

# Budget Impact Analysis of the First-Line Treatments of Relapsing Remitting Multiple Sclerosis in Spain

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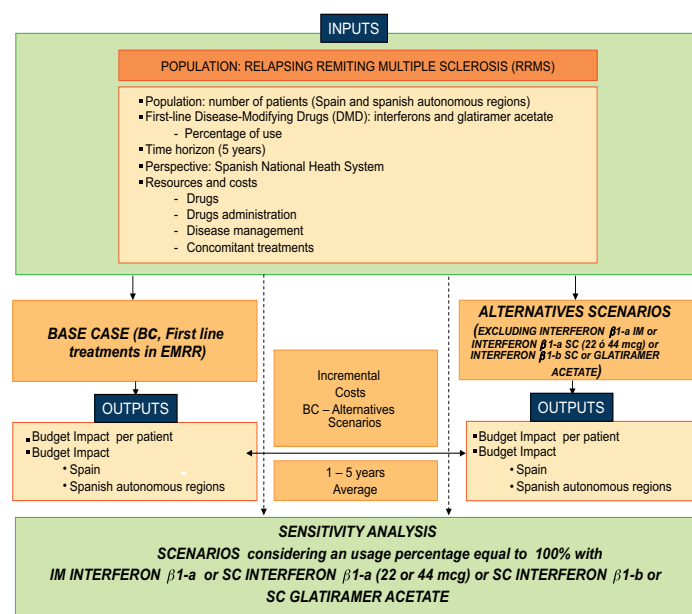
## Introduction

- Multiple Sclerosis (MS) is a chronic neurological disease with a high prevalence among young adults. In Spain it is estimated to affect more than 30 patients per 100,000 inhabitants<sup>(1)</sup>.
- Treatment used as first-line of Relapsing Remitting Multiple Sclerosis (RRMS) therapy are glatiramer acetate and the interferons  $\beta$ -1a and  $\beta$ -1b<sup>(2)</sup>.
- RRMS management imply a high economic burden for the National Health System.

## Methods

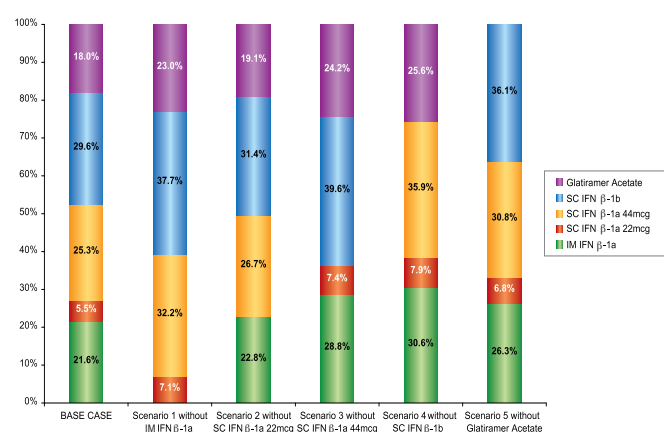
- A budget impact model was designed to compare the cost of RRMS treatment in different settings, using a 5 year time horizon.
- It was considered 22,255 patients with RRMS in the model<sup>(3)</sup>.
- A reference setting of base case using all the available first-line treatments (interferons and glatiramer acetate) was compared with 5 alternatives scenarios excluding each one of these treatments (Figure 1).
- It was considered different percentages of administration of each medication (Figure 2).
- Sensitivity analysis was performed where the usage percentage of each disease modifying drugs (DMD) was set to 100%.

Figure 1. Budget impact model structure



- The cost analysis (€ 2010) includes, direct medical resources:
  - Drug costs, ex-factory prices were considered for the followings DMD packages:
    - Intramuscular interferon  $\beta$ -1a (Avonex<sup>®</sup>) 30 mcg / 0.5 ml, 4 pre-filled syringes. € 835.82

Figure 2. Usage percentage of the DMD considered for each of the scenarios



- Subcutaneous interferon  $\beta$ -1a 22mcg (Rebif<sup>®</sup> 22), 12 syringes of 0.5 ml with 22 mcg (6 MIU) € 778.15
- Subcutaneous interferon  $\beta$ -1a 44mcg (Rebif<sup>®</sup> 44), 12 syringes of 0.5 ml with 44 mcg (6 MIU) € 1,167.21
- Subcutaneous interferon  $\beta$ -1b (Betaferon<sup>®</sup>) 250 mcg / ml, 15 vials + 15 pre-filled syringes € 929.68
- Subcutaneous interferon  $\beta$ -1b (Extavia<sup>®</sup>) 250 mcg / ml 15 vials + 15 pre-filled syringes € 929.68
- Glatiramer Acetate (Copaxone<sup>®</sup>) 20 mg/ml; 28 pre-filled syringes of 1 ml € 781.25
- Administration:
  - For each administration of intramuscular therapies is required an outpatient visit to nursing (€ 16.75).
  - Subcutaneous therapies were considered self-administered but with a previous training with a nurse (€ 11.99)
- Disease management
  - Visits: 4 visits per year
  - Diagnostic procedures per year considered were: 4 hematology, 4 biochemical, 4 liver function tests, 1 Computerized Axial Tomography, 1 Magnetic Resonance, 1 lumbar puncture and 1 cerebrospinal fluid studies, for all the therapies

## Objective

To assess the budget impact of the treatment for Relapsing Remitting Multiple Sclerosis (RRMS), interferons and glatiramer acetate, from the Spanish National Health System (NHS) perspective.

- Concomitant Treatment: Percentage of patients treated with amitriptyline (28.6%), baclofen (48.4%), gabapentin (35.1%), lorazepam (1.5%), methylprednisolone (9.2%), modafinil (37.1%), oxybutynin (15.5%), propranolol (0.4%), sildenafil (0.2%) and tizanidine (12.7%). Was also considered concomitant paracetamol with intramuscular interferon  $\beta$ -1a
- Unitary cost data were obtained from the health costs database e-Salud and drugs Catalogue<sup>(3,4)</sup> (Table 1)
- Discount rate of 3% to costs was applied

Table 1. Disease management and concomitant treatments unitary costs (€ 2010)

Disease Management	Units	(€ 2010)
<b>Visits</b>		
First visit Neurology	Per visit	156.37
Successive visit Neurology	Per visit	93.82
<b>Diagnostics Procedures</b>		
Hematology	Per procedure	11.39
Biochemical	Per procedure	14.88
Liver function tests	Per procedure	14.71
Computerized Axial Tomography	Per procedure	129.30
Nuclear magnetic resonance	Per procedure	200.52
Lumbar puncture	Per procedure	206.36
Cerebrospinal fluid studies	Per procedure	36.23
<b>Concomitant Treatments</b>		
Paracetamol 2,600 mg (analgesic / antipyretic)	Per day	0.0172
Amitriptylina 75 mg (depression)	Per day	0.0667
Baclofen 30 mg (spasticity)	Per day	0.1860
Gabapentin 900 mg (pain)	Per day	0.5310
Gabapentin 2400 mg (seizures)	Per day	1.4193
Lorazepam 5 mg (vertigo)	Per day	0.0360
Methylprednisolone 2000 mg (Relapses)	Per day	11.3360
Modafinil 300 mg (Fatigue)	Per day	5.0160
Oxybutinin 15 mg (bladder control)	Per day	0.1410
Propranolol 120 mg (tremors)	Per day	0.1194
Sildenafil 50 mg (sexual dysfunction)	Per day	1.3729
Tizanidina 12 mg (anxiety/insomnia)	Per day	0.4640

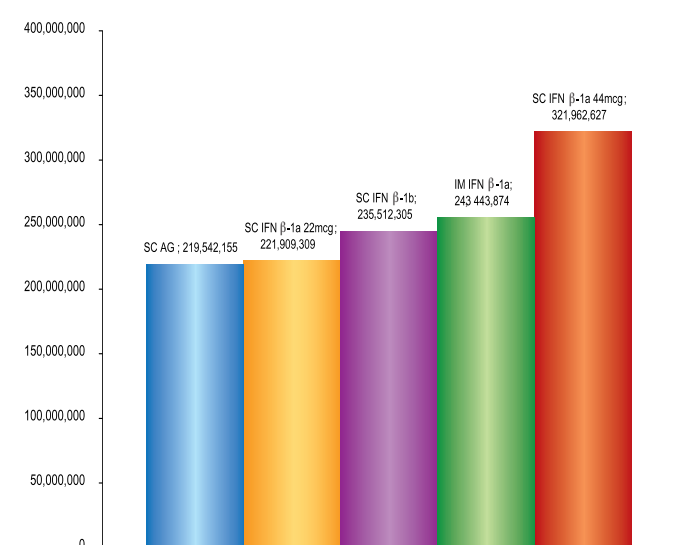
## Results

- Considering a cohort of 22,255 patients with RRMS, the mean global budget impact per year would be € 260,775,470 in the base case
- Pharmacological costs were the key drivers of total cost (90%)
- The setting that excluded glatiramer acetate increase the budget impact in a 3.23% (€ 372 per patient per year)

Table 2. General Results

	BASE CASE	Scenario 1 without IM IFN $\beta$ -1a	Scenario 2 without SC IFN $\beta$ -1a 22mcg	Scenario 3 without SC IFN $\beta$ -1a 44mcg	Scenario 4 without SC IFN $\beta$ -1b	Scenario 5 without Glatiramer Acetate
<b>Budget impact (average)</b>						
IM IFN $\beta$ -1a	55,076,646	0	57,721,629	72,946,409	77,437,173	66,523,209
SC IFN $\beta$ -1a 22mcg	12,285,382	15,686,129	0	16,461,893	17,475,328	15,012,363
SC IFN $\beta$ -1a 44mcg	81,323,013	103,678,288	86,096,691	0	115,504,092	99,224,992
SC IFN $\beta$ -1b	72,481,064	92,403,113	76,733,543	96,972,946	0	88,434,121
Glatiramer Acetate	39,609,366	50,497,775	41,934,444	52,995,163	56,257,677	0
Total	260,775,470	262,265,305	262,486,307	239,376,411	266,674,271	269,194,684
Average budget impact BASE CASE vs		-1,489,835	-1,710,837	21,399,058	-5,898,801	-8,419,214
Average budget impact per patient	11,540	11,606	11,615	10,593	11,800	11,912
Incremental costs per patient BASE CASE vs		-66	-75	947	-260	-372

Figure 3. Sensitivity analysis considering a 100% of usage with each DMD



## Conclusions

The use of glatiramer acetate in the treatment of Relapsing Remitting Multiple Sclerosis patients is a cost-saving strategy, that would decrease the budget impact from the National Health System perspective in Spain.

## References

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