Evaluating the Cost-Effectiveness of Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI) Compared with Other Available Single-Inhaler Triple Therapies for the Treatment of Patients with Moderate-to-Severe COPD in Spain

Treatment with once-daily FF/UMEC/VI would be a dominant option versus BUD/GLY/FOR and BDP/FOR/GLY in patients with moderate-to-severe COPD in Spain, remaining cost-effective even in scenarios in which comparator prices were reduced

Digital poster

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Background

- Chronic obstructive pulmonary disease (COPD) is one of the top three causes of death worldwide and represents a major public health challenge[1]
- Inhaled corticosteroid, long-acting beta-2 agonist and long-acting muscarinic antagonist triple therapy is recommended for patients with COPD who are at increased risk of frequent or severe exacerbations[1]
- In a frequentist network meta-analysis (NMA) of triple therapies in adults with moderate-to-severe COPD, once-daily single-inhaler fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) showed greater improvements in lung function and reduced exacerbation risk versus twice-daily budesonide/glycopyrronium/formoterol (BUD/GLY/FOR) and beclometasone/formoterol/glycopyrronium (BDP/FOR/GLY)[2]

Objectives

- To assess the cost-effectiveness of FF/UMEC/VI versus BUD/GLY/FOR and BDP/FOR/GLY in adults with moderate-to-severe COPD from the perspective of the Spanish National Health System (NHS)
- To characterise the expected clinical impact in terms of moderate and severe exacerbations, lung function (forced expiratory volume in the first second [FEV_1]), health status (St. George's Respiratory Questionnaire-COPD [SGRQ-C]), exercise capacity (**distance traveled in the 6-minute walk test [**6MWT]) and survival

Methods

- A validated and previously published COPD disease progression model (GALAXY)[3] used linked risk equations to predict healthcare costs, quality-adjusted life years (QALYs) and incremental cost-effectiveness ratios (ICERs). All model assumptions and data used were reviewed and validated by local clinical experts
- The original GALAXY risk equation used to estimate utilities was replaced with a Spain-specific linear regression equation, based on a Spanish observational study[3,4]
- Baseline population characteristics were extracted from the IMPACT study[5], using the intent-to-treat (ITT) population (n=10,355) **(Table 1)**

Table 1. Model inputs – Population characteristics[5]

Baseline demographics and clinical characteristics	ITT base-case population (n=10,355)
Female, %	34.0
Age (years), mean (SE)	65.3 (0.08)
BMI (kg/m^2), %	
<21	17
21≤ 30	58
>30	25
Any cardiovascular comorbidity, %	44
Any other comorbidity, %	57
History of exacerbation ≥1, %	99.91
mMRC score ≥2, %	37
Smokers, %	35
Height (cm), mean (SD)	167.5 (9.25)
Number of exacerbations in the previous year, mean (SD)	1.71 (0.01)
Severe exacerbations, mean	0.30
Starting SGRQ*, mean (SE)	50.7 (0.25)
Initial FEV_1%, mean (SD)	45.5 (0.15)
Starting FEV_1 (L), mean	1.2153
Fibrinogen (mg/dl), mean (SD)	477.5 (2.37)
6MWD (m), median (SD)	365.8 (2.74)

Notes: Standard error was assumed to correspond to 10% of the mean for unknown errors. *Refers to the total SGRQ score. Sources: IMPACT Clinical Trial Supplemental Material[5].
6MWD, distance traveled in the 6-minute walk test; BMI, body mass index; CVD, cardiovascular disease; FEV1, forced expiratory volume in the first second; ITT, intention to treat; mMRC, modified Medical Research Council; SD, standard deviation; SE, standard error; SGRQ, St. George's Respiratory Questionnaire.

- Treatment effects and medication use were based on a NMA in adults with symptomatic COPD[2] **(Table 2)**

Table 2. Model inputs – Comparative efficacy[5]

Comparator	FF/UMEC/VI vs. comparator (mean differences)		
	Change in FEV1, mean (95% CI)	Change in SGRQ, mean (95% CI)	Exacerbations, RR (95% CI)
BUD/GLY/FOR (320/18/9.6 mcg)	111.22 (79.80, 142.63) p<0,0001	−0.66 (−2.53, 1.21) p = 0,4871	0.62 (0.45, 0.86) p= 0,0044
BDP/FOR/GLY* (100/6/12.5 mcg)	46.70 (15.21, 78.20) p = 0,0037	−1.43 (−3.47, 0.61) p = 0,1687	0.73 (0.51, 1.04) p = 0,0774

Negative SGRQ values indicate clinical improvement. SGRQ values correspond to total SGRQ and, in the model, were transformed to SGRQ-C by dividing them by 0.9. *BDP/FOR/GLY 100/6/12.5 mcg corresponds to an extrafine formulation. Source: Authors' elaboration based on the evidence included in the indirect comparison.
BDP/FOR/GLY, beclometasone/formoterol/glycopyrronium; BUD/GLY/FOR, budesonide/glycopyrronium/formoterol; CI, confidence interval; FEV_1, forced expiratory volume in the first second; FF/UMEC/VI, fluticasone furoate/umeclidinium/vilanterol; NMA: Network Meta Analysis; SGRQ, St. George's Respiratory Questionnaire.

- NHS perspective was chosen, so direct healthcare costs (€, 2026) of treatments, exacerbations and COPD management were informed by Spanish public sources and published literature; a 3% annual discount rate for costs and benefits was applied based on Spanish guidelines[6]. Treatment acquisition costs for FF/UMEC/VI and both comparators were €72.59,[7] for a 30-day supply. At recommended dose per day, daily costs for FF/UMEC/VI and both comparators were €2.42
- For the base-case analysis, the time horizon and duration of treatment effect were 3 years, to align with prior analyses[4]
- A series of one-way sensitivity analyses and a probabilistic analysis were performed to test the robustness of base-case results and to evaluate uncertainty

Results

- In the base-case analysis, FF/UMEC/VI increased quality-adjusted survival (+0.094 quality-adjusted life years [QALYs] vs BUD/GLY/FOR and 0.052 QALYs vs BDP/FOR/GLY) while reducing total costs by €1,223 and €879 per patient respectively. FF/UMEC/VI was therefore a dominant option and would be considered cost-effective under a willingness to pay threshold of €30,000[8,9] per QALY **(Table 3)**

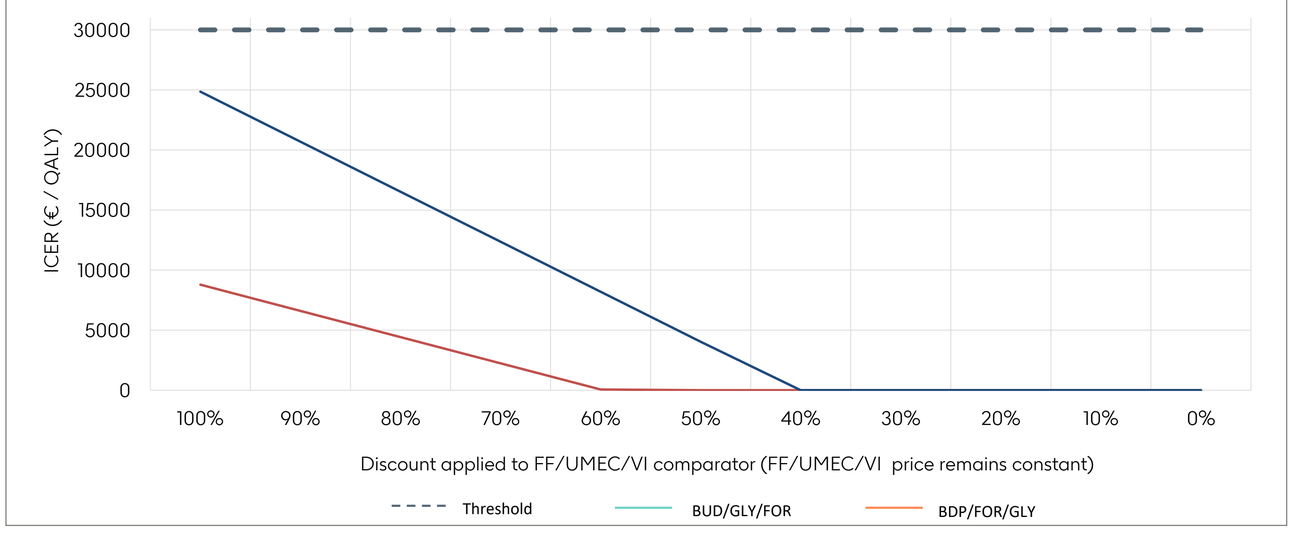
Table 3. Base-case results for FF/UMEC/VI vs BUD/GLY/FOR and BDP/FOR/GLY

	FF/UMEC/VI	BUD/GLY/FOR	FF/UMEC/VI	BDP/FOR/GLY
Cumulative exacerbations (3-year timeframe)				
Moderate exacerbations	2.518	3.712	2.863	3.712
Severe exacerbations	0.528	0.777	0.600	0.777
Total exacerbations	3.045	4.489	3.463	4.489
Severe exacerbations PPPY	0.185	0.274	0.211	0.274
Total exacerbations PPPY	1.068	1.583	1.218	1.583
Outcomes (3-year timeframe)				
LYs (undiscounted)	2.850	2.836	2.844	2.836
QALYs	1.892	1.798	1.850	1.798
Costs (3-year timeframe)				
Drug costs	€2,434	€2,427	€2,428	€2,439
Non-drug costs	€5,213	€6,442	€5,574	€6,442
Total costs	€7,646.68	€8,869.68	€8,002.47	€8,881.07
Incremental results	FF/UMEC/VI vs BUD/GLY/FOR		FF/UMEC/VI vs BDP/FOR/GLY	
Costs	€−1,223		€−879	
QALYs	0.094		0.052	
ICER (€ per QALY gained)	Dominant		Dominant	

BDP/FOR/GLY, beclometasone/formoterol/glycopyrronium; BUD/GLY/FOR, budesonide/glycopyrronium/formoterol; FF/UMEC/VI, fluticasone furoate/umeclidinium/vilanterol; LY, life years; ICER, incremental cost-effectiveness ratios; PPPY, per patient per year; QALY, quality-adjusted life years.

- FF/UMEC/VI remained dominant vs both BUD/GLY/FOR and BDP/FOR/GLY across all scenario analyses
- In the probabilistic sensitivity analysis (1,000 Monte Carlo simulations), FF/UMEC/VI was dominant in ~96% of iterations versus BUD/GLY/FOR and ~98% versus BDP/FOR/GLY, with a 100% probability of being cost-effective versus both comparators at €30,000 per QALY
- Price threshold analysis showed that FF/UMEC/VI would remain dominant while BUD/GLY/FOR costs ≥€29/month (~60% discount). Only when BUD/GLY/FOR falls below €22/month does the ICER become positive. FF/UMEC/VI also remains dominant while BDP/FOR/GLY costs ≥€36/month (~50% discount) **(Figure 1)**

Figure 1. ICER of FF/UMEC/VI vs comparators as a function of comparator discount



BDP/FOR/GLY, beclometasone/formoterol/glycopyrronium; BUD/GLY/FOR, budesonide/glycopyrronium/formoterol; **FF/UMEC/VI,** fluticasone furoate/umeclidinium/vilanterol; ICER, incremental cost-effectiveness ratios; QALY, quality-adjusted life years.

Conclusion

Triple therapy treatment with FF/UMEC/VI would be a dominant option (less costly and more effective) versus BUD/GLY/FOR and BDP/FOR/GLY in patients with moderate-to-severe COPD, and remained cost-effective even when comparator prices were reduced, improving health outcomes and reducing healthcare costs from the Spanish NHS perspective

Abbreviations

6MWD, distance traveled in the 6-minute walk test; BDP/FOR/GLY, beclometasone/formoterol/glycopyrronium; BMI, body mass index; BUD/GLY/FOR, budesonide/glycopyrronium/formoterol; CAT, COPD Assessment Test; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; FEV1, forced expiratory volume in the first second; FF/UMEC/VI, fluticasone furoate/umeclidinium/vilanterol; ICER, incremental cost-effectiveness ratios; ITT, intention to treat; LY, life years; NHS, National Health System; PPPY, per patient per year; QALY, quality-adjusted life years; SD, standard deviation; SE, standard error; SGRQ, St. George's Respiratory Questionnaire.
error; SGRQ, St. George's Respiratory Questionnaire.

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