the total drug spending. Consequently, payers have begun to adopt agreements with drug manufacturers called “outcomes-based contracts,” in which “the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.” In therapeutic areas with uncertainty regarding clinical outcomes that are dependent on high-cost specialty medications, outcomes-based contracts can be a tool to reduce financial risk for payers and for drug manufacturers. With a high treatment cost, large number of therapy choices, and variability of responses to therapy across patients, multiple sclerosis is a compelling therapeutic area to support outcomes-based contracts.

**BACKGROUND:** In therapeutic areas with uncertainty regarding clinical outcomes that are dependent on high-cost specialty medications, outcomes-based contracts can be a tool to reduce financial risk for payers and for drug manufacturers. With a high treatment cost, large number of therapy choices, and variability of responses to therapy across patients, multiple sclerosis is a compelling therapeutic area to support outcomes-based contracts.

**OBJECTIVE:** To identify the necessary conditions to support the widespread adoption of outcomes-based contracts for high-cost drug therapy, with a focus on disease-modifying therapies for multiple sclerosis.

**METHODS:** We conducted a series of in-depth, semi-structured phone interviews during fall 2018 with 17 healthcare stakeholders representing payers, manufacturers, and industry consultants, all of whom had some involvement in outcomes-based contract development or evaluation. The qualitative data management program from QSR International, N-VIVO 11, was used to store, organize, categorize, analyze, and produce visualization tools to explore, map ideas, and understand themes from the data.

**RESULTS:** Overall, payers and manufacturers agreed that outcomes-based contracts are an effective vehicle to mitigate financial risk and deliver value for disease-modifying therapies for multiple sclerosis, but they noted that the widespread adoption of outcomes-based contracts was tempered by 5 broad categories of challenges, including data-related issues, outcome measurement and confounding factors, regulatory barriers, levels of risk mitigation, and patient adherence. The majority of participants were receptive to using blood-based clinical biomarkers as outcomes-based contract end points, as long as the biomarkers are validated, accurately predict clinical outcomes, are well-established in the therapeutic area, and are readily accessible to various stakeholders.

**CONCLUSION:** Our findings indicate there is general support from payers and drug manufacturers to adopt outcomes-based contracts for disease-modifying therapies for multiple sclerosis. However, some conditions need to be met to allow their widespread adoption, including resolving data issues, ensuring patient adherence to therapy, having a level of risk mitigation that is significant for both parties to make the endeavor economically worthwhile, and fostering a supportive regulatory environment. Blood-based clinical biomarkers that meet certain criteria could be viable end points in outcomes-based contract for disease-modifying therapies for multiple sclerosis and can address many of the necessary conditions regarding data issues, including timeliness.

**KEY WORDS:** disease-modifying therapies, multiple sclerosis, outcomes-based contracts, payers, risk mitigation, specialty medications
KEY POINTS

- Outcomes-based contracts can reduce the risk associated with specialty medicines for payers and for drug manufacturers.
- This study was conducted to identify conditions that support the use of outcomes-based contracts, with a focus on disease-modifying therapies for multiple sclerosis.
- The study was based on in-depth interviews with 17 payers, drug manufacturers, and healthcare consultants who had developed or evaluated outcomes-based contracts.
- Respondents noted that outcomes-based contracts provide value for disease-modifying therapies, but several challenges present continuing obstacles.
- Adopting outcomes-based contracts is challenged mostly by data-related issues, as well as by confounding factors, patient adherence, regulation, and level of risk mitigation.
- Blood-based clinical biomarkers can be outcomes-based contract end points for disease-modifying therapies, if an appropriate biomarker test is available.
- This pilot study provides a starting point for stakeholders to create outcomes-based contract structures for high-cost specialty medications.

contracts, payers receive assurances that they will “get their money’s worth,” and drug manufacturers are provided earlier access to their drugs and have significant sales for successful drugs. A typical mechanism of risk sharing in an outcomes-based contract is a rebate or supplemental rebate to the payer if the drug does not meet its agreed-on outcomes measures (ie, end points).

Several outcomes-based contracts have been implemented in healthcare over the past decade, and the pace of their implementation is quickening.1 A total of 62 outcomes-based contracts have been publicly announced in the United States between 2009 and 2019.4 A 2018 survey conducted by Avalere Health showed that more than 25% of all health plans have an outcomes-based contract in place.5 In all, 85% of those health plans expressed interest in pursuing additional contracts.5 A well-known example of an outcomes-based contract is between Novartis and multiple private insurers for its heart failure combination drug, sacubitril plus valsartan; under these contracts, hospitalization rates may determine whether additional rebate payments are paid to insurers.6

Multiple sclerosis is a compelling therapeutic area for outcomes-based contracts, because of the number of disease-modifying therapies that are on the market for this disease, spanning 3 routes of administration, high drug costs,7 and variability in patient responses to therapies.8 In clinical trials, US Food and Drug Administration (FDA)-approved disease-modifying therapies for multiple sclerosis have demonstrated a reduction in the number of disease relapses, a delay in disability progression, and the ability to limit new disease activity (as seen on magnetic resonance imaging [MRI]); these drugs are the mainstay of treatment for patients with multiple sclerosis.8

According to Express Scripts’ 2018 Drug Trend Report, in 2018, medications for the treatment of multiple sclerosis were the fourth costliest drug therapy category, averaging $55.81 per member annually.9 Drug manufacturers and payers have begun experimenting with the use of outcomes-based contracts for disease-modifying therapies for multiple sclerosis.10 The 2018 survey by Avalere Health revealed that 10% of outcomes-based contracts target immune or inflammatory disease states,7 yet little is known about the details of those contracts.

The widespread adoption of outcomes-based contracts in the United States involves significant challenges.17 Organizations such as AMCP (Academy of Managed Care Pharmacy) and ISPOR (International Society for Pharmacoeconomics and Outcomes Research) have identified some challenges and provided strategies to develop, evaluate, implement, and monitor these contracts.12 To further understand these challenges and offer some insights on how to overcome them, we conducted a series of market research interviews with industry representatives. The interviews’ objectives were to:

1. Identify payer and manufacturer perspectives on outcomes-based contracts
2. Learn how end points are selected for use in outcomes-based contracts
3. Explore the potential role of blood-based clinical biomarkers as end points in outcomes-based contracts
4. Explore the applicability of outcomes-based contracts to disease-modifying therapies for multiple sclerosis
5. Identify the necessary conditions for the widespread adoption of outcomes-based contracts.

Methods

A total of 58 representatives from payers (national, regional, and local health insurance plans, pharmacy benefit managers), drug manufacturers, and industry consultants were invited to participate in our study. The invitees were targeted based on their experience with outcomes-based contracts and, for the manufacturers, their disease-modifying therapy portfolios related to multiple sclerosis. Specific individuals were identified through the AMCP; the Pharmacy Quality Alliance; the primary investigator, Octave Bioscience; and LinkedIn.
Throughout the coding process, an iterative approach was taken in fall 2018. The invitation included the study purpose, the summary data in aggregate. Each interview was transcribed and or-30 to 45 minutes and were deidentified; we reported the results. Semi-structured phone interviews lasted 0.5 to 1 hour. We organized the data using QSR International’s NVivo 11 software. Throughout the coding process, an iterative approach was used to reexamine the original data as themes defined as codes were merged, expanded, deleted, or divided.  

### Results

A total of 17 individuals, representing payers, drug manufacturers, and industry consultants, responded to the study invitation, all of whom had some involvement in outcomes-based contract development or evaluation. In all, 7 of the participants were from payer organiz-
Challenges to Success

The study participants identified challenges that have hindered the widespread adoption of outcomes-based contracts. These participants identified the most frequently reported category of challenges, including selecting end points. Other cited challenges were related to confounding factors, regulatory issues, and level of risk mitigation.

In an outcomes-based contract, participants reported that both parties must agree on the end points, what data to collect, how the data will be collected and interpreted, and how much time can pass before the data will be available to payers. The first data challenges reported were identifying, defining, and agreeing on meaningful end points. The end points need to be simple, easily measurable in available data sets, objective, and clinically relevant. The payers reported a preference for end points that can be measured with pharmacy and medical claims data. In addition, the participants agreed that the parties must concur on the population to be measured and the time frame of the contract. In our study, the reported target contract durations to measure outcomes successfully ranged from 3 months to 3 years, with a median of 1 year.

The preferred number of end points varied across the respondents. Some respondents preferred multiple end points, particularly for complex diseases. Other respondents preferred keeping only 1 or 2 end points, making the interpretation of success simpler.

The frequently measured outcomes-based contract end points included medication adherence, event avoidance (eg, relapse, strokes, myocardial infarction), hospitalizations or admissions, laboratory values (eg, hemoglobin [Hb]A1c, low-density lipoprotein [LDL] levels), and disease progression.

In the study, payers and manufacturers reported challenges with data collection and analysis. The participants noted that there needs to be an adequate data collection infrastructure in place for measuring and monitoring outcomes. They also noted that it is important that the data collected are accurate, are collected in a timely manner, and do not require a significant cost to access. Payers expressed concern about needing enough sample sizes, whereas drug manufacturers reported challenges with reconciliation and the transfer of data between parties.

The study respondents reported that end points should be related to the use of the drug and should not be influenced by confounding factors. For example, they noted that manufacturers require good medication adherence for patients' data to be included in an outcomes-based contract. The common measures of medication adhe-
implementation. Payers reported that some outcomes-based contracts had a rebate level that was too small to mitigate the payer’s risk appropriately. Effort should equal reward.

**Outcomes-Based Contracts**

Disease relapse rates are the most often used end points in outcomes-based contracts for multiple sclerosis. However, payers reported that disease relapse rates are subjective and are difficult to capture and monitor in the claims data. To identify a relapse, payers have used a hospitalization or a course of steroids as proxies. Other end points that are currently used in outcomes-based contracts for multiple sclerosis reported by participants include changes in MRI, emergency department visits, and the number of symptom-free days. End points that would be based on patient-reported outcomes, such as the number of symptom-free days, will require a method to capture this information, according to the participants.

There was skepticism among the study participants related to the value of MRI data in outcomes-based contracts in multiple sclerosis. The respondents questioned the direct correlation between MRI data and disease progression. In addition, payers reported that using MRI data as outcomes-based contract end points would increase the costs of testing, data capture, and analysis.

The respondents were receptive to the use of a blood-based clinical biomarker to measure multiple sclerosis disease activity as an outcomes-based contract end point, and they believed that the development of this type of biomarker could increase the adoption of outcomes-based contracts for multiple sclerosis. A biomarker provides an objective outcome measure that may provide timely results and be less sensitive to comorbid conditions in measuring disease activity than physician observation or patient-reported symptoms.

One payer reported that a biomarker for multiple sclerosis would “help you see in a reasonable time frame something that might otherwise be hard to measure in a short period of time.” The adoption of blood-based biomarker data for outcomes-based contracts for multiple sclerosis would require the biomarker to be established and validated as predictive of long-term clinical outcomes (eg, disability, disease progression), and its data must be made available to the participants.

Our findings showed some encouraging consensus regarding the future use of outcomes-based contracts for multiple sclerosis among payers, manufacturers, and industry consultants (Table 3). The respondents agreed that high-cost specialty medications, including disease-modifying therapies for multiple sclerosis, are particularly attractive subjects for outcomes-based contracts. The respondents also agreed that the cost of data collection and

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**Table 3 Possible Solutions to Marketplace Challenges**

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which healthcare technologies and therapeutic areas are appropriate for an outcomes-based contract?</td>
<td>Identify disease areas with robust end points that are meaningful to all parties</td>
</tr>
<tr>
<td>Access to clinical data</td>
<td>Explore methodologies that provide for better access to data</td>
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<tr>
<td></td>
<td>Explore patient-reported outcomes tools</td>
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<tr>
<td>Data infrastructure inadequate for measuring/monitoring relevant outcomes</td>
<td>Include a third party for data analysis</td>
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<tr>
<td></td>
<td>Target data that are sufficient to drive contracts</td>
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<tr>
<td>Sample size</td>
<td>Expand risk tolerance for smaller patient numbers</td>
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<tr>
<td></td>
<td>Include all patients in a population</td>
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<tr>
<td></td>
<td>Create contracts based on each patient, not a population of patients</td>
</tr>
<tr>
<td>Identifying, defining, and measuring meaningful outcomes</td>
<td>Explore the use of blood-based biomarkers</td>
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<tr>
<td></td>
<td>Focus on outcomes that are:</td>
</tr>
<tr>
<td></td>
<td>- Easily measurable</td>
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<tr>
<td></td>
<td>- Simple</td>
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<tr>
<td></td>
<td>- Clinically relevant</td>
</tr>
<tr>
<td>Contract duration and timelines</td>
<td>Surrogate and escalating end points could be used to align outcomes with the allotted time period</td>
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<tr>
<td></td>
<td>New end points that are manifested in a shorter time frame may be developed</td>
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<tr>
<td>Regulatory barriers</td>
<td>Work with professional associations, such as AMCP, to promote legislative relief</td>
</tr>
<tr>
<td>Significant additional effort required to establish/execute outcomes-based contracts</td>
<td>Standardize and simplify contracts</td>
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<tr>
<td></td>
<td>Develop technology that allows for easier tracking of patient progress toward end points</td>
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AMCP indicates Academy of Managed Care Pharmacy.
analysis needs to be sufficiently low to make the economics of the outcomes-based contract acceptable.

Discussion

Although the respondents agreed that end points must be measurable, clearly defined, objective, and realizable in a relatively short period of time, differences surfaced when the respondents reported which end points to use to measure the success or failure of a drug. Payers wanted to use claims data that were easily accessible, and they were concerned about not having access to clinical data beyond the standard medical and pharmacy claims data sets. Tracking the success of an outcomes-based contract may be more challenging when the end point, such as a laboratory value, only resides in the patient’s electronic health record. If a payer does not have access to these data, the payer must look for surrogate end points to develop an outcomes-based contract.

This approach can be problematic because surrogate measures do not necessarily correlate with the clinical outcomes of focus. Manufacturers were concerned that other data, such as laboratory or electronic medical record data, were needed to ensure that the claims data accurately portrayed a patient’s response or nonresponse to medication therapy.

The end points in an outcomes-based contract may include patient-centered outcomes, such as disease relapse rates or cardiovascular events, or intermediate end points, such as HbA1c values or LDL levels. Overall, the simplicity of outcomes measurement of an outcomes-based contract will be key. Easily accessible drug outcomes measurement data that are agreed to by both parties will be a critical element of success of outcomes-based contracts and will minimize the resource utilization and cost associated with contract execution.

Payers reported challenges in selecting end points for outcomes-based contracts in a progressive neurologic disorder, such as multiple sclerosis. For example, given their subjective definitions, disease relapses are viewed as an unpopular choice for an end point. Other end point candidates, such as changes in MRI over time, do not always directly correlate with multiple sclerosis disease progression, especially in advanced stages of the disease. Notwithstanding, because of the high cost of disease-modifying drugs for multiple sclerosis on the market, the number of these agents, and the variability of responses across patients, multiple sclerosis is a compelling therapeutic area for the adoption of outcomes-based contracts. Successful early control of disease progression in patients with multiple sclerosis can provide value to payers and to manufacturers and can prolong the ability of patients to remain active.

An end point that can quickly measure whether a disease-modifying therapy for multiple sclerosis is meeting therapeutic goals would be a significant asset to prolonging a patient’s quality of life and slowing disease progression. The study respondents agreed that clinical biomarkers that meet specific criteria that correlate to clinical outcomes (eg, disability, disease progression) may serve as an objective basis for payers and for manufacturers to measure the success of disease-modifying therapies under an outcomes-based contract and may increase the adoption of outcomes-based contracts related to disease-modifying therapies for multiple sclerosis. Consequently, if a blood-based clinical biomarker can be identified that could accurately measure disease progression, an outcomes-based contract could be developed around this measure.

Contract duration and timing may vary depending on the target population and the specific outcome. Today, the efficacy of a disease-modifying therapy for multiple sclerosis is typically evaluated in an 18- to 24-month time frame. However, most patients are enrolled in health plans on an annual basis; an outcomes-based contract in which end points cannot be realized within a 6- to 12-month time frame may affect the value for payers when member turnover occurs. Ultimately, the payer must pay in full for the drug at the time of dispensing and may not realize any value-based outcome payment until years later. This could create a challenge from a budgeting perspective in trying to estimate the potential return on investment of outcomes-based contracts.

There was consensus by the respondents that once the sources of the data and the end points are agreed on, having the data easily accessible to all stakeholders is important. Because most laboratory data (and presumably biomarker data) are more easily obtained from the electronic health record as opposed to standard claims files, health plans would need to identify an alternate way to capture and monitor this agreed on end point, assuming they are unable to obtain the outcomes measurement directly from the laboratory tests. Accessibility of the data is critical, and all stakeholders need to have confidence that the data will be collected, shared, and interpreted in an unbiased manner.

Some health plans have used the prior authorization and reauthorization process to capture data from the physician at agreed-on checkpoints for prescription renewals. A check on disease progression could be a required question regarding prior authorization reauthorizations. Alternatively, or in tandem, a purpose-built software platform could be engaged to allow stakeholders access to the end point measures. Payers may need to work with physician providers and laboratory vendors (eg, Quest Diagnostics or LabCorp) to gain access to relevant laboratory data. Independent third-party outcomes measurements are also an option used by some
organizations to reduce bias and effort associated with the measurement of outcomes.\textsuperscript{16}

The respondents in our study also agreed that it is important that the contract terms are clear and prescriptive with respect to the collection, integration, and analysis of the data. Not having a large enough sample size to achieve statistical significance may be a barrier to an outcomes-based contract that does not measure each patient’s success independently.

The drug in question must also be a primary driver of the outcome measure. The consensus among study participants was that outcomes-based contracts could include elements in the contract design to monitor and/or improve adherence. One way to incorporate medication adherence support in an outcomes-based contract would be to only include in the contract patients who met a prespecified threshold.\textsuperscript{2} There was agreement among the respondents about the need to have a minimum threshold for patient adherence to therapy. There was disagreement as to whether other confounding factors, such as comorbid conditions, should eliminate a specific patient’s data from consideration.

Payers and manufacturers want to mitigate risk; outcomes-based contracts with meaningful economic consequences can mitigate the payer’s risk of paying for a drug that doesn’t work, while mitigating the drug manufacturer’s risk of not selling the desired volumes of a successful drug. Overall, an outcomes-based contract needs to be designed so that it provides benefit in some form to all parties involved, including the payer, the manufacturer, and the patient.\textsuperscript{2}

Finally, the respondents agreed that regulations such as Medicaid best price and the federal Anti-Kickback Statute have presented hurdles for drug makers to engage in outcomes-based contracts with health plans. Changes to the legal infrastructure that include additional safe harbors will encourage a broader adoption of outcomes-based contracts.\textsuperscript{2}

Limitations

The primary limitation of this study is its small sample size. Another major limitation is the broad nature of the questions.

Because of the low response rate (only 29\% of participants who were contacted agreed to participate in our study), there is a likelihood of some element of response bias.

Finally, 2 participants reported minimal experience with outcomes-based contracts, and this paradigm is still nascent.

Conclusions

Payers and drug manufacturers in this study agreed that outcomes-based contracts are an effective vehicle to mitigate risk and deliver value for disease-modifying therapies for multiple sclerosis, but they noted that widespread adoption of outcomes-based contracts is tempered by 5 broad categories of challenges, including data-related issues, outcomes measurement and confounding factors, patient adherence to the therapy, regulatory barriers, and levels of risk mitigation. The 2 parties to the contract must agree on the data elements that define success; how these data shall be measured, stored, and accessed; and how to do all this in a cost-effective manner.

A software platform that stores and provides data reports to stakeholders and is sufficient to track an outcomes-based contract may help to reduce the cost of access to data. Manufacturers prefer that the end points used should be relatively insulated from comorbid conditions, which will likely fuel their desire to incorporate laboratory and electronic health record data into the outcome’s analyses; they are less confident that claims data alone will provide an accurate assessment of a medication’s effectiveness.

Key conditions are needed to facilitate widespread adoption of outcomes-based contracts. First, payers prefer to rely on claims data because of their accessibility and unambiguity. Second, blood-based biomarkers that meet specific criteria, accurately correlate to clinical outcomes, and are observable in a relatively short time frame may bridge this gap and may serve as effective end points for payers and manufacturers to measure the success or failure of a disease-modifying therapy for multiple sclerosis. Third, patients need to be engaged in an adherence support program to ensure that the medication regimens are being followed. Fourth, regulators, such as the US Department of Health & Human Services, will need to allow payments from outcomes-based contracts to be included in safe harbors from antikickback laws if beneficiaries are to benefit from outcomes-based contract arrangements. Finally, the level of risk mitigation in an outcomes-based contract needs to be significant for both parties to make the endeavor economically worthwhile.

These key conditions provide payers, drug manufacturers, and regulators a road map to start creating viable outcomes-based contract structures for disease-modifying therapies for multiple sclerosis and for other high-cost medications.

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Author Disclosure Statement

Dr Gray is an employee of Sanofi and a former employee of Octave Bioscience, which sponsored this study. Mr Kenney has no conflicts of interest to report.
Outcomes-Based Contracts Gaining Traction: Innovative Therapies Will Require Innovative Payment Methods

By Gary Branning, MBA
Professor, Pharmaceutical Management, Rutgers Business School, Newark and New Brunswick, NJ, and President, Managed Market Resources

As outlined in the study by Gray and Kenney that included 17 healthcare stakeholders, the willingness to engage in outcomes-based contracts is at an all-time high, and one would expect many more contracts. Gray and Kenney outline 5 broad categories of challenges, including data-related issues, outcome measurement and confounding factors, regulatory barriers, levels of risk mitigation, and patient adherence, which have limited stakeholders’ widespread adoption of outcomes-based contracts. Globally, pharmaceutical manufacturers and payers have been engaging in these types of agreements over the past 2 decades, although the United States only recently gained traction in this area in 2014, and it continues to increase the number of outcomes-based contracts incrementally each year.

**DRUG MANUFACTURERS:** Manufacturers are incentivized to enter outcomes-based contracts for a variety of reasons, whether to differentiate their drug from already established in-class competition and gain preferred formulary positioning, or to guarantee value in disease states (ie, rare and orphan diseases) that to date have been vague. For manufacturers, outcomes-based contracts can mean faster coverage, higher sales volumes for drugs, and increased access to drugs, and can demonstrate the company’s commitment to its drug by standing behind its performance throughout the contract period.

Complicating the execution of outcomes-based contracts for manufacturers are the various regulatory and operational challenges that need to be addressed before entering into an outcomes-based contract. There are 2 main federal drug price regulations that complicate the contracting process. The first is regarding the Anti-Kickback Statute that prohibits the exchange of anything of value with the intent to influence—its vague language is
a concern when dealing with an agreement for medication adherence support by the manufacturer. The second key regulatory statute is the ceiling on rebates created by the Medicaid “best price” policy. In addition to the regulatory hurdles, operational barriers of determining the appropriate outcome measures and defining value over a specified time frame that is acceptable to the payer also complicate the process.

**PAYERS:** Payers buy in for the opportunity to improve performance and outcomes via real-world data that demonstrate a drug cost-effectiveness, and to create a “safety net” in the event that the measured outcomes are not met.

The growth of specialty drugs and the burden on payers contribute to an unsustainable health system. Going forward, innovative therapies will require innovative payment methodologies.

Complicating the execution of outcomes-based contracts for payers are concerns regarding the duration of the agreement, because the length of time can be affected by the beneficiary’s longevity in the health plan and the lack of portability of the terms, considering that individuals or employers move from one payer to another and their investment follows. In addition, the shared risk between the manufacturer and the payer usually begins with the payer.

Before seeing the results of the predefined measurable outcome, the payer is responsible for covering the cost of those prescriptions, which could be quite high for these innovative therapies. Depending on the outcome, this could mean covering a few dozen prescriptions over months or even a few years. By design, the US healthcare system does not allow payers to capitalize on the positive aspect of those long-term savings. Predictability for a payer is a key component of success, and outcomes-based contracts can be unpredictable.

**MULTIPLE SCLEROSIS:** The majority of outcomes-based contracts are used in the areas of oncology and hematology, where innovative drugs can be costly but potentially lifesaving for patients. Outcomes-based contracts are helpful in clinical areas where there is still uncertainty about a drug’s efficacy in the real world. In multiple sclerosis, as discussed by Gray and Kenney, there is significant variability in the patient population: individuals may respond in different ways to various disease-modifying therapies, contraindications can limit options for certain patients, risk tolerance varies between patients and their physicians, and general tolerability to medications differs, among other factors that complicate the agreed-on end points. Given all these factors, coupled with the often-significant price tag, drugs for the treatment of multiple sclerosis are an attractive prospect for outcomes-based contracts.

**MANUFACTURERS/PAYERS:** Payers and drug manufacturers have expressed challenges with data collection and analysis, beginning simply with the lack of necessary data infrastructure to implement the contract. Upfront data may also be necessary to effectively evaluate the components of the contract. Improper data management techniques can limit the types and increase the complexity of the contracts that are available.

Having an established infrastructure in place to measure effectively and to monitor outcomes is crucial to the success of the outcomes-based contract. The growth of specialty drugs and the burden on payers contribute to an unsustainable health system. Going forward, innovative therapies will require innovative payment methodologies.