New Perspectives on the MS Patient Journey
Case Study

CBI Conference
August 18, 2016
Today’s Discussion

• Discuss how being a market leader creates both challenges and opportunities when helping to address payer needs
• Define our customer needs for today and understand tomorrow’s needs based on future healthcare delivery models
• Creating a strategic process and approach for engaging a broader and deeper set of stakeholders within a payer
• Engaging customers “beyond the brand”
• Designing a blueprint for becoming a strategic partner of choice with payers
Being a Market Leader Creates Both Opportunities and Challenges

<table>
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<th>Opportunities</th>
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<tr>
<td>• The landscape of MS treatment has grown crowded over the last decade; 14 disease-modifying therapies (DMTs) for MS are now approved by the FDA</td>
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<td>• Biogen’s portfolio of 5 branded agents has a 44% market share</td>
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<table>
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<th>Challenges</th>
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<td>• MS is a top 5 spend</td>
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<td>• MS DMT costs (~$65,000 PPPY) have accelerated at rates beyond inflation and on pace with drugs in similar high cost biologic classes</td>
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<td>• Payers are increasingly concerned with these rising costs and are becoming more stringent with their management of the class</td>
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Payer Dynamics Impacting Multiple Sclerosis

**BENEFIT DESIGN**
- Shift to the pharmacy benefit
- Addition of specialty tiers
- Preferred products
- Increased patient copays/coinsurance
- Limiting use of co-pay cards

**UTILIZATION MANAGEMENT**
- Lack of guidelines creates ad hoc
  - Use of prior authorizations (PA)
  - Limited formularies
  - Increased use of restrictions, including step therapy (ST)
  - Restricted access to new products
  - Pricing/Contracting pressure

**DISTRIBUTION CHANNELS**
- Reduced incentives for buy-and-bill (physician purchase)
- Specialty pharmacy mandates
- Limited pharmacy options
- Plan/Provider Consolidation

**SITE OF CARE SHIFT**
- Preferred sites of care
- Adjustment of reimbursement methodologies across sites of care
- 340B pricing

The Goals of Our Key Stakeholders Are Changing in the Face of Healthcare Reform

Our stakeholders are significantly impacted by the Triple Aim and turbulent implementation of healthcare reform

- Improving the patient experience of care
- Improving the health of populations
- Reducing per capita cost of healthcare

"...it is now possible to describe feasible, evidence-based care system designs that achieve gains on all three aims at once: care, health, and cost. The remaining barriers are not technical; they are political."

...and Pursuit of the “Triple Aim” Is Changing the Interplay Between Key Stakeholders

This dynamic has created an opportunity for Biogen to enhance its collaborations with payers, in particular
Engaging Our Payer, PBM, and SPP Stakeholders at the Highest Level

Our Key Diverse Stakeholders

- Quality
- Sales and Marketing
- Pharmacy
- Case Management
- Provider Relations
- Medical
- C-Suite
Who Is Our Customer? What is Their Role?

**Pharmacy**
- Cost of care
- Pharmacy utilization
- Pharmacy benefit plans
- Formulary management

**Medical**
- Prior authorization
- Utilization management
- Formulary review
- Medical policy
- MLR

**Quality**
- Effectiveness of treatments
- Patient satisfaction
- Processes
- Performance goals
- Quality improvement policies & measurement systems
  - External regulations

**Case Management**
- Decrease fragmentation and duplication of care
- Appropriate use of services
- Patient quality of life
- Patient compliance

**Sales and Marketing**
- Membership retention
- Member acquisition
- Plans benefits and features
- Increase penetration of payer’s plans in the marketplace

**C-Suite**
- Strategic leadership
- M+A
- Shareholder value

**Provider Relations**
- Providers
- Specialty/retail pharmacy networks
- Hospitals
- Home health
- Site of care
The Evolving Healthcare Landscape Demands Thoughtful Cross-Stakeholder Collaboration

Biogen is Committed to Stakeholder Collaborations to Help Advance Quality of Patient Care

- Neurologists and Professional Groups
- Patient Community and Advocacy Groups
- Academic Centers
- Payers
- Integrated Delivery Networks

Care Today → Future Care
Our Account Manager Model

- **Attributes**
  - Analytical
  - Ethical
  - Personable & engaging
  - Professional
  - Innovative & patient

- **Capabilities**
  - Business acumen
  - Strategic thinking
  - Collaboration & teamwork
  - Influence
  - Developing broader and deeper relationships
  - Advocacy development
  - Influence mapping
  - Deep understanding of customer’s business
  - Problem solving/innovation
  - Consultative Selling

- **Behaviors**
  - Focus on priorities/sense of urgency
  - Innovation & creativity
  - Crisp, high-quality decision-making
  - Accountability
  - Collaboration/teamwork
  - Mutual respect, trust, integrity/honesty, and ethics

- **Knowledge**
  - Knowledge of:
    - The account
    - Managed care
    - The product
    - Disease state
  - Knowing the healthcare market dynamics and trends
  - Understanding of resources

HIRC, Best Programs & Best People Service 2014
Our Highest Aspiration: Becoming a Strategic Partner of Choice

Further differentiate yourself in ways that play to your unique position in the marketplace.

Demonstrate the value of existing portfolio in the rapidly changing payer marketplace.

Develop deep and broad strategic relationships with your customers.

Establish broader collaborations with customers that can build value for your products.
Multiple Sclerosis: New Perspectives on the Patient Journey

**SITUATION**

- Payers expect Biogen, as an industry leader in MS, to educate them about different types of patients that may be of importance to health plans to assist in the management of MS.
- The current approach, 1-2 year snapshots of claim data, doesn’t tell the complete journey of what happens to patients with chronic progressive conditions like MS.
- While MS is fairly prevalent, payers don’t appreciate the individuality of the condition and try to actively cost manage a chronic condition that has variable patient heterogeneity.

**GOAL**

- Build an objective and credible storyline on the MS patient journey:
  - Underscore heterogeneity of the condition
  - Role of disability progression
  - Potential impact on the payer system
  - Importance of timely treatment
- Find the BIG IDEA to tell the complete story in an impactful way to payers.
Multiple Sclerosis: Payer Perspectives on the Patient Journey

**Background Section**
Sets the context for the discussion of findings

**Snapshot Analysis Section**
- Presents descriptive statistics for 2013 data
  - Prevalence
  - Incidence
  - DMT treatment rate
  - Healthcare costs

**Longitudinal Analysis Section**
- Presents patient-level data capturing patterns of care during a 10-year period for the years 2003-2014
  - Disability progression
  - DMT treatment initiation
  - DMT impact
  - DMT use patterns

**Implications Section**
- Highlights potential important implications for payers and supporting findings
Important Background Information

Scope of This Work

- In this study, we examined the healthcare costs and disease markers of patients identified with multiple sclerosis (MS). The context is the changes in disease burden over the course of several years, including the years leading up to diagnosis.

- The source for the information in these slides comes from the white paper titled *Multiple Sclerosis: New Perspectives on the Patient Journey* that will be available in April 2016.

Data Sources

- For our commercial analysis, we used the Truven Health Analytics MarketScan® Commercial Databases (2003-2014). These databases include health insurance claims across the continuum of care as well as enrollment data for tens of millions of insured lives from self-funded large employers and health plans across the United States.

- Wolters Kluwer’s Medi-Span database was used to identify AWP unit prices for all DMT drugs. Medi-Span is a comprehensive drug data source that contains brand and generic drug names, national drug code (NDC), generic product identifier (GPI), manufacturer information, and various price metrics for close to 200,000 drug products.
Important Background Information

Caveats and Sponsorship

• This material shows averages across patients. Individual patients may have higher or lower costs, disease markers, and DMT use than the averages shown. In charts that show care by category, not all patients will receive all categories shown.

• This work was commissioned by Biogen. The paper reflects the research of the authors and was developed with the intent to provide insight to financial and medical decision-makers within payer organizations. It should not be considered an endorsement of any policy or product by Milliman, Inc. Medical therapy, especially biotechnology, is a rapidly changing field, and readers should note that this paper may not reflect current therapeutic considerations. The patient journey is individualized and may differ from patient to patient.

• The figures presented here are, unless otherwise noted, national averages developed from historical databases. Because of the variability in healthcare and health benefits, these figures may not be appropriate for particular organizations or particular purposes.

• As with any economic or actuarial analysis, it is not possible to capture all factors that may have significant impact on healthcare utilization and cost. Interpretations of these data may vary. Further, no algorithm for identifying MS patients and relapses will be perfect. Different identification algorithms could produce different results. It is important to note that individual patient characteristics and situations may also vary.
Snapshot Analysis
Non-DMT Items Made Up Approximately 37% of the Average Allowed Cost for Patients With MS

ALLOWED PPPM CLAIM COSTS BY SERVICE CATEGORY
FOR PATIENTS WITH MS IN 2013

Hospitalizations, skilled nursing facility stays, and ER visits made up nearly one-quarter of non-DMT costs
Untreated Patients With MS Appeared to Have Higher Costs for Non-DMT Items Than DMT-Treated Patients

In 2013, the unadjusted average monthly non-DMT cost among patients with DMT use was approximately 18% lower than among those without DMT use. Potential confounding factors like age, gender, and disease duration were not adjusted for in this analysis.
Longitudinal Analysis
Traditionally in Clinical Trials, Disability in MS Has Been Assessed Using the Expanded Disability Status Scale (EDSS)$^1$

**DISABILITY PROGRESSION BASED ON THE EDSS$^2$**

- **EDSS 0.0 – 3.0:** Minimal to moderate disability
  - Normal neurologic exam

- **EDSS 4.0:** Fully ambulatory despite severe disability
  - Relatively severe disability; able to walk without assistance for 500 meters

- **EDSS 5.0 – 9.0:** Loss of ambulation; fully daily activities impaired
  - Disability affects daily routine; able to walk without assistance for 200 meters
  - Assistance required to walk
  - Restricted to wheelchair
  - Confined to bed

The EDSS score is largely affected by physical mobility, but it may under-represent common functional impairments in MS, including cognitive impairment, fatigue, pain, and depression$^{1,3}$

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$^a$For scores EDSS 1.0, 2.0, and 3.0, the disability refers to the maximum impairment in a single functional system. It is possible for such individuals to qualify for disability benefits due to other factors or to combinations of factors.

Neurological Impairments Have Been Shown to Be Highly Prevalent Among Patients with MS

PATIENT-REPORTED SYMPTOMS OF NEUROLOGIC IMPAIRMENT

Percentage of RRMS Patients With Selected Symptoms (N=447)

- Fatigue: 80%
- Difficulty remembering: 52%
- Pain: 52%
- Difficulty concentrating: 44%
- Depression: 39%
- Mood swings: 29%
- Irritability: 27%

Many neurological impairments have been linked to higher healthcare costs and/or lost productivity (eg, absenteeism, presenteeism)2,3

Insurance Claims of Newly Diagnosed Patients Were Used to Identify Indicators of Disability and Impairment

**EDSS-DERIVED DISABILITY INDICATORS** *(identified through diagnosis codes and/or non-DMT prescription drug treatment)*

- Spasticity
- Bladder dysfunction
- Cognitive/behavioral dysfunction\(^a\)
- Visual impairment
- Mobility impairments requiring a cane, walker, wheelchair, or specialty bed

**RELATED NEUROLOGICAL IMPAIRMENT INDICATORS** *(identified through non-DMT prescription drug treatment)*

- Pain
- Fatigue
- Depression
- Cognitive impairment\(^b\)

\(^a\)Identified through medical claims with relevant diagnosis codes (e.g., ICD-9 codes for dementia, mild cognitive impairment, pseudobulbar affect, etc).

\(^b\)Identified through pharmacy claims for relevant prescription drug therapies (e.g., acetylcholinesterase inhibitors for the treatment of dementia).
EDSS-derived Disability and Neurological Impairment Indicators Were Observed in Many Patients With MS

CUMULATIVE DISTRIBUTION OF PATIENTS WITH MS BY THE NUMBER OF DISABILITY/IMPAIRMENT INDICATORS DURING THE COURSE OF THE DISEASE

Indicators of disability and functional impairment were evident in claims for many patients before MS diagnosis was established and appeared to increase during the course of the disease.

*Identified by prescriptions filled for particular non-DMT drug classes.
Non-DMT Costs Appeared to Increase Above the Prior Years’ Level in the Second and First Years Prior to Diagnosis

 ALLOWED PPPM COSTS ASSOCIATED WITH NON-DMT SERVICES DURING THE COURSE OF THE DISEASE (including 95% CIs and trended to 2015)

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<tr>
<th>Years From Initial MS Diagnosis</th>
<th>Average Allowed PPPM for Non-DMT Cost</th>
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<tbody>
<tr>
<td>Year -5</td>
<td>$591</td>
</tr>
<tr>
<td>Year -4</td>
<td>$612</td>
</tr>
<tr>
<td>Year -3</td>
<td>$655</td>
</tr>
<tr>
<td>Year -2</td>
<td>$732</td>
</tr>
<tr>
<td>Year -1</td>
<td>$1128</td>
</tr>
<tr>
<td>Year 0</td>
<td>$1614</td>
</tr>
<tr>
<td>Year 1</td>
<td>$1146</td>
</tr>
<tr>
<td>Year 2</td>
<td>$1162</td>
</tr>
<tr>
<td>Year 3</td>
<td>$1145</td>
</tr>
<tr>
<td>Year 4</td>
<td>$1180</td>
</tr>
<tr>
<td>Year 5</td>
<td>$1226</td>
</tr>
<tr>
<td>Year 6</td>
<td>$1252</td>
</tr>
<tr>
<td>Year 7</td>
<td>$1157</td>
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Non-DMT costs appeared to peak in the year following MS diagnosis and reduced somewhat thereafter
Approximately 33% of Newly Diagnosed Patients With MS Had No DMT Claims in the 2 Years After Diagnosis

DMT treatment patterns following a 2-year period for patients newly diagnosed with MS in 2012

Approximately 1 out of 3 patients transitioned to a different DMT within 2 years after initiating treatment.
Potential Implications For Payers
Up to 12 Years of Commercial Insurance Claims Were Analyzed to Help Provide New Perspectives on the Patient Journey in MS

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<tr>
<th>POTENTIAL IMPlications</th>
<th>RELEVANT FINDINGS</th>
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| Claims data may be a resource to help understand the patterns and progression of MS and its impairments | • Markers of disease progression  
• DMT use patterns  
• Predictive modeling |
| Disease burden in MS may be assessed through various markers of disease progression and functional impairment | • Disease burden based on indicators of  
  – EDSS-derived disability  
  – Related neurological impairment |
| Longitudinal claims analyses may help assess the potential cost impact of chronic drug therapies | • Potential DMT impact on non-DMT costs  
  – Approximately 18% difference in unadjusted non-DMT costs in 2013  
  – Reduction in non-DMT costs equivalent to approximately 7% of DMT spend  
  • An estimated 16% reduction in non-DMT costs when adjusted for DMT use in 2013 |
These Data May Be Relevant to Aspects of Current Expert Opinion\(^a\) in the Treatment of MS

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<tr>
<th>EXPERT OPINION</th>
<th>DMT treatment should be initiated soon after the diagnosis is established(^1-(^3))</th>
<th>Due to the heterogeneity of patients with RMS, access to a broad range of DMT options is important(^3,(^4))</th>
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<tr>
<th>RELEVANT FINDINGS</th>
<th>UNDER-TREATMENT • 33% of patients with MS remained untreated within 2 years after diagnosis</th>
<th>DIVERSE RESOURCE UTILIZATION • Considerable variations in allowed costs were exhibited</th>
</tr>
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<td>RELATIVELY FREQUENT TRANSITIONING • Approximately 31% of patients switched to a different DMT within 2 years after initiating treatment</td>
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\(^a\)Expert opinion is based on the following references:
Establishing Deeper Partnerships With Payers by Sharing Cutting-Edge Insights

The MS Patient Journey

Whitepaper
Multiple Sclerosis: New Perspectives on the Patient Journey

Congress Presence (AMCP/ASEMBIA)
• 1-hour Product Theater at Key Conferences
  – Milliman author presentation of in-depth analysis
  – Speaker panel with unbranded physician and patient stories
• Congress booth set up with Virtual Reality videos from white paper highlighting 3 patient types
  – Newly diagnosed
  – Relapse
  – Disabled
• Significant Promotion at Congresses

Materials for Account Managers
• MS Patient Journey Executive Summary Presentation for AMs (PPT)
• PDF of White Paper for AM distribution (print & electronic)
• Annotated whitepaper & objection handler
MS Patient Journey – US Payers

What have we accomplished thus far? What’s next?

Results to Date…

• Distribution of the white paper to payer & employer customers
• MS Patient Journey symposia at AMCP and ASEMBIA conferences were well attended
• Executive summary presentations to national and regional customers

Next Steps…

• Additional non-personal promotion
  – Targeted email, social media
• Additional symposia
• Explore MS Patient Journey in Medicare/Medicaid populations
Lessons Learned

• As a leader in Multiple Sclerosis, Biogen will continue to evolve as payers needs shift toward alternative payment models, integrated delivery, and population health

• Having a “true” strategic process and approach for engaging broader & deeper relationships is critical to gain customer trust and level set therapeutic understanding

• Playing “beyond the brand” is a “must do” to maintain market leadership

• Defining the blueprint for becoming a strategic partner of choice with payers can come from one big idea
Questions?