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BUDGET IMPACT ANALYSIS OF SUBCUTANEOUS OCRELIZUMAB FOR RELAPSING MULTIPLE SCLEROSIS IN ITALY: A HOSPITAL PERSPECTIVE

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Objective

- Ocrelizumab administered via intravenous infusion (OCR-IV) is an established disease-modifying therapy (DMT) for patients with relapsing multiple sclerosis (RMS)[1,2]. Its biannual dosing supports improved adherence and persistence, which are key to sustained clinical benefit[3,4].
- A subcutaneous formulation of ocrelizumab (OCR-SC) has been developed that reduces administration time while maintaining comparable safety and efficacy[5,6].
- This study assessed the economic impact of OCR-SC for the treatment of RMS within the Italian DMT market from the hospital perspective.

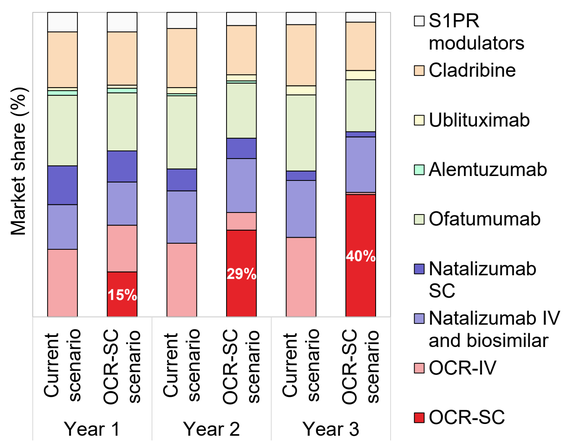
Methods

A **dynamic budget-impact (BI) model** with an underlying **Markov structure** was developed to estimate the **3-year** financial impact of the adoption of OCR-SC on the budget of **Italian hospitals**.

Budget impact

- The model compared a 'current scenario,' in which OCR-SC is not yet available, with an 'OCR-SC scenario,' reflecting the expected changes in the treatment mix after its introduction.
- The **pool of eligible patients** was estimated by application of local epidemiological data to the Italian population (*Table 1*).
- Eligible patients were allocated to DMTs based on **projected market shares** (*Figure 1*).

Figure 1 – Market share: current vs. OCR-SC scenario



S1PR modulators: fingolimod and biosimilar, ozanimod, ponesimod, siponimod

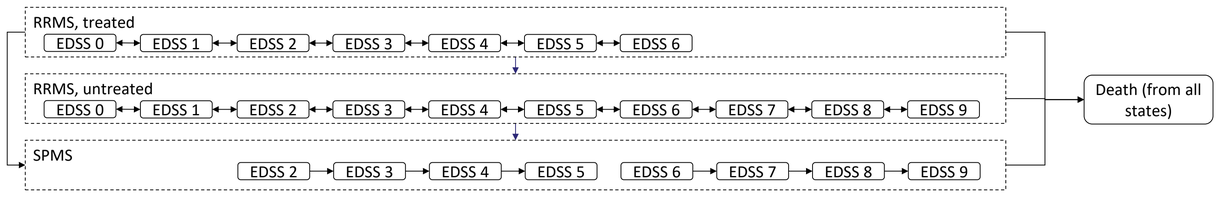
Table 1 – Patient flow

	Value
Adult Italian population	50,170,040[7]
Prevalence	0.227%[8]
Incidence	0.006%[8]
% RRMS	85.0%[8]
% treated patients	72.4%[8]
% prevalent switch	20.0%

Each year, new patients eligible for OCR-SC—both treatment-naive and switcher—were included and followed over the analysis horizon.

Markov model

Figure 2 – Markov model structure



RRMS: relapsing-remitting multiple sclerosis; SPMS: secondary progressive multiple sclerosis; EDSS: expanded disability status scale.

The cohort enters the model distributed across RRMS health states according to OCR-IV trials data[1,2]. In each model 1-year cycle, patients in model can transit between EDSS scores within "RRMS, treated"; discontinue treatment; progress to SPMS (with an EDSS score at least 1 point higher than the last score before conversion to SPMS); or transition to death. SPMS patients can progress to a health state with a higher EDSS score (between 2 and 9), but they cannot regress to a lower EDSS score or return to an SMRR health state. The model considers relapses as events occurring within health states. DMTs included in the model could reduce the disability progression and the relapse rate in RMS patients. The DMTs interruption was assumed when patients developed an EDSS level equal or higher than seven or when they developed SPMS.

- **Natural history probabilities** and **annualized relapse rates** were obtained from MS registries and published literature[9-11], while **relative treatment effects** related to disability progression and relapses were derived from a network meta-analysis[12].
- **Mortality** was estimated from Italian age- and sex-specific life tables, adjusted for EDSS-related MS risk[13,14].
- **Adherence and persistence** come from Italian real-world data (RWD)[3-4]. The impact of non-adherence on relapse rates was estimated from published RWD, which demonstrated that adherent patients had lower risk of having MS relapses than non-adherent patients[15-16].
- **Unit costs,** expressed in 2024 euro, were collected from Italian sources from a **hospital perspective** (*Table 2*). Drug acquisition costs were considered in a scenario analysis.

Table 2 – Cost inputs

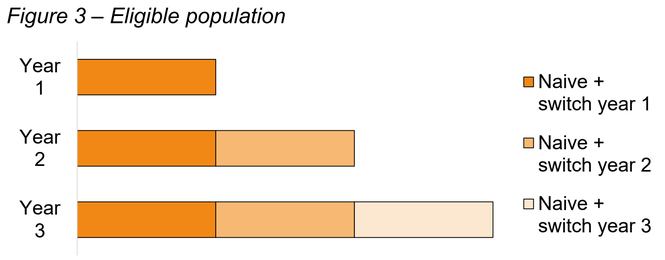
Drug administration (consumable, hospital overheads, healthcare working time)	Estimated from natalizumab IV/SC costs (EASIER time&motion study[17]), adjusted by infusion/post-infusion times recommended by SmPC; premedication included when applicable.*
Treatment monitoring (for each DMT)	Estimated based on healthcare resource consumption, informed by national guidelines, therapeutic monitoring in SmPCs, and the ocrelizumab NICE appraisal[19], with national tariffs applied[20].¥
Disease management (by EDSS level)	Retrieved from an Italian cost-of-illness study[11,22].§
MS relapse	€ 1,638/relapse[23]
Adverse events (AE) management	Estimated by multiplying annual AE incidence, derived from a previous economic evaluation[24], by management costs. Non-serious AE were assumed to be a physician visit[21]. Serious AE were assumed to require hospitalization (€926/day[25]), with average duration from national SDO data[26].
Drug acquisition	Maximum hospital tender price[27].

*Oral administration costs were assumed to be zero, except for the first dose of fingolimod (and other S1PR modulators), which includes ECG and blood pressure monitoring[18]. ¥ For ofatumumab and ublituximab, the same resource use as ocrelizumab was assumed. Specialist visit costs were calculated by valuing healthcare personnel activities, assuming a 30-minute visit.[21] § Including hospitalizations, pharmacological therapies, outpatient visits, and diagnostic exams not associated to DMTs or relapse.

Results

- The **estimated annual eligible patient population** was **15,870** (14,017 prevalent switchers; 1,852 incident treated cases), corresponding to a cumulative total of 47,609 patients over 3 years (*Figure 3*). Of these, 13,251 were treated with OCR-SC.

Figure 3 – Eligible population

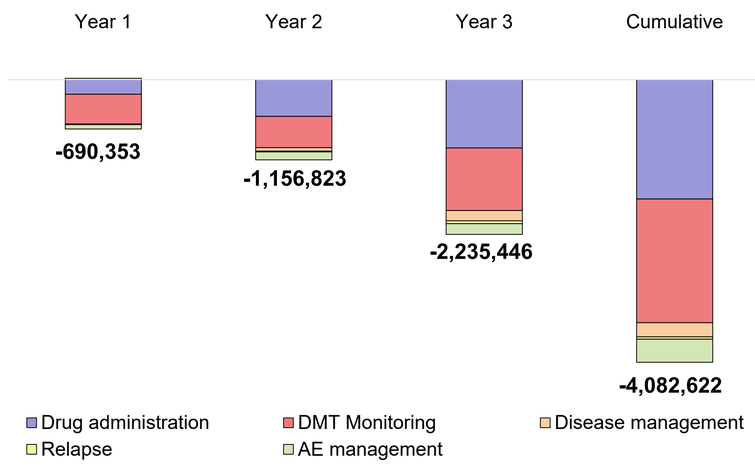


- The **introduction of OCR-SC** led to **cost reduction across all cost categories**, resulting in cumulative savings of up to €2.2 million at the third year for Italian hospitals, driven by the increasing utilization of OCR-SC (*Table 3*, *Figure 4-5*).

Table 3 – BI results: current scenario without OCR-SC vs. OCR-SC scenario

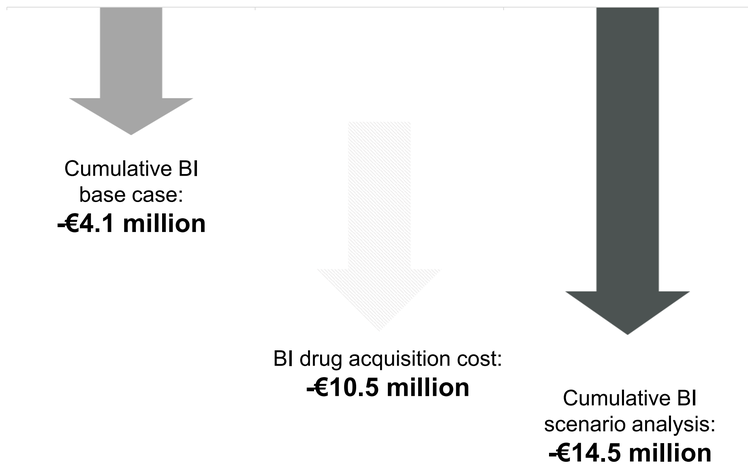
	Year 1	Year 2	Year 3
Current scenario (€)			
Drug administration	1,835,044	3,288,806	4,558,543
DMT Monitoring	6,266,447	8,605,177	11,473,475
Disease management	46,308,650	102,729,454	167,769,061
Relapse	6,841,802	14,408,727	22,439,135
AE management	5,678,043	10,599,887	13,938,401
Total	***66,929,987***	***139,632,051***	***220,178,615***
OCR-SC scenario (€)			
Drug administration	1,626,311	2,758,873	3,574,153
DMT Monitoring	5,835,574	8,153,457	10,568,477
Disease management	46,300,423	102,680,605	167,621,183
Relapse	6,863,344	14,396,017	22,397,193
AE management	5,613,981	10,486,276	13,782,163
Total	***66,239,634***	***138,475,227***	***217,943,169***

Figure 4 – BI (€)



Drug administration costs accounted for 42.2% of the economic impact.

Figure 5 – Base case vs. scenario analysis including drug acquisition costs



When **including drug acquisition costs**, absolute **savings increased** substantially to €14.5 million.

Conclusions

- The **introduction of OCR-SC** in Italy for RMS treatment can help **save hospital resources** by **reducing drug administration time**.
- Additionally, the **enhanced adherence and persistence** associated with ocrelizumab and its **established high efficacy** may help **reduce costs** related to relapses and disease progression.

References

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