

Exploring the Potential Health Economic Value of Vicadrostat, a novel Aldosterone Synthase inhibitor and Empagliflozin in

Chronic Kidney Disease



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Objectives

This study investigates the long-term economic and clinical potential of the novel vicadrostat and empagliflozin to reduce direct healthcare costs through improved patient outcomes.

Introduction

£7 billion

40% ↓ uACR

Ph3 ongoing

Chronic Kidney Disease (CKD) represents a clinical and economic challenge, with annual healthcare expenditures amounting to £7 billion in the UK alone, primarily driven by kidney replacement therapy and hospitalizations.

The phase-2-trial (NCT05182840) demonstrated up to 40% urine albumin-creatinine ratio (uACR) reduction, highlighting the potential therapeutic value of the aldosterone synthase inhibitor - vicadrostat (10mg) with empagliflozin (SGLT2 inhibitor) for delaying CKD progression and reducing associated cardiovascular risks¹.

The EASi-KIDNEY™ (NCT06531824) Phase 3 trial, expected to be completed in 2028, is investigating the efficacy and safety of vicadrostat and empagliflozin in 11,000 participants, with CKD.

Risk increases with higher uACR:

Compared with a reference population**, individuals with moderate kidney dysfunction*are at³:

2.4 fold

increased risk of heart failure

2.2 fold

increased risk of cardiovascular mortality

37 fold

increased risk of kidney replacement therapy

Methods

15+ HTAs model

A previously validated CKD progression model (CKD-PM, figure 1), used in over 15 health technology assessments across multiple countries, projected the long-term impact of uACR changes on outcomes and costs².

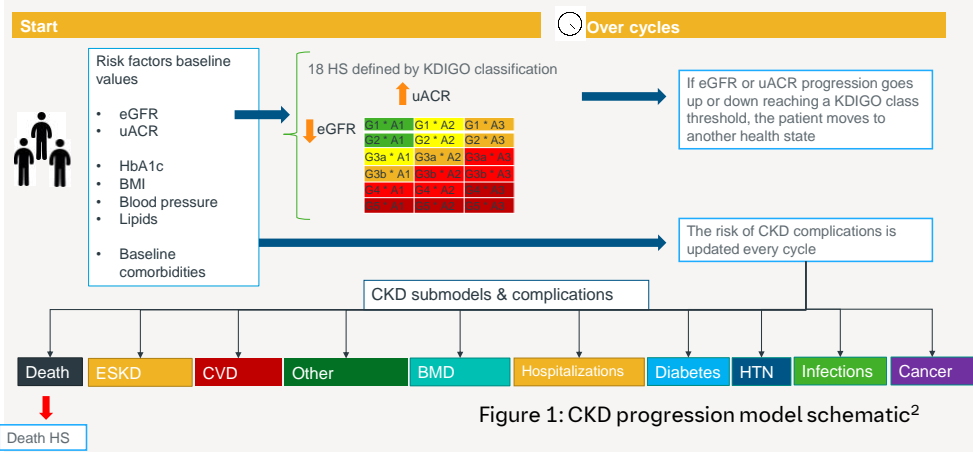


Figure 1: CKD progression model schematic²

Methods



Baseline characteristics (Table 1) and the impact on uACR (Table 2) were derived from a 14-week phase-2-trial, assessing various doses of vicadrostat or matching placebo on a background therapy of empagliflozin or matching placebo¹.



All participants received an ACE-inhibitor or ARB (standard of care, SoC). The treatment effects on estimated glomerular filtration rate (eGFR) were not considered. Instead, the natural progression of eGFR observed in the CRIC registry data was programmed according to the patient's eGFR and uACR values at the start of each annual cycle in the CKD-PM simulation.

UK

The base-case analysis was conducted for the UK, using 3.5% annual discount rates, a lifelong time horizon, and a 3-year treatment duration. UK default utilities and complication costs were used. Treatment costs were not applied.

Table 1: Baseline patient characteristics (n=586)

Parameter	Mean	SD
Age (years)	63.8	11.3
Male (%)	66.6	-
eGFR (ml/min per 1.73 m2)	51.9	17.7
uACR (mg/g)	757.9	930.5
BMI (kg/m2)	29.93	5.47
HbA1c (%)	6.85	1.32
TC (mg/dL)	174.9	48.8
SBP (mmHg)	133.8	15.7

Table 2: Treatment efficacy

Full cohort	Empa + SoC		Vicadrostat + Empa + SoC	
	Mean	SE	Mean	SE
uACR [mg/g] *Ratio Week 14/Baseline	1.01	0.06	0.70	0.06

Results

Among the doses tested, 10mg vicadrostat+empagliflozin+SoC showed the largest reductions in uACR (Table 2: Treatment efficacy).

£3,433 cost savings

Compared to empagliflozin+SoC, the model projected potential non-drug lifetime cost savings of £3,443 with vicadrostat+empagliflozin+SoC, primarily driven by delayed kidney replacement therapy (Table 3).

0.34 LY and 0.29 QALY gains

Compared to empagliflozin+SoC, the model projected gains of 0.34 life-years and 0.29 quality-adjusted life-years with vicadrostat+empagliflozin+SoC (Table 3).

Savings and life years gained are driven by the delay in kidney replacement therapy. This extended life expectancy results in higher total costs for other complications.

Results

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Table 3: Model outcomes	Empa + SoC	Vicadrostat + Empa + SoC
Total discounted costs (£)	103,492	100,149
Total discounted QALYs	7.41	7.70
Total LYs/discounted LYs	12.96/9.92	13.51/10.26
Time to kidney replacement therapy (y)	8.92	9.69
Incremental cost (£)		-3,443
Incremental LYs/QALYs		0.34/0.29
Incremental cost (£) per QALYs		Dominant

Table 4: Breakdown of costs (total costs and normalized per LY)

	Empa + SoC (Total costs)	Vicadrostat + Empa + SoC (Total costs)	Empa + SoC (Cost /LY)	Vicadrostat + Empa + SoC (Cost /LY)
Monitoring (£)	23,867	23,614	1,842	1,748
Kidney replacement therapy (£)	43,662	39,011	3,369	2,888
ESKD (conservative therapy) (£)	1,521	2,100	117	155
CVD Complications (£)	5,773	5,971	446	442
Anemia (£)	3,936	3,981	304	295
Other CKD Complications (£)	13,110	13,483	1,012	998
BMD (£)	7,415	7,626	572	564
AKI (£)	861	905	66	67
Infections (£)	3,253	3,354	251	248
Cancers (£)	95	105	7	8

Conclusions

Simulation modeling positions **vicadrostat+empagliflozin** as a **promising treatment for CKD**. It yields cost savings by improving patient outcomes and reducing complications, particularly the need for KRT. Although some complications incurred higher total costs due to extended lifespan, the overall modeled benefits are significant. Given that the modeled scenario was conservative and did not account for the treatment effects on eGFR, it is anticipated that further cost savings, e.g., due to CV risk reduction, as well as QALYs and LYs benefits, may be observed. These hypotheses await validation from the ongoing EASi-KIDNEY™ Phase 3 trial.

Abbreviations

BMD, Bone mineral disorder; BMI Body Mass Index; CKD, Chronic kidney disease; CVD, Cardiovascular disease; eGFR, estimated glomerular filtration ratio; ESKD, End stage kidney disease; DBP, Diastolic blood pressure; HS, Health state; HTN, Hypertension; KDIGO, Kidney Disease Improving Global Outcomes; LY, Life years; QALY, Quality adjusted life years; SBP, Systolic blood pressure; SGLT2i, Sodium Glucose Transporter 2 inhibitor; SoC: Standard of Care; TC, Total cholesterol; uACR, urine albumin creatinine ratio

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Disclosures

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Footnotes

- * stage G3aA2 CKD
**Individuals with an eGFR of 90–104 mL/min/1.73 m2 and a uACR <10 mg/g

