# Estimated Prevalence of First-Dose Cardiac Observation in Patients Taking Ponesimod

**David M Kern,[1] Hoa H Le,[2] Maria Ait-Tihyaty,[3] Alexander Keenan[2*]**

[1]Janssen Research & Development, LLC, Titusville, NJ; [2]Janssen Scientific Affairs, LLC, Titusville, NJ; [3]Janseen Global Medical Affairs, LLC, Titusville, NJ.

*Presenting Author

## INTRODUCTION

- Ponesimod is an orally active, selective sphingosine-1-phosphate (S1P1) receptor modulator that induces rapid, dose-dependent, and reversible reductions in peripheral blood lymphocyte count by preventing the lymphocyte egress from lymphoid organs[1]
- Upon initiation of ponesimod, first-dose 4-hour monitoring is recommended in the US prescribing information for patients with Relapsing Multiple Sclerosis (RMS) with sinus bradycardia (heart rate <55 beats per minute), first- or second-degree atrioventricular (AV) block, a history of myocardial infarction (MI), or heart failure (HF)[2]
- A robust evaluation of the expected percent of patients in real world clinical practice who are recommended for first dose 4-hour monitoring prior to starting ponesimod is unknown

## OBJECTIVE

- This study aimed to estimate the prevalence of patients in the real-world, using 4 insurance claims databases, who have conditions where first-dose 4-hour monitoring upon initiating ponesimod is recommended

## METHODS

- This retrospective cohort study utilized real-world claims data from 4 US-based administrative claims databases:
  - IBM® MarketScan® Commercial (CCAE)
  - IBM MarketScan Medicare Supplemental (MDCR)
  - IBM MarketScan Multi-State Medicaid (MDCD)
  - Optum Clinformatics® Data Mart Database

### Eligibility criteria

- Diagnoses of MS (ICD-10-CM code G35*) between October 1, 2016 and the most recent available date
- Two diagnoses of MS with unique calendar dates within 365 days of each other or an inpatient hospitalization visit with a diagnosis of MS. The most recent is considered the index date
- At least 365 days of observation in the database prior to the index date to allow for the capture of diagnosed conditions

### Subset analysis: Patients with MS and with no ponesimod contraindications

- Patients with MS with any evidence of conditions that are contraindications of ponesimod, and thus making the patient ineligible to receive the medication, were excluded:
  - MI in the past 6 months
  - Unstable angina in the past 6 months
  - Stroke or transient ischemic attack in the past 6 months
  - Hospitalization for HF in the past 6 months
  - Second- or third-degree AV block, sick sinus syndrome, or sinoatrial block diagnosis in the past year with no evidence of a pacemaker

*Note: there is no code specific to relapsing forms of MS (RMS), and no valid algorithm exists to identify these patients accurately. Therefore, all MS patients were included, not just the subset with RMS.

### Data analysis

- The analysis estimates the prevalence of any conditions that are recommended for first-dose cardiac monitoring:
  - HF any time prior (including index date)
  - Bradycardia in past 365 days (including index date)
  - MI any time prior (including index date)
  - AV block in past 365 days (including index date)
- Patients could fall into more than one category and be counted in those categories. Proportion of patients with any condition that are recommended for first-dose cardiac monitoring was calculated as (number of patients with MS with at least one condition)/(number of patients with MS) for two cohorts: (1) all patients with MS and (2) only patients without contraindications for ponesimod
- Descriptive statistics were used to analyze data

## RESULTS

### Study cohort

- The majority of the patients in each cohort were females. The mean age of patients was nearly 50 years in CCAE and MDCD, 57 years in Optum, and 71 years in MDCR

**Table 1: Cohort attrition and demographics for each database**

| | IBM CCAE | | IBM MDCR | | IBM MDCD | | Optum SES | |
|---|---|---|---|---|---|---|---|---|
| | N | % Remain | N | % Remain | N | % Remain | N | % Remain |
| MS diagnoses on or after 1 Oct 2016 | 72,258 | | 7372 | | 28,435 | | 80,113 | |
| ≥1-year prior observation time (all patients with MS) | 55,994 | 77.5% | 6065 | 82.3% | 24,629 | 86.6% | 58,011 | 72.5% |
| No contraindications | 53,889 | 96.2% | 5194 | 85.6% | 22,101 | 89.7% | 52,999 | 90.7% |
| **Demographics** | N=53,889 | | N=5194 | | N=22,101 | | N=52,999 | |
| Gender, female, n (%) | 41,088 | 76.2% | 3862 | 74.3% | 17,339 | 78.4% | 39,851 | 75.8% |
| Mean age (SD), years | 48.4 (11.0) | | 71.1 (7.6) | | 49.5 (14.2) | | 56.6 (14.0) | |

IBM CCAE, IBM® MarketScan® Commercial; IBM MDCD, IBM MarketScan Medicare Supplemental; IBM MDCR, IBM MarketScan Multi-State Medicaid; MS, multiple sclerosis; Optum SES, Optum Clinformatics® Data Mart Database.

### All patients with MS

- In the commercial insurance database (CCAE), 9.0% of patients had conditions requiring first-dose 4-hour monitoring. The prevalence was higher in other databases, in which patients were generally older in age and/or had disabilities

**Table 2: Prevalence of conditions recommended for first-dose monitoring prior to starting ponesimod for all patients with MS**

| | IBM CCAE N = 55,994 | | IBM MDCR N = 6065 | | IBM MDCD N = 24,629 | | Optum SES N = 58,011 | |
|---|---|---|---|---|---|---|---|---|
| | n | % Remain | n | % Remain | n | % Remain | n | % Remain |
| Any condition | 5043 | 9.0% | 1909 | 31.5% | 6650 | 27.0% | 11,617 | 20.0% |
| HF any time prior | 1754 | 3.1% | 1186 | 19.6% | 4022 | 16.3% | 6294 | 10.8% |
| MI any time prior | 1217 | 2.2% | 645 | 10.6% | 2238 | 9.1% | 3816 | 6.6% |
| Bradycardia in prior year | 2765 | 4.9% | 733 | 12.1% | 2445 | 9.9% | 5117 | 8.8% |
| AV block in prior year | 139 | 0.2% | 136 | 2.2% | 209 | 0.8% | 680 | 1.2% |

Note: Sums of prevalence of individual conditions are higher than the overall prevalence due to patients being diagnosed with more than one condition requiring first-dose monitoring.

AV, atrioventricular; HF, heart failure; IBM CCAE, IBM® MarketScan® Commercial; IBM MDCD, IBM MarketScan Medicare Supplemental; IBM MDCR, IBM MarketScan Multi-State Medicaid; MS, multiple sclerosis; MI, myocardial infarction; Optum SES, Optum Clinformatics® Data Mart Database.

### Patients with MS and with no contraindication for ponesimod

- In the commercial insurance database (CCAE), 7.6% had conditions requiring first-dose 4-hour monitoring (HF, 2.4%; MI, 1.5%; bradycardia, 4.4%; AV block, 0.2%)
- In databases of non-commercial patients (MDCD) and older populations (MDCR, Optum), the prevalence of patients with no contraindications requiring first-dose 4-hour monitoring was higher (Optum, 14.8%; MDCD, 21.9%; MDCR, 24.3%)

**Table 3: Prevalence of conditions recommended for first-dose monitoring prior to starting ponesimod for patients with no contraindication for ponesimod**

| | IBM CCAE N = 53,889 | | IBM MDCR N = 5194 | | IBM MDCD N = 22,101 | | Optum SES N = 52,999 | |
|---|---|---|---|---|---|---|---|---|
| | n | % Remain | n | % Remain | n | % Remain | n | % Remain |
| Any condition | 4082 | 7.6% | 1263 | 24.3% | 4841 | 21.9% | 7775 | 14.8% |
| HF | 1277 | 2.4% | 691 | 13.3% | 2662 | 12.0% | 3569 | 6.8% |
| MI any time prior | 826 | 1.5% | 373 | 7.2% | 1377 | 6.2% | 2091 | 4.0% |
| Bradycardia in prior year | 2355 | 4.4% | 480 | 9.2% | 1838 | 8.3% | 3520 | 6.7% |
| AV block in prior year | 91 | 0.2% | 70 | 1.3% | 121 | 0.5% | 343 | 0.7% |

Note: Sums of prevalence of individual conditions are higher than the overall prevalence due to patients being diagnosed with more than one condition requiring first-dose monitoring.

AV, atrioventricular; HF, heart failure; IBM CCAE, IBM® MarketScan® Commercial; IBM MDCD, IBM MarketScan Medicare Supplemental; IBM MDCR, IBM MarketScan Multi-State Medicaid; MI, myocardial infarction; Optum SES, Optum Clinformatics® Data Mart Database.

## LIMITATIONS

- Administrative claims data are primarily used for reimbursement purposes and lack clinical detail
- Heart rate measurements were not available
- The IBM CCAE and Optum databases consist of commercially insured individuals and should only be generalized to a similar population
- The IBM MDCR and Optum databases include patients who receive supplementary Medicare coverage (i.e., additional, purchased coverage), which may not be generalizable to the overall Medicare population

## CONCLUSIONS

- Findings indicate that >90% of commercially-insured patients will not require first-dose 4-hour monitoring for treatment with ponesimod
- First-dose monitoring was more common in non-commercially insured and Medicare eligible populations

**References**

1. D'Ambrosio D et al. *Ther Adv Chronic Dis*. 2016;7(1):18-33.
2. PONVORY™ (Ponesimod). Tablets. 04/2021. Janssen Pharmaceutical Inc.; Titusville, NJ.

**Disclosures**

DMK is an employee of Janssen Research & Development, LLC, and holds stock in Johnson & Johnson. HHL and AK are employees of Janssen Scientific Affairs, LLC, and hold stock in Johnson & Johnson. MAT is an employee of Janssen Global Medical Affairs, LLC, and holds stock in Johnson & Johnson.

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