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REAL-WORLD COST-UTILITY OF FARICIMAB VERSUS CURRENT AND FUTURE ANTI-VEGF THERAPIES IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION IN ITALY

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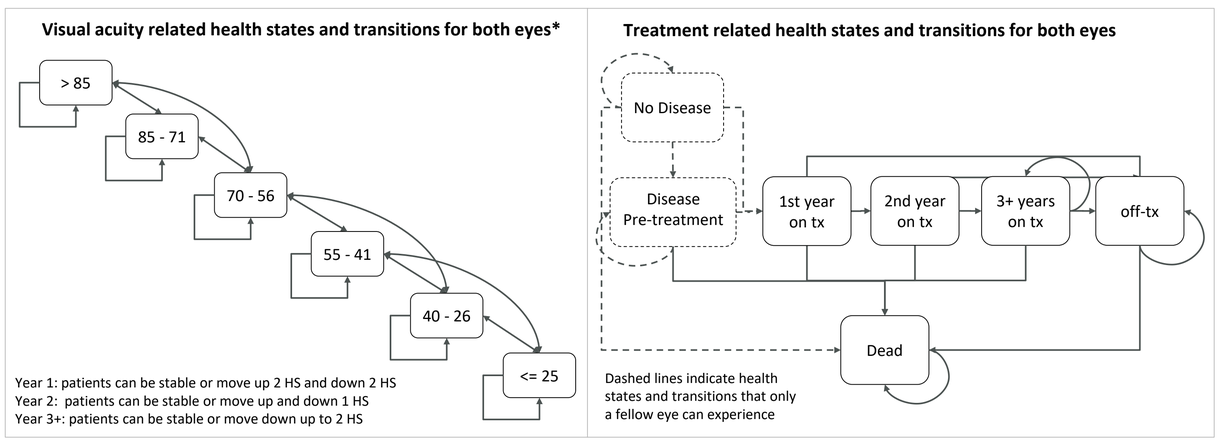
Objective

- In Italy, established anti-vascular endothelial growth factor (VEGF) therapies have shown suboptimal adherence and persistence in clinical practice [1].
- The real-world evidence (RWE) has corroborated findings from faricimab clinical trials (F-CTs) in neovascular age-related macular degeneration (nAMD) [2,3]: the VOYAGER (NCT05476926) study validated its effectiveness [4], while the FARIT study (SL45055) confirmed its durability [5].
- This study aimed to evaluate the cost-utility of faricimab versus current and future anti-VEGF (standard of care, SoC) in a real-world setting from the perspective of Italian National Health Service (NHS).

Methods

- A 28-day cycle Markov model was used to estimate lifetime clinical outcomes and costs of nAMD patients treated with faricimab and SoC (*Figure 1*).

Figure 1 – Model scheme



Patients enter the model based on the initial visual acuity (VA), with distribution derived from F-CTs. To model clinical progression, three time periods were considered: (i) year 1, the induction phase during which most of the visual improvements occur; (ii) year 2, defined by disease stabilization and maintenance of achieved improvements; (iii) year 3+, characterized by the possibility of reducing treatment intensity and long-term maintenance.

The transition probabilities are assumed to be independent of the VA and are held constant after the second year.

Patients who discontinued treatment were treated with the best SoC, with an assumed average loss of 10.9 letters [6].

*7.3% of patients were assumed to have both eyes affected, with respective second-eye development incidences of 1.4% per model cycle [6].

- SoC was defined as a mix of on-label anti-VEGFs (73% aflibercept, 27% ranibizumab) according to National Observatory on the Use of Medicines 2023 consumption report (*Figure 2*) [7].
- SoC treatment effectiveness at year 1, injection frequency, and persistence were sourced from the RADIANCE study (*Figure 3 and 4*) [1].
- Pending availability of a single RWD source to capture both faricimab local effectiveness and treatment patterns with adequate follow-up, two scenarios were investigated (*Figure 3 and 4*):

	Efficacy year 1 (mean BCVA/VA change from baseline)	Injection frequency (Number of injection per year)	Persistence (Annual treatment discontinuation)
A	VOYAGER [3]*	F-CTs [1,2]	F-CTs [1,2]
B	F-CTs [1,2]	FARIT [4]	FARIT [4]^

*Mean VA (as proxy of best corrected VA, BCVA) change from baseline at year 1 was assumed to be equal to that observed at 6 months, consistent with the trend reported in F-CTs. ^Treatment persistence was 100% in year 1, with discontinuation from year 2 onward informed by F-CTs data.

Figure 3 – Scenario A: RWE mean VA change year 1

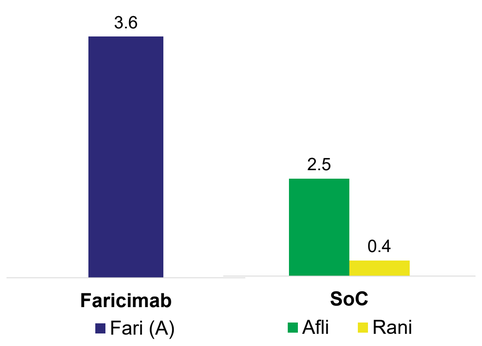
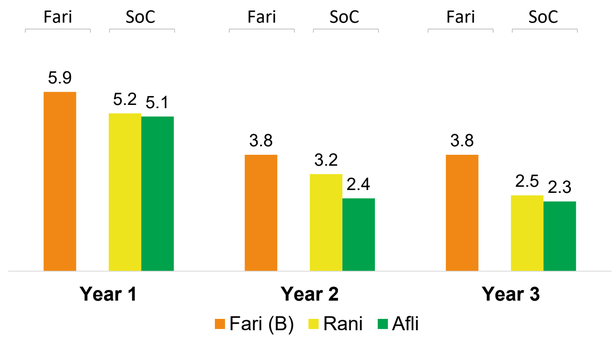


Figure 4 – Scenario B: Italian RWE Injection frequency



- For year 2, transition probabilities were derived from F-CTs, with comparator efficacy adjusted proportionally based on the number of doses. From year 3 onward, an average loss of 2.5 letters was assumed for all treatments [6].
- General population mortality rates were adjusted to account for increased mortality in patients with visual disabilities, in line with NICE analyses [6].
- Quality of life was based on published utilities [8], with decrements applied for intravitreal (IVT) administration [6,8].
- Direct costs (drug acquisition and administration) were retrieved from Italian sources (*Table 1*) [9, 10]. List prices were applied for current drugs, and estimated for future biosimilars in line with current legislation [11].
- Societal perspective including indirect costs (loss of productivity and social security) was also evaluated [5,12-14].

Table 1 – Unit costs

Category	Item		Value (€)
Direct	Faricimab		700.19
	Aflibercept 2mg (biosimilar)*		444.00
	Ranibizumab (biosimilar)		494.91
	IVT administration		268.15
Indirect	Productivity loss/injection day		85.08
	Social security cost/month	25≤VA<55 letters	183.91
		VA<25 letters	792.97

*Estimated in line with current legislation

Indirect costs

The cost of productivity loss for patients and caregivers was estimated based on the mean time required for administration (6.5 hours [12]), assuming that 65% of patients were accompanied by a caregiver [12]. Hourly monetary value of paid and unpaid work and employment rates for both patients and caregivers were sourced from the literature [5,13].

The social security costs were derived from the literature [14].

- A lifetime horizon (25 years) was considered, with costs and health outcomes discounted at 3% annually.
- Probabilistic sensitivity analysis (PSA) was conducted to evaluate input parameter uncertainty.

Results

- Faricimab generated an **additional** 1.11 and 1.35 Quality Adjusted Life Year (**QALY**) compared to SoC in scenarios A and B, respectively, with **incremental costs** of approximately €33k and €35k per patient (*Table 2*).
- The incremental cost-utility ratio (**ICUR**) ranged **from €26k to €30k per QALY gained**, with over **85% probability of cost-effectiveness** at a willingness-to-pay threshold of €33k per QALY (*Figure 5*).
- When including indirect costs, the incremental cost decreased to roughly €19k in both scenarios and, consequently, improved the ICUR (*Table 3*).

Table 2 – Summary results – NHS perspective

	SoC	Scenario A		Scenario B	
		Fari	Δ	Fari	Δ
LYs	9.40	9.73	0.33	9.80	0.40
QALY	4.92	6.03	1.11	6.27	1.35
Direct costs (€)	7,096	40,263	33,167	42,238	35,143
ICUR (€/QALY)	-	-	**29,849**	-	**26,071**

Figure 5 – Cost-effectiveness acceptability curve

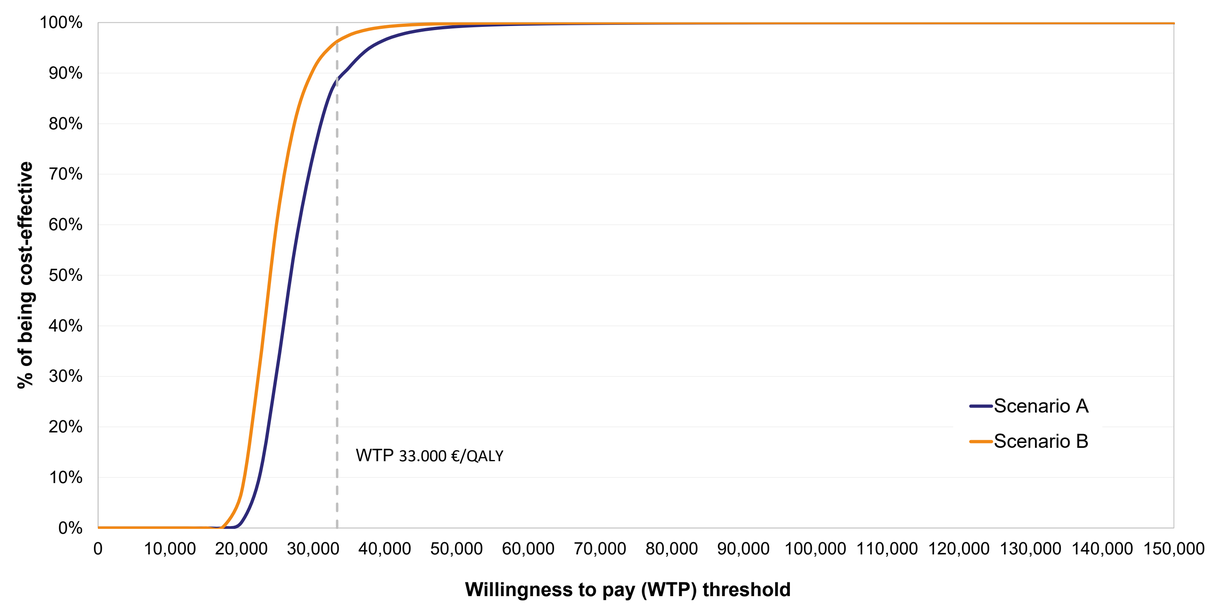


Table 3 – Summary results – societal perspective

	SoC	Scenario A		Scenario B	
		Fari	Δ	Fari	Δ
LYs	9.40	9.73	0.33	9.80	0.40
QALY	4.92	6.03	1.11	6.27	1.35
Total costs (€)	44,417	63,774	19,357	*63,295*	18,877
Direct costs (€)	*7,096*	*40,263*	*33,167*	*42,238*	*35,143*
Indirect costs (€)	*37,321*	*23,511*	*-13,810*	*21,057*	*-16,265*
ICUR (€/QALY)	-	-	**17,420**	-	**14,005**

Conclusions

- **Faricimab** was **cost-effective** compared to **current and future anti-VEGF biosimilars** (aflibercept 2mg and ranibizumab) for nAMD treatment in the Italian real-world setting across both scenarios.
- Its value, driven by **improved durability and persistence**, is further strengthened when **societal perspective** (indirect costs) are considered.
- A limitation of this analysis is the combined use of RCT and real-world data; further evaluations based solely on real-world evidence are needed to confirm these findings.

References

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