A Retrospective Cohort Study to Assess the Patient Characteristics, Clinical and Economic Outcomes and Treatment Patterns in People with Primary Progressive Multiple Sclerosis in the United States

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BACKGROUND

- Primary progressive multiple sclerosis (PPMS) is characterized by a gradual and continuous worsening of neurological function from disease onset, without initial relapses or remissions[1]
- Approximately 10%–15% of people with multiple sclerosis (MS) develop PPMS; however, its diagnosis is challenging due to confounding comorbidities, lack of specific magnetic-resonance imaging markers, and reliance on accurate clinical history, which can delay the treatment and only one disease-modifying therapy (DMT) is approved for treatment of PPMS [2,3]
- Data on the clinical and economic burden as well as treatment patterns, particularly in the context of real-world evidence, are limited for the PPMS population

OBJECTIVE

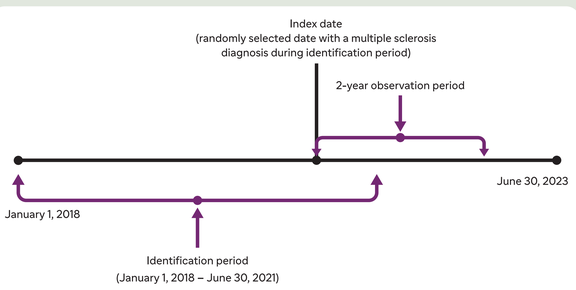
- To understand the patient demographics, clinical characteristics, economic outcomes, and patterns in people with PPMS in the United States (US)

METHODS

Study design and population

- A retrospective, cohort-analysis study was conducted from January 1, 2018, to June 30, 2023, using a large, integrated US-based administrative claims database (**Figure 1**)
- The index date was defined as a randomly selected date with an MS diagnosis during the identification period (January 1, 2018, to June 30, 2021)
- People with PPMS required continuous enrollment with a health plan during the 2-year observation period following the index date

Figure 1: Study time frame



Study measures

- Baseline demographics, Charlson Comorbidity Index (CCI), Kurtzke Functional Systems (KFSS)-adapted disability score, specific comorbidities of interest, healthcare resource utilization (HCRU), and healthcare costs (HCCs) were captured during the 2-year observation period
- HCRU included use of specific services, inpatient admissions, emergency department (ED) visits, and non-ED outpatient service visits
- HCCs included costs of medical claims, pharmacy, and cost of infections
- Treatment patterns for DMTs were tracked during the 2-year observation period

Statistical analysis

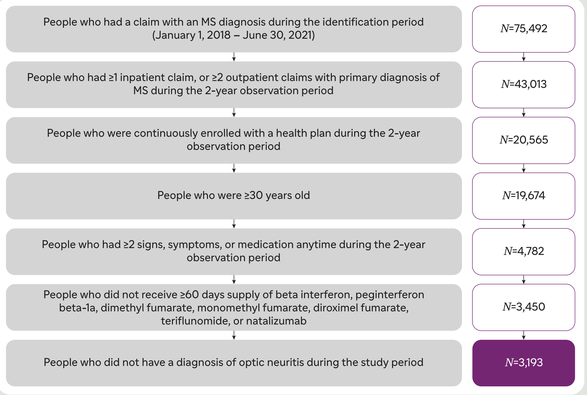
- Descriptive statistical analyses were used for all study measures
- All costs were reported in US dollars (adjusted to Year 2023)

RESULTS

Baseline demographics

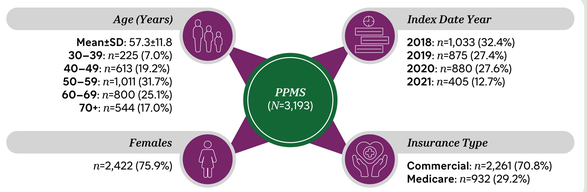
- A total of 3,193 people with PPMS were included in the study (mean±standard deviation [SD] age, 57.3±11.8 years; female, 75.9%; and commercially insured, 70.8%) (**Figure 2 and 3**)

Figure 2: Attrition chart for the identification of PPMS cohort in the claims database



N is the total study population.
MS, multiple sclerosis; PPMS, primary progressive multiple sclerosis.

Figure 3: Demographics of the PPMS cohort



Data presented as *n* (%) unless otherwise specified. *N* is the total study population. *n* is the subset of people with PPMS.
PPMS, primary progressive multiple sclerosis; SD, standard deviation.

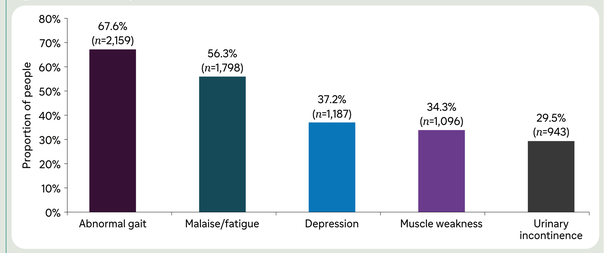
Clinical characteristics

- The mean±SD KFSS-adapted disability score for the PPMS cohort was 4.8±1.9
  - Most people (46.2%; *n*=1,475) had a moderate KFSS-adapted disability score (3.0–5.5), followed by 38.0% (*n*=1,212) with a severe score (>6), and 15.8% (*n*=506) with a mild score (0–2.5)
- At index, the mean±SD number of relapses recorded in people with PPMS was 1.3±2.3
  - Most people (22.7%; *n*=725) had one relapse, followed by 16.0% (*n*=510) with three or more relapses and 12.1% (*n*=385) with two relapses; 49.3% (*n*=1,573) of people with PPMS had no relapse
- Infections, leukopenia, and elevated liver transaminase levels were reported in 82.1% (*n*=2,621), 2.5% (*n*=81), and 1.0% (*n*=32) of people with PPMS, respectively

Specific comorbidities of interest

- The mean±SD CCI score for the PPMS cohort was 2.1±2.5, with majority (32.2%; *n*=1,028) of people having a CCI score of ≥3
- The top five most common MS-related comorbidities were abnormal gait, malaise/fatigue, depression, muscle weakness, and urinary incontinence (**Figure 4**)
- The majority people with PPMS reported other comorbidities (84.5%; *n*=2,697); whereas 31.6% (*n*=1,008) reported autoimmune comorbidities

Figure 4: Most frequent MS-related comorbidities in the PPMS cohort

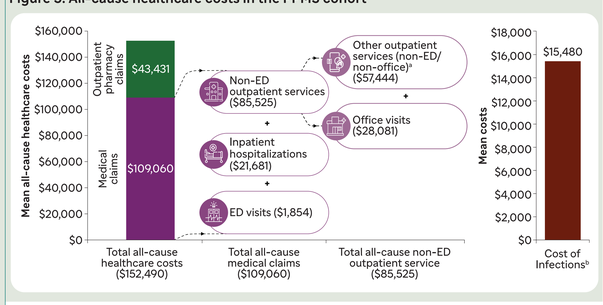


Data presented as the percentage of people. *n* is the subset of people with PPMS.
MS, multiple sclerosis; PPMS, primary progressive multiple sclerosis.

Healthcare resource utilization and healthcare costs

- The use of ambulatory devices (cane, walker, wheelchair, orthotics, Bioness–74.9%; *n*=2,393), occupational therapies (74.8%; *n*=2,388), and physical therapies (66.3%; *n*=2,117) were common among people with PPMS
- By the end of 2-year observation period, all-cause ED visits and all-cause hospitalizations were reported in 46.3% (*n*=1,478) and 33.0% (*n*=1,055) of people with PPMS, respectively
  - The mean±SD length of hospital stay in the PPMS cohort was 13.2±27.3 days
- The mean±SD number of non-ED outpatient services utilized was 79.1±54.6, which was primarily attributed to physician visits (40.2±33.0) and other outpatient services (non-ED/non-office, 39.0±43.3)
- The mean total all-cause HCCs was $152,490, which was primarily driven by costs of medical claims ($109,060) and outpatient pharmacy claims ($43,431) in people with PPMS (**Figure 5**)

Figure 5: All-cause healthcare costs in the PPMS cohort

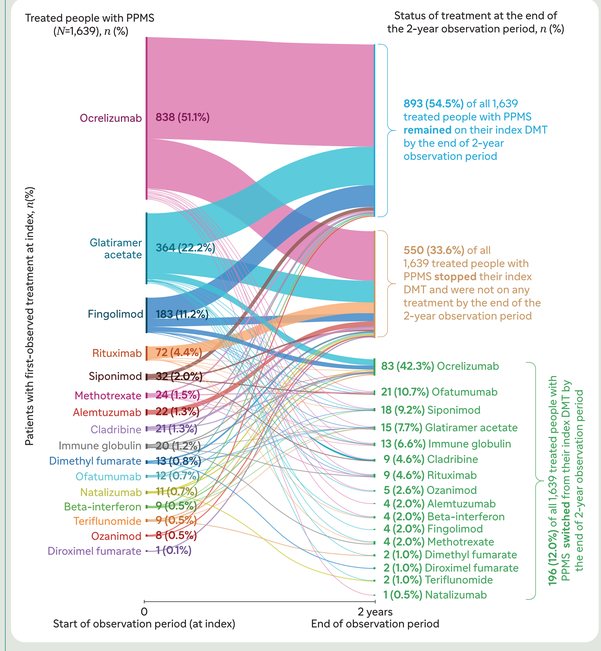


Data presented as the mean cost. [a]Includes outpatient hospital, laboratory, home care, and telehealth; these services constitute approximately 90% of other outpatient services. [b]Costs of medical claims with a diagnosis of infections in any field plus the costs of antibiotics or antivirals pharmacy claims with days of supply <21 days filled within 7 days of an infection medical claim.
ED, emergency department; PPMS, primary progressive multiple sclerosis.

Treatment patterns

- At index (*N*=3,131), 50.3% (*n*=1,577) of people with PPMS were treated with DMT and 49.6% (*n*=1,554) were not treated with any DMT
- The top three most commonly reported DMTs by the end of 2-year observation period were ocrelizumab (28.9%; *n*=923), glatiramer acetate (11.9%; *n*=379), and fingolimod (5.9%; *n*=187)
- Among treated PPMS population (*N*=1,639), 54.5% (*n*=893) remained on their index DMT through end of 2-year observation period, 33.6% (*n*=550) stopped DMT treatment, and 12.0% (*n*=196) switched DMTs by the end of 2-year observation period (**Figure 6**)

Figure 6: Treatment patterns in people with PPMS



Data presented as *n* (%) unless otherwise specified. *N* is the total study population. *n* is the subset of people with PPMS.
DMT, disease-modifying therapy; PPMS, primary progressive multiple sclerosis.

LIMITATIONS

- People with PPMS may have been potentially misclassified, influencing patient identification and associated outcomes
- Additionally, the findings may not be generalizable to populations beyond those with commercial insurance coverage, such as uninsured individuals and adults aged 65 years or older

CONCLUSIONS

- Overall, people with PPMS experienced substantial clinical and economic burden, characterized by high comorbidity rates, increased HCRU and HCCs, and low treatment rates, highlighting an unmet need in this population with only one approved DMT in the US

Disclosures
Nupur Greene: Employee of Sanofi and may hold stocks or stock options in the company.
Ashis K. Das, Eunice Chang, Marian H. Tarbox and **Michael S. Broder**: At the time the study was conducted, employees of PHAR (now a part of ADVI Health), which was paid by Sanofi to conduct the research described in this abstract. PHAR also discloses financial relationships with the following commercial entities outside of the submitted work: Akcea, Amgen, Celgene, Delfi Diagnostics, Dompe, Exact Sciences Corporation, Genentech, Gilead, GRAIL, Greenwich Biosciences, Ionis, Nobelpharma, Novartis, Pardes, Prothena, Pfizer, Recordati, Regeneron, Sanofi US Services, and Sunovion.

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