Budget Impact Analysis of Ponesimod for Relapsing Multiple Sclerosis in the United States

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BACKGROUND

- Relapsing multiple sclerosis (RMS) induces significant burden on societal health care–associated costs[1]
- Ponesimod is a sphingosine-1-phosphate receptor modulator that was approved by the US Food and Drug Administration for the treatment of RMS in March 2021[2]
  - In a phase 3 trial against teriflunomide, ponesimod was shown to significantly reduce the primary efficacy endpoint, annualized relapse rate, by 30.5% (P <0.001). Ponesimod also was associated with a 56% relative risk reduction in combined unique active lesions per year (P <0.001)[3]
  - Ponesimod also displayed rapid elimination,[4] reversible reduction in lymphocyte counts,[5] low potential for drug-drug interactions,[6] and overall ease of use[7]
- Budget impact analysis (BIA), which is increasingly required for drug formulary approval or reimbursement,[8] can estimate the budgetary impact of adding ponesimod into the current, crowded multiple sclerosis treatment space

OBJECTIVE

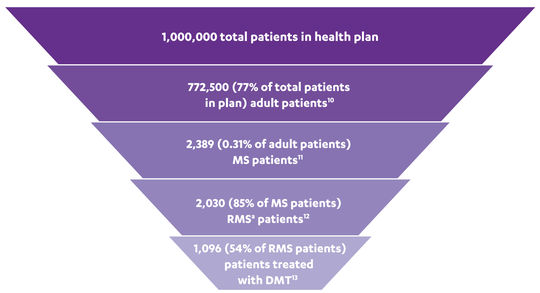
- A population-based BIA was developed to inform health care decision makers. This analysis estimated the budgetary impact of adding ponesimod to a formulary list by assessing the drug acquisition and administration costs of all disease-modifying therapies (DMTs) for RMS currently on the market

METHODS

Study Design

- An interactive BIA was developed in Excel that reflected a third-party payer perspective in the United States within a 3-year time horizon
  - Key steps included in the BIA[8,9]:
    1. Estimate the treatment-eligible population
    2. Select a time horizon
    3. Identify two market scenarios, current (without ponesimod) and new (with ponesimod)
    4. Estimate drug and administrative costs and changes in the annual budget
- Epidemiologic data were used to calculate the proportion of patients in a hypothetical health plan who are eligible for treatment with ponesimod (**Figure 1**)
  - For a health plan with 1 million members, the treatment-eligible population of patients with RMS was estimated to be 1,096 patients each year
- The time horizon was 3 years, from 2021 to 2023

Figure 1. Number of patients estimated to be eligible for treatment based on a sample population size of 1 million.



MS, multiple sclerosis; RMS, relapsing multiple sclerosis; DMT, disease-modifying therapy; PPMS, primary progressive multiple sclerosis.
[a]Assumed RMS = MS – PPMS.

Market Scenarios

- Market scenarios were based on projections of trends observed in Symphony Health Solutions data[14] from 2016 to 2019 (**Table 1**)
- The analysis evaluates 2 scenarios: 1) current market scenario without ponesimod on the market; and 2) new market scenario with ponesimod on the market
- The expected share uptakes for ponesimod are 1.0%, 2.5%, and 4.0% for the years 2021, 2022, and 2023, respectively

Table 1. Market Scenarios[a] Without and With Ponesimod

	Current market scenario (without ponesimod), %			New market scenario (with ponesimod), %		
	Year			Year		
DMT	2021	2022	2023	2021	2022	2023
Ponesimod	0	0	0	1.0	2.5	4.0
Pegylated interferon-beta–1a	0.7	0.4	0.3	0.7	0.4	0.3
Interferon-beta–1a	6.3	4.8	3.9	6.2	4.7	3.7
Interferon-beta–1b	0.6	0.4	0.3	0.6	0.4	0.3
Glatiramer acetate	12.4	9.8	8.3	12.3	9.6	8.0
Fingolimod	7.3	5.9	4.1	7.2	5.8	3.9
Siponimod	2.8	3.6	4.0	2.8	3.5	3.8
Ozanimod	1.7	2.5	2.9	1.7	2.4	2.8
Teriflunomide	6.2	4.9	4.5	6.1	4.8	4.3
Dimethyl fumarate	17.0	14.2	12.8	16.8	13.8	12.3
Monomethyl fumarate	0	0	0	0	0	0
Diroximel fumarate	5.8	7.5	8.3	5.7	7.3	8.0
Cladribine	1.3	1.7	2.0	1.3	1.7	1.9
Alemtuzumab	0.1	0.1	0.1	0.1	0.1	0.1
Natalizumab	8.0	7.1	6.6	7.9	6.9	6.3
Ocrelizumab	19.5	18.8	19.4	19.3	18.3	18.6
Ofatumumab	10.4	18.3	22.6	10.3	17.8	21.7
Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

DMT, disease-modifying therapy.
[a]Percentages indicate market share for each DMT and may not add up to 100.0% due to rounding.

- The base-case assumption was that ponesimod captures shares proportionally weighted to other DMT shares
  - The number of patients on each DMT was calculated as the product of the treatment-eligible population size and the market shares of each DMT
- Total annual per member per month (PMPM) and administrative costs were reported

Drug Acquisition and Administration Costs

- Annualized drug acquisition costs were calculated for each DMT based on US Prescribing Information and wholesale acquisition cost prices (**Table 2**)

Table 2. Annual Drug Acquisition Cost for Each DMT

DMT	Annual drug acquisition cost ($)
Ponesimod[a]	98,417
Pegylated interferon-beta–1a	93,994
Interferon-beta–1a	103,786
Interferon-beta–1b	81,122
Glatiramer acetate[b]	52,438
Fingolimod	110,736
Siponimod	97,566
Ozanimod	89,931
Teriflunomide	98,121
Dimethyl fumarate	100,759
Monomethyl fumarate	69,818
Diroximel fumarate	90,705
Cladribine[c]	80,495
Alemtuzumab[d]	92,585
Natalizumab	97,365
Ocrelizumab	66,950
Ofatumumab	103,750

DMT, disease-modifying therapy.
[a]Current pricing assumption for ponesimod.
[b]Assumed 50% Copaxone® and 50% Glatopa®.
[c]Assumed a mean weight of 70 kg, and an average annual cost was calculated based on a 3-year period.
[d]An average annual cost was calculated based on a 3-year period.

- Administrative costs were estimated based on the following assumptions (**Table 3**):
  - Cost for the first hour of intravenous (IV) drug administration: $72.18[15]
  - Cost for ≥2 hours of IV drug administration: $22.01[15]
  - Hourly cost for a nurse: $37.24[16]

Table 3. Annual Administrative Costs for Injectable/Infusion DMTs

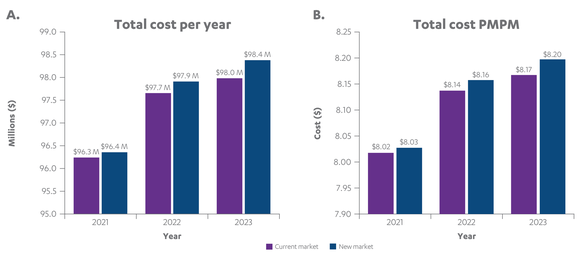
DMT	Cost	Notes
Interferons and glatiramer acetate	$62.07	Taught by a nurse (3 hours of day nurse's time) and self-administered for the first year. In subsequent years, continuing issues required 1 hour of nurse's time per year. Administrative information for interferons was assumed to be the same as that of glatiramer acetate[17]
Alemtuzumab	$506.77	Five 4-hour infusions in the first year and three 4-hour infusions in subsequent years[18]
Natalizumab	$938.34	Thirteen (every 4 weeks) 1-hour infusions[18]
Ocrelizumab	$312.85	Two 2.5-hour infusions and one 3.5-hour infusion in the first year and 2.17 infusions of 4 hours in subsequent years[18]

DMT, disease-modifying therapy.

RESULTS

- Given projected uptakes of 1.0% (11 patients), 2.5% (27 patients), and 4.0% (44 patients), adding ponesimod increased total annual costs from $96,270,677 to $96,386,964 in 2021, from $97,687,596 to $97,942,891 in 2022, and from $98,011,264 to $98,406,790 in 2023 (**Figure 2**; **Table 4**)
  - These values translated to PMPM increases of $0.01 in 2021, $0.02 in 2022, and $0.03 in 2023 (**Table 5**)
- Drug acquisition costs accounted for almost all of the total annual cost; administrative costs only accounted for 0.14% to 0.17% of costs
  - Because ponesimod displaced injectable/infusion DMTs (**Table 3**), administrative costs decreased

Figure 2. (A) Total cost per year and (B) total cost PMPM in market scenarios.



PMPM, per member per month.

Table 4. Total Annual Costs in Current and New Market Scenarios

	Current market scenario (without ponesimod)			New market scenario (with ponesimod)		
	Year			Year		
	2021	2022	2023	2021	2022	2023
Total cost per year ($)	96,270,677	97,687,596	98,011,264	96,386,964	97,942,891	98,406,790
Drug acquisition cost	96,107,547	97,539,305	97,867,999	96,225,465	97,798,308	98,269,255
Administrative cost	163,130	148,291	143,265	161,499	144,583	137,535
Total cost PMPM ($)	8.02	8.14	8.17	8.03	8.16	8.20

PMPM, per member per month.

Table 5. Ponesimod Budget Impact

	Year		
	2021	2022	2023
Impact on total annual treatment cost ($)	116,287	255,295	395,526
Drug acquisition cost	117,919	259,003	401,256
Administrative cost	–1,631	–3,707	–5,731
Impact on PMPM cost ($)	0.01	0.02	0.03

PMPM, per member per month.

LIMITATIONS

- Model inputs are uncertain and can greatly impact the results of a BIA
  - Projections of current trends for market shares are inherently uncertain, although estimations pass face-validity based on current market trends

CONCLUSIONS

- Because of high disease variability, patients with RMS can benefit from access to the full range of treatment options
- The addition of ponesimod to a formulary list was estimated to have only a minimal impact on the annual budget of a commercial health plan
  - This was due, in part, to the modest projected uptake of ponesimod into a market that includes many DMT options with similar price ranges

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DISCLOSURES

Hoa H. Le is an employee of Janssen Scientific Affairs, LLC and a shareholder of Johnson & Johnson, Inc.

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