

Budget Impact Analysis of Dexamethasone Intravitreal Implant for Treatment of Diabetic Macular Oedema in Spain

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INTRODUCTION

- Diabetic macular edema (DME) is an ocular disease with high impact on diabetes mellitus patients, being the main cause of blindness in these patients¹.
- Current DME management comprises an optimised metabolic control (glycaemia, blood pressure, lipid profile and renal function), apart from other therapies such as laser photocoagulation and pharmacological treatment².
- Diabetic retinopathy and DME have a great economical impact due to direct costs and also indirect costs related to decreasing patient incomes and a greater need in social care due to worsening of visual impairment³. DME patients overall direct costs are more than double than in diabetic non-DME patients⁴.

OBJECTIVE

- To assess the economic impact following the inclusion of an intravitreal implant of dexamethasone for the treatment of DME.

METHODS

- A budget impact model was designed to estimate healthcare costs for adult patients with DME for a 3-year period (2016-2018), from the Spanish National Health System (NHS) perspective.
- Currently approved therapies were considered:
 - Dexamethasone 700 µg intravitreal implant
 - Aflibercept 40 mg/ml solution for injection
 - Ranibizumab 10 mg/ml solution for injection
- Treated patient population was defined with an epidemiological algorithm by applying Spanish DME prevalence (6.41%) and incidence (0.82%) in diabetic patients^{5,6,7}. Local experts in retina and vitreous determined that 80% of eligible patients were treated and 60% were affected with DME bilaterally in Spain.
- A scenario without the inclusion of dexamethasone was compared to a scenario where dexamethasone was included, based on the proportional use of the available alternatives obtained from an internal market research and the expert panel (Table 1).

Table 1. Percentage of use of available therapies

THERAPEUTIC OPTION	SCENARIO 1 (without dexamethasone intravitreal implant)			SCENARIO 2 (with dexamethasone intravitreal implant)		
	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
BASE CASE (market research)						
Dexamethasone intravitreal implant	0 %	0 %	0 %	20 %	30 %	40 %
Aflibercept	30 %	40 %	50 %	20 %	25 %	30 %
Ranibizumab	70 %	60 %	50 %	60 %	45 %	30 %
ALTERNATIVE SCENARIO (expert opinion)						
Dexamethasone intravitreal implant	0 %	0 %	0 %	40 %	70 %	80 %
Aflibercept	30 %	35 %	50 %	20 %	15 %	10 %
Ranibizumab	70 %	65 %	50 %	40 %	15 %	10 %

- Detailed resource consumption reflecting clinical practice was provided from the local expert panel (Table 2).
- The following direct medical costs were included (€, 2016):
 - Drug acquisition costs** (ex-factory prices with mandatory deduction). To estimate these costs, frequency of annual injections and number of vials used per injection (no drug wastage) were considered.
 - Administration costs** (intravitreal injection)
 - Patient monitoring costs** (routine visits and tests: optical coherence tomography, ophthalmoscopy, fluorescein angiography, tonometry and visual acuity)
 - Management of ocular adverse events** (cataracts, increased intraocular pressure, endophthalmitis, vitreous haemorrhage and retinal detachment) and cardiovascular adverse events.
- Unitary costs were obtained from national databases and literature⁸⁻¹¹. No discount rate was applied.
- Sensitivity analyses were performed to assess model robustness.

Table 2. Price per vial and resource use

		Dexamethasone intravitreal implant	Aflibercept	Ranibizumab
Price per vial (ex-factory price - 7.5% deduction)		€878.75	€686.35	€686.35
Injections per vial/implant†		1.0	3.0	2.0
Number of annual injections (unilateral DME)*	Year 1	2.5	7.0	8.0
	Year 2	2.0	4.0	5.0
	Year 3	1.5	3.0	4.0
Number of annual medical visits	Year 1	6.0	7.0	8.0
	Year 2	4.0	4.0	5.0
	Year 3	4.0	3.0	4.0
Number of annual diagnostic tests (except fluorescein angiography)	Year 1	6.0	7.0	8.0
	Year 2	4.0	4.0	5.0
	Year 3	4.0	3.0	4.0
Number of annual diagnostic tests (fluorescein angiography)	Year 1	1.0	1.0	1.0
	Year 2	0.5	0.5	0.5
	Year 3	0.5	0.4	0.5

* Bilateral DME patients received twice the number of injections that unilateral DME patients

† Off-label split of vials for more than one patient is considered

RESULTS

- Annual eligible population were 152,290 patients in 2016, 170,465 in 2017 and 188,524 in 2018.
- The inclusion of intravitreal dexamethasone implant would lead to annual cost savings of 53.35 (-4.2%), 16.36 (-1.8%) and 7.69 million euros (-0.9%) (Table 3).
- Total costs were reduced mainly by the fewer annual injections required by dexamethasone.
- The average incremental costs were €-350, €-96 and €-41 per patient-year.
- Sensitivity analyses showed that a higher percentage of use of dexamethasone intravitreal implant would result in greater savings (-11.2%, -9.2% and -1.8%) for 2016-2018 period.

Table 3. Budget Impact Analysis results

		2016	2017	2018
S1	Total Annual Cost	€1,271,970,308.92	€922,833,799.98	€845,471,615.38
	Total Annual Cost per Patient	€8,352.31	€5,413.63	€4,484.70
S2	Total Annual Cost	€1,218,621,033.67	€906,478,757.32	€837,785,299.34
	Total Annual Cost per Patient	€8,001.99	€5,317.68	€4,443.93
Total Incremental Cost (S2 vs. S1)		€-53,349,275.25	€-16,355,042.66	€-7,686,316.04
Total Incremental Cost per Patient (S2 vs. S1)		€-350.31	€-95.94	€-40.77
% of Increment		-4.2 %	-1.8 %	-0.9 %

S1: Scenario 1 (without dexamethasone intravitreal implant); S2: Scenario 2 (with dexamethasone intravitreal implant)

CONCLUSIONS

- The inclusion of an intravitreal dexamethasone implant for the treatment of DME would lead to cost-savings for the Spanish NHS, mainly by reducing the administration costs.

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