Poster #EE602

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OPTIMIZING THERAPEUTIC STRATEGIES FOR MULTIPLE SCLEROSIS IN ITALY: A BUDGET IMPACT ANALYSIS

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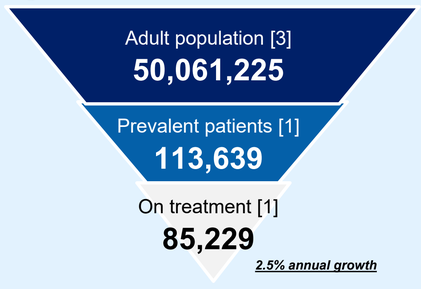
INTRODUCTION

- Multiple sclerosis (MS) places a considerable burden on both patients and the Italian National Health Service (NHS).
- In Italy, a prevalence of ≈137,000 individuals with MS has been estimated with an incidence of 3,600 new cases each year [1].
- The average annual cost per patient suffering from MS is estimated in € 45,000 for a total annual expenditure of € 6 billion [2].
- This analysis aims to explore the potential economic and clinical impact of optimizing the use of currently available therapies in the Italian setting over a three-year time horizon.

METHODS

- **Target population** Target patients were estimated starting from the Italian population and applying national epidemiological data considering prevalent patients and patients on treatment. A 2.5% annual increase was assumed (Figure 1).

Figure 1. Patient funnel



- **Model structure** The model compares the current treatment landscape (Table 1) with a more efficient scenario ("alternative scenario") involving increased use of ofatumumab (about 5% every year at the expense of ocrelizumab, natalizumab and cladribine), and generics/biosimilars (about 30% every year at the expense of their respective brands).

Table 1. From current scenario to alternative scenario: market shares

Treatments	Current scenario				Alternative scenario		
	Year 1	Year 2	Year 3		Year 1	Year 2	Year 3
Ofatumumab#	**10.5%**	**14.9%**	**15.5%**	+5%	**15.5%**	**19.8%**	**20.6%**
Ocrelizumab	16.4%	17.4%	18.3%		13.9%	15.0%	15.8%
Alemtuzumab	0.1%	0.0%	0.0%		0.1%	0.0%	0.0%
Cladribine	4.6%	4.6%	4.6%		4.1%	4.1%	4.1%
Natalizumab IV	**7.1%**	**4.0%**	**2.0%**		**3.5%**	**1.7%**	**0.6%**
Natalizumab SC	**1.2%**	**2.0%**	**2.5%**		**0.6%**	**0.9%**	**0.8%**
Natalizumab bio§	**2.4%**	**3.1%**	**4.5%**		**4.5%**	**4.6%**	**5.6%**
Fingolimod	**6.2%**	**4.4%**	**2.7%**	+30%	**3.5%**	**1.9%**	**0.8%**
Fingolimod gx§	**1.2%**	**1.9%**	**4.0%**		**3.9%**	**4.4%**	**5.9%**
Teriflunomide	**4.0%**	**3.8%**	**3.0%**		**4.8%**	**3.7%**	**1.5%**
Teriflunomide gx§	**6.0%**	**8.1%**	**9.4%**		**5.3%**	**8.2%**	**10.9%**
Dimetilfumarato	**17.0%**	**12.0%**	**8.0%**		**8.4%**	**4.6%**	**1.6%**
Dimetilfumarato gx§	**0.7%**	**3.0%**	**5.5%**		**9.3%**	**10.4%**	**11.9%**
Ponesimod	1.1%	1.0%	1.0%		1.1%	1.0%	1.0%
Ozanimod	3.6%	3.0%	3.0%		3.6%	3.0%	3.0%
Siponimod	3.9%	3.8%	3.0%		3.9%	3.8%	3.0%
Ublituximab	4.0%	6.0%	9.0%		4.0%	6.0%	9.0%
Others	10.0%	7.0%	4.0%		10.0%	7.0%	4.0%

Abbreviations: bio, biosimilar; gx, generic; IV, intravenous; SC, subcutaneous.
 # ofatumumab market increases at the expense of ocrelizumab (-50%), natalizumab (-10%) and cladribine (-40%).
§ Starting from the current market, yearly percentages of gx/bio were estimated by summing up gx/bio shares only and dividing them by the sum of gx/bio and brands together (grey background cells). In the alternative scenario, such proportions were increased by 30% every year and were used to redistribute each treatment between brand and gx/bio (red background cells).

- **Economic inputs** The analysis included drug acquisition and administration costs, as well as expenses related to monitoring and managing adverse events from the Italian National Health Service (NHS) perspective:
  i. Drug prices were valued using ex-factory prices net of mandatory legal discounts [4].
  ii. Administration costs were sourced from regional tariffs equal to € 205.00 for intravenous (IV) administration and € 135.00 for the subcutaneous (SC) one [5, 6].
  iii. Monitoring costs were computed as an average yearly cost for each item weighting: the cost as per the latest current Italian tariffs, the percentage of patients undergoing monitoring and the annual frequency of such events [7, 8].
  iv. Adverse events (AEs) were sourced from published clinical trials and divided into severe and non-severe ones. Severe AEs were estimated in € 1,419.00 (Diagnosis-Related-Group 13) [9], while non-severe ones were valued with the cost of a specialist visit.

RESULTS

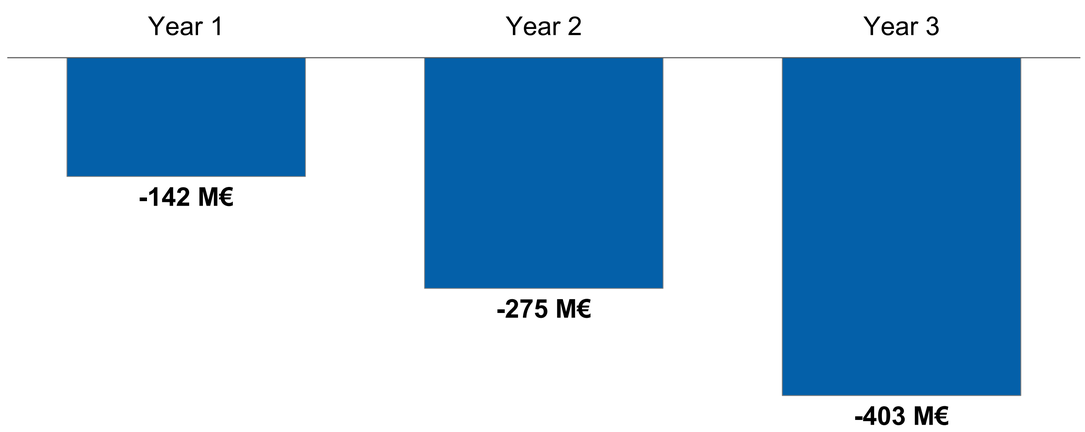
- Over a three-year time horizon, under the current scenario, the total costs for the NHS were estimated in € 4.15 billions (with drug costs accounting for 95.3% of the total).
- The alternative scenario accounted instead for € 3.7 billions with more than 95% of the cost given by drugs acquisition (Table 2).

Table 2. Budget Impact (BI) results

	Current Scenario (A)	Alternative scenario (B)	BI (B-A)	% change
Drugs	€ 3,921,069,672	€ 3,539,487,446	-€ 381,582,226	-9.73%
Administration and monitoring	€ 163,325,618	€ 142,442,950	-€ 20,882,668	-12.79%
Adverse events	€ 30,988,422	€ 30,434,859	-€ 553,563	-1.79%
Total	**€ 4,115,383,711**	**€ 3,712,365,254**	**-€ 403,018,457**	**-9.79%**

- The potential optimization, introduced in the alternative scenario for patients with MS, resulted in savings of about 4 million Euros (-9.79% with respect to the current scenario): €382 million in drug acquisition (-9.73%), and €21 million for administration, monitoring, and managing adverse events (-14.57%) (Table 2, Figure 3).

Figure 3. Cumulative BI



- Such savings could allow an additional 6,613 patients per year to potentially access high-efficacy therapies (ofatumumab, ocrelizumab, natalizumab, ublituximab) or an additional 7,262 to access ofatumumab only.

Key findings & Conclusions

- The alternative MS treatment scenario, which involves increased use of ofatumumab and generics/biosimilars, projects € 403 million in total cost savings over three years for the Italian NHS.
- This strategy is also associated with improved allocative efficiency by significantly reducing the total administration time for patients and healthcare facilities.

Allocative efficiency analysis

- Starting from the BI model results, an additional analysis exploring the allocative efficiency of the alternative scenario has been calculated in terms of time saved due to therapeutic strategy optimization.
- In-hospital administration times, divided between IV and SC administration routes, were obtained from Filippi et al. 2024 [10] (Table 3). The analysis included the evaluation of patient's length of stay in the MS center for the administration, the evaluation of the active working time of healthcare professionals (HCPs), and the evaluation of time of durable equipment use (e.g., chair).
- For home treatments (i.e., oral therapy and SC home administration of ofatumumab) no time was considered

Table 3. Mean administration times per patient

Variable	IV	SC
Time spent in outpatient setting	152 minutes	78 minutes
Chair time	125 minutes	51 minutes
HCP time	30 minutes	10 minutes

- Total times were calculated by applying the inputs above to the number of target patients estimated over the three years and distributed among available treatments in the two analyzed scenarios.
- Over a three-year time horizon, the alternative scenario could allow in this analysis an increase in home treatments in almost 5% (Figure 4).
- Similarly, the total administration time could drop down to about 15% for each variable considered (Figure 5).

Figure 4. Home treatment percentage

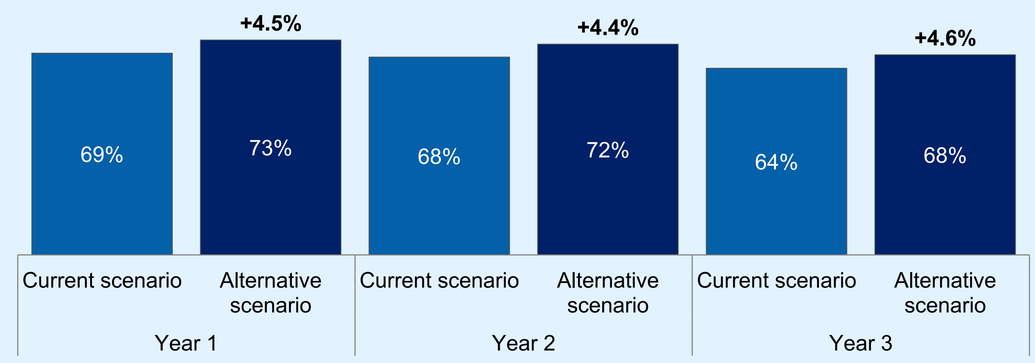
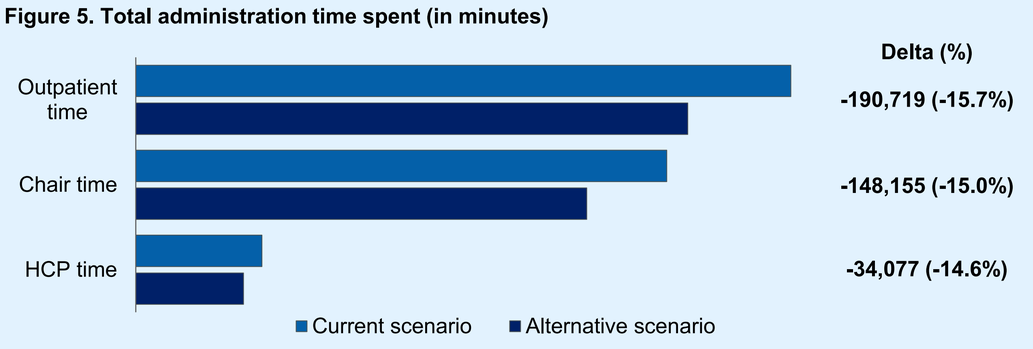


Figure 5. Total administration time spent (in minutes)



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ISPOR Glasgow 2025

Acknowledgements This analysis was funded by Novartis SpA, Italy.