EE107

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PONESIMOD INDICATED FOR PATIENTS WITH ACTIVE RELAPSING FORMS OF MULTIPLE SCLEROSIS: A BUDGET IMPACT ANALYSIS FROM THE ITALIAN NATIONAL AND REGIONAL HEALTH CARE SERVICE PERSPECTIVE

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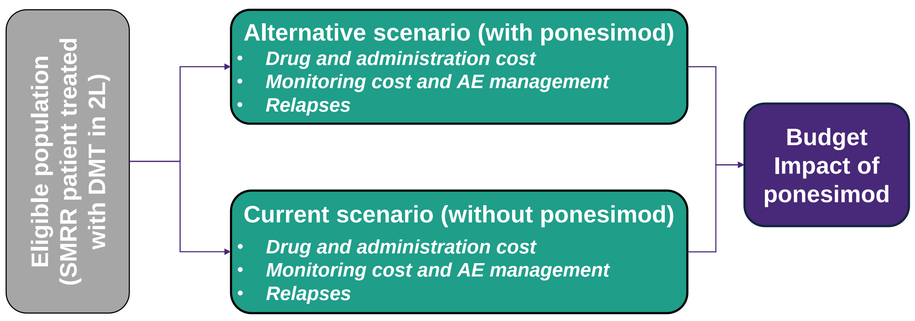
Objective

- Multiple sclerosis (MS) is a chronic, progressive neurological disease characterized by localized inflammation, demyelination, and axonal degeneration. Relapsing-remitting (RR)MS is the most common form with 80-85% of cases diagnosed [1].
- Ponesimod is an oral disease modifying therapy (DMT) that was recently reimbursed in Italy as second line treatment (2L) for RRMS.
- This analysis assesses the budget impact of switching Italian patients currently receiving any DMT to ponesimod.

Methods

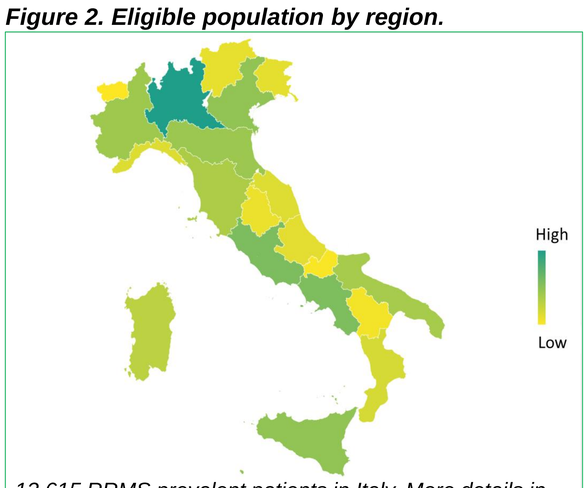
- A budget impact model was developed to compare expected costs in a scenario that considers ponesimod as a 2L treatment option of RRMS reimbursed by the Italian National and Regional Health Service (NHS) and a scenario in which ponesimod is not available yet (***Figure 1***).

Figure 1. Model structure



- Eligible patient population was identified using Italian-specific epidemiological data (***Figure 2***) [1,2]. Market share switching rates for various DMTs, displayed in ***Table 1***, came from an Italian survey of 260 MS treating neurologists [3].
- Unit costs of DMTs, adverse event (AE) management and cost of relapses, reported in Euro-2022, were collected from published literature [7,8] and institutional Italian data [4-6]. For drugs, ex-factory price net of mandatory discounts was considered [4] (***Table 2***).
- Natural history of relapse rates for RRMS and rate ratios for each DMT, applied to the average natural history relapse rates, came from published literature [12,13].

Figure 2. Eligible population by region.



13,615 RRMS prevalent patients in Italy. More details in Figure A1 of supplementary material on-line.

Table 1. Market shares in current and alternative scenarios

Treatment	Current scenario			Alternative scenario		
	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Ponesimod				1.0%	5.2%	8.6%
Alemtuzumab	8.1%	8.4%	8.6%	8.0%	7.9%	7.8%
Cladribine	8.8%	9.1%	9.3%	8.7%	8.6%	8.5%
Dimethyl fumarate	8.5%	7.9%	7.4%	8.4%	7.5%	6.8%
Fingolimod	14.5%	13.5%	12.6%	14.4%	12.8%	11.5%
Glatiramer acetate	3.2%	3.2%	3.1%	3.2%	3.0%	2.9%
Interferone	5.8%	5.4%	5.1%	5.7%	5.1%	4.7%
Siponimod	5.5%	5.7%	5.8%	5.4%	5.4%	5.3%
Ozanimod	2.0%	2.5%	2.9%	2.0%	2.4%	2.7%
Ofatumumab	1.4%	2.1%	2.7%	1.4%	2.0%	2.4%
Ocrelizumab	14.8%	16.1%	17.2%	14.7%	15.3%	15.7%
Teriflunomide	6.4%	6.3%	6.2%	6.3%	5.9%	5.6%
Natalizumab	20.8%	19.9%	19.1%	20.6%	18.8%	17.5%

Table 2. Unit costs (per pack)

Cost item	List price (€)
Ponessimo PO	1039.68
Alemtuzumab IV	7953.29
Cladribine PO	1918.72
Dimethyl fumarate PO (*)	1040.58
Fingolimod PO (*)	1624.50
Glatiramer acetate SC	694.29
Interferon SC/IM (**)	781.70
Siponimod PO	962.31
Ozanimod PO	1138.46
Ofatumumab SC	1233.21
Ocrelizumab IV	5640.63
Teriflunomide PO (*)	927.54
Natalizumab IV	1624.50

(*) An additional reduction was applied to expired patent's drugs. Specific annual uptake of generic was from market research.
(**) Average cost including interferon beta-1a/1b and peginterferon beta-1a

Administration:
The cost of administration of intravenous drugs was taken from MAC Tariff (€205) for administration of infusion therapy for chronic disease [6]. The cost of oral administration was assumed to be zero. However, during the first dose of fingolimod, patients require 6 hours of continuous monitoring, whose cost (€108.46) was approximated based on the all- inclusive tariffs for recommended inpatient and outpatient services (electrocardiogram, general visit and blood pressure control) [4].

Relapse cost:
Relapse cost per event was considered equal to €410 [7].

Monitoring costs and Adverse event management:
Annual frequency of health resources consumption was derived from NICE guidelines [9-11] and unit costs were taken from literature [8] or national DRG tariff [4].

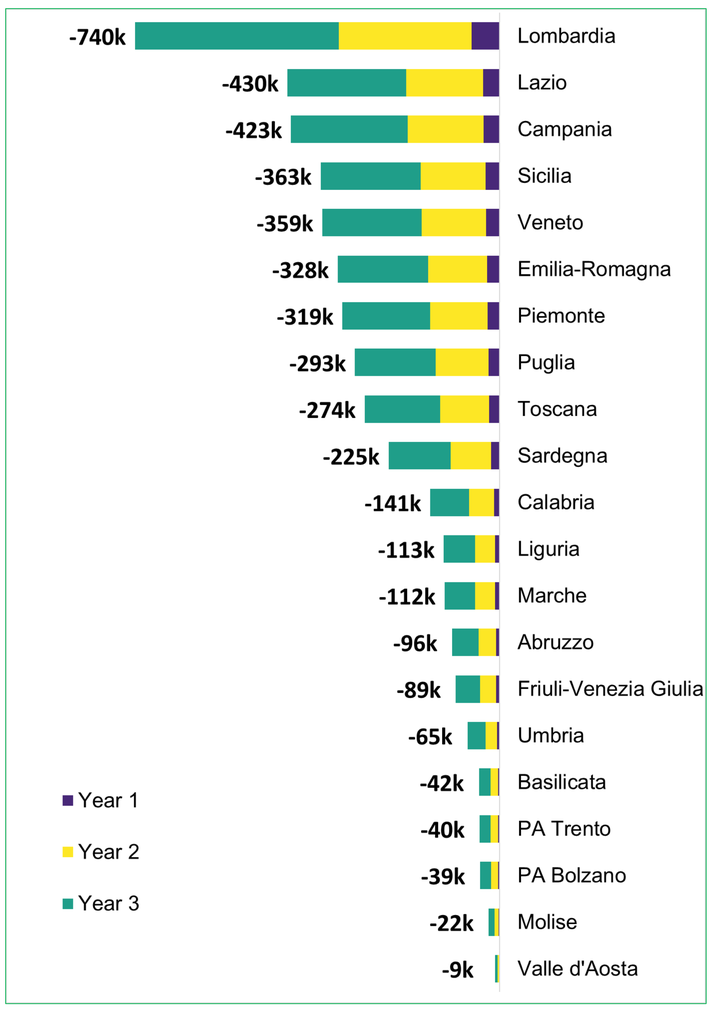
Results

- Approximately **2199** patients are expected to switch to ponesimod in Italy over 3 years (**135**, **762,** and **1302** during year 1, 2, and 3, respectively).
- The total cost of patients treated with ponesimod was estimated at € 30.1 M, of which € 29.8 M for drug acquisition and € 0.3 M for drug administration, AE and relapse management (*more details in Table B1 of supplementary material on-line*).
- The alternative scenario incorporating ponesimod will lead to an overall **NET SAVINGS OF € 4.5M** as compared to a current scenario without ponesimod. This negative budget impact accompanying the introduction of ponesimod is driven by savings from drug acquisition, drug administration, AE management when compared to the current scenario where patients are treated with 2L monoclonal antibodies (mAbs) (***Table 3***).
- ***Figure 3*** shows cumulative cost-savings by region.

Table 3. Estimated costs in the scenarios compared (Italy) *– results in € / 000*

	Current scenario			Alternative scenario			Budget impact		
	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Drug acquisition cost	223,292	225,714	230,640	222,986	224,282	228,467	-306	-1,432	-2,173
Drug administration and monitoring costs	4,898	4,100	4,18	4,855	3,889	3,858	-43	-211	-322
Adverse event costs	375	381	387	373	369	368	-2	-12	-19
Relapse costs	1,544	1,589	1,637	1,547	1,602	1,660	3	13	23
Total costs	**230,109**	**231,784**	**236,882**	**229,760**	**230,142**	**234,353**	**-349**	**-1,642**	**-2,529**

Figure 3. Budget impact by region



a. Cost-saving by region are mainly driven by RRMS prevalence, since costs for resource consumption are comparable among regions.

Conclusions

- The introduction of ponesimod for the treatment of RRMS resulted in estimated **net savings of € 4.5 M** to the Italian NHS over 3-years that was largely driven by cost savings for drug acquisition, drug administration, and AE management versus 2L mAbs.

References

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