

Cost-effectiveness analysis of voclosporin vs mycophenolate or belimumab in the treatment of patients with lupus nephritis from the Spanish National Healthcare System perspective

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INTRODUCTION

- Voclosporin (VCS) is an oral immunosuppressant agent for active lupus nephritis (LN) class III, IV and V (also included mixed classes III/V and IV/V), which proved to be effective in AURORA-1 and AURORA-2 trials¹⁻⁵.

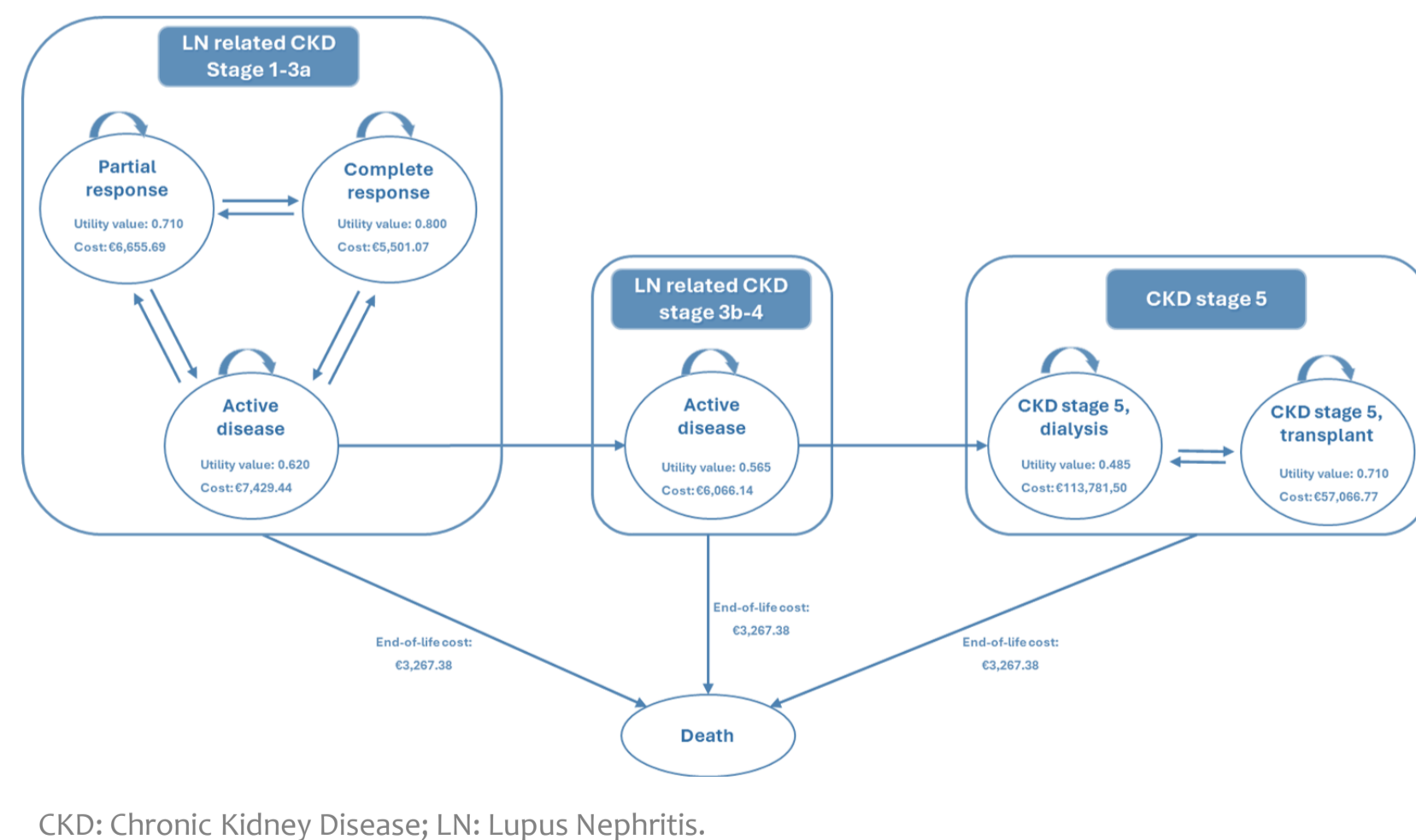
AIM

This study aims to estimate the cost-effectiveness of VCS in combination with mycophenolate mofetil (MMF) vs MMF alone or vs belimumab (BEL) in combination with MMF or cyclophosphamide (CYC), for Spanish patients with LN III-V (and mixed classes) from the perspective of the Spanish National Health System (NHS).

METHODS

- A Markov model with health states according to the specific stages of chronic kidney disease (CKD) (Figure 1) was used to estimate, in 6-months cycles, the lifetime costs and health benefits for oral VCS (combined with MMF), MMF alone and BEL (combined with MMF or CYC). Half cycle correction and an annual discount rate of 3% were applied⁶. Clinical experts validated the parameters and assumptions.
- Patients with LN class III-V were modeled (age 33.2 ± 11.0, 87% women, 65 ± 16 Kg and BSA of 1.71 m²)^{1,4}.
- Clinical efficacy and safety data were derived from pivotal phase III clinical trials AURORA-1 (NCT03021499)⁴ and AURORA-2 (NCT03597464)⁵ comparing VCS+MMF vs. MMF, and from a network meta-analysis comparing VCS vs. BEL+MMF/CYC, using BLISS-LN trial (NCT01639339)⁷.
- Utilities^{1-5,8-16} and mortality rates¹⁷ proceeded from literature. Total costs (€, 2024) included pharmaceutical (ex-factory prices)¹⁸, intravenous-IV (€233.81)¹⁹ and subcutaneous-SC (€20.62)¹⁹ administration, CKD-management^{19,20}, end-of-life²¹ and adverse events costs¹⁹.
- The authorized posology²² was considered for VCS, MMF and BEL (IV: 95% and SC: 5%).
- The effect of future price reduction following BEL biosimilars availability, joined to alternative proportions of BEL formulations usage, were tested through linear regression analyses.

Figure 1. Markov model, costs and utilities per health state.



CKD: Chronic Kidney Disease; LN: Lupus Nephritis.

RESULTS

- In the base case, VCS resulted in 1.30 additional life years (LYs) vs. MMF, 1.22 additional quality-adjusted life years (QALYs) and provided an incremental total cost of €17,762 per patient. Compared with MMF, VCS was a cost-effective option (€14,543 per QALY) for €27,000/QALY willingness-to-pay (WTP)²³.
- When comparing VCS vs. BEL, VCS was a dominant option, yielding 0.06 additional LYs vs. BEL 0.06 additional QALYs and reducing total costs by €-42,398 per patient (Table 1).

Table 1. Lifetime results per patient estimated in the cost-effectiveness analysis.

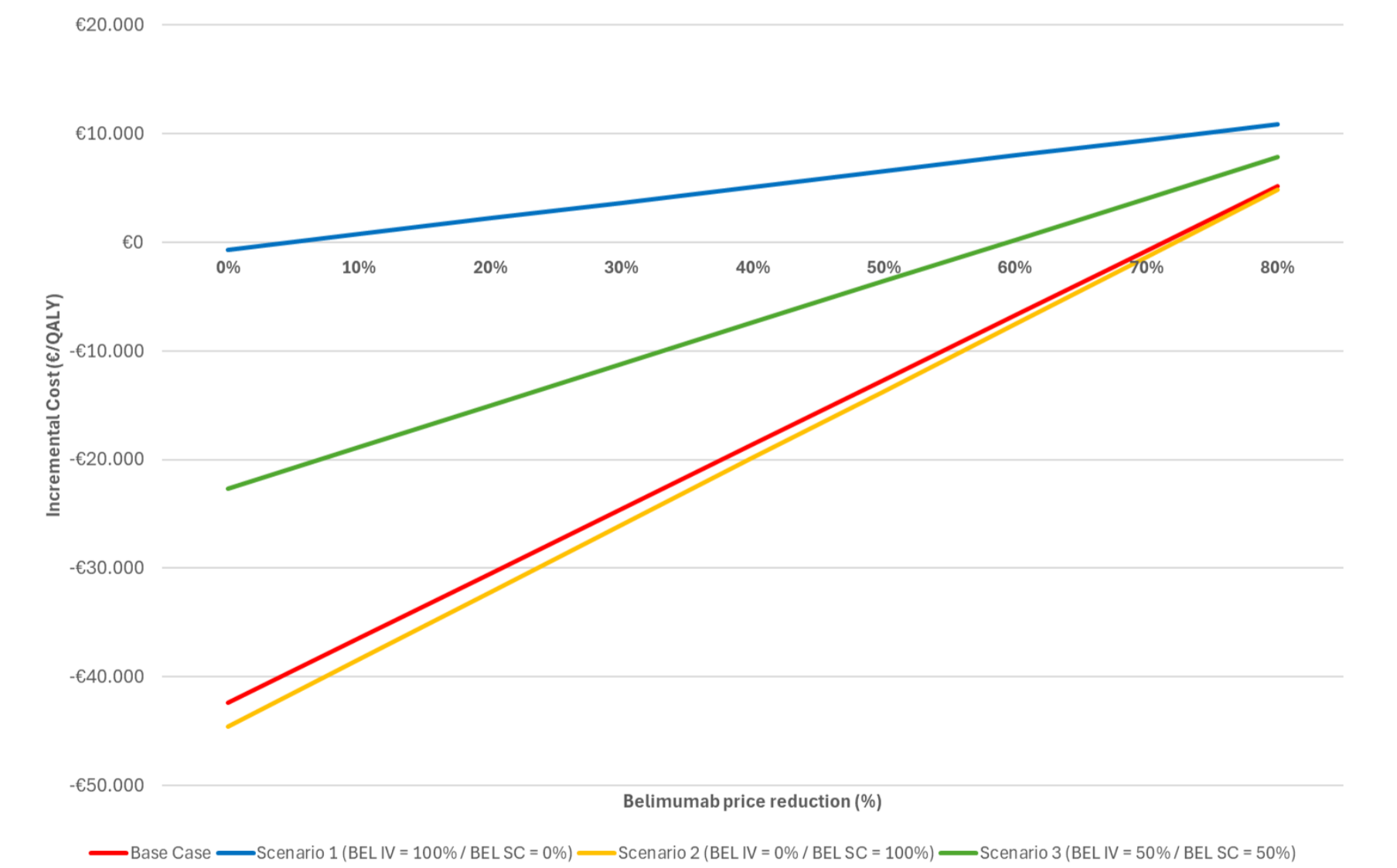
	VCS + MMF	MMF	BEL + MMF/CYC	Δ (VCS + MMF vs. MMF alone)	Δ (VCS + MMF vs. BEL + MMF/CYC)
LYG	20.95	19.66	20.89	+ 1.30	+ 0.06
QALYs	16.47	15.25	16.41	+ 1.22	+ 0.06
Total costs (€)	€205,828	€188,065	€248,226	+ €17,762	- €42,398

BEL: Belimumab; CYC: Cyclophosphamide; LY: Life Year; MMF: Mycophenolate Mofetil; QALY: Quality-Adjusted Life Year; VCS: Voclosporin.

- In all regression models (Figure 2), VCS vs. BEL remained a cost-saving option, even for BEL price reductions above 50% when equivalent use is assessed for IV and SC BEL (50% of patients using each administration route).
- In the base-case setting, considering reductions of almost 70% in BEL's price, VCS would still be a dominant alternative in patients with LN III-V.

Figure 2. Linear regression models for incremental cost of VCS + MMF vs. BEL + MMF/CYC after price reductions.

BEL: Belimumab; CYC: Cyclophosphamide; IV: Intravenous; MMF: Mycophenolate Mofetil; QALY: Quality-Adjusted Life Year; SC: Subcutaneous; VCS: Voclosporin.



CONCLUSION

In the current situation, the use of VCS could provide more health benefits and cost-savings for the Spanish NHS. Even if BEL price was heavily reduced, VCS would still be a cost-effective intervention for treatment of patients with LN III-IV (and mixed classes).