B-Cell Directed Therapies for IgA Nephropathy: Effectiveness and Value

Public Meeting — February 26, 2026

Meeting materials available at: https://icer.org/assessment/iga-nephropathy-2025/

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Participating Members of the CTAF

Elizabeth J. Murphy, MD, DPhil, CTAF Chair, Professor of Clinical Medicine, UCSF, Chief of Endocrinology and Metabolism Division

- **Ralph Brindis, MD, MPH**, Clinical Professor of Medicine, UCSF
- **Bob Collyar**, Patient Advocate, Patient Advocates in Research
- **Felicia Cohn, PhD,** Bioethics Director, Kaiser Permanente Orange County
- **Sanket Dhruva, MD, MHS, FACC,** Associate Professor of Medicine, UCSF School of Medicine
- **Rena Fox, MD**, Professor of Medicine, UCSF
- **Jeffrey Hoch, PhD,** Professor, University of California, Davis
- **Jeffrey Klingman, MD**, Chief of Neurology, Kaiser Permanente, Walnut Creek
- **Sei Lee, MD, MAS**, Professor of Medicine, UCSF Geriatrics
- **Joy Melnikow, MD, MPH,** Professor emeritus, University of California, Davis
- **Kavita V. Nair, PhD**, Professor of Neurology and Pharmacy, CU Skaggs School of Pharmacy & Pharmaceutical Sciences, Anschutz Medical Campus
- **Ann Raldow, MD, MPH**, Associate Professor, UCLA
- **Rita Redberg, MD, MSc, FACC, FAHA**, Professor of Medicine, Araxe Vilensky Endowed Chair in Cardiology, Core Faculty, Philip R Lee Institute for Health Policy Studies, Director, Inquiry Program, UCSF Division of Cardiology
- **Anthony Sowry**, Patient Advocate, National Patient Advocate Foundation

Patient Experts

Anthony "Tony" Pisa, Individual Living with IgAN

- *Tony is a volunteer Patient Advocate with NephCure*

Samantha Schweisthal, Individual Living with IgAN

- *Samantha is a volunteer Patient Ambassador for the state of Alabama with the IgAN Foundation*

Clinical Experts

Jonathan Barratt, PhD, FRCP, Professor of Renal Medicine, University of Leicester

- *Dr. Barratt has received funds from health care companies including; Calliditas, Vera Therapeutics, Otsuka, AstraZeneca, Argenx, Biogen, Novartis,Vertex, Takeda, Biohaven*

Shikha Wadhwani, MD, MS, FASN, Associate Professor of Medicine, Division of Nephrology and Hypertension, University of Texas Medical Branch

- *Dr. Wadhwani has received funds from health care companies including; Calliditas, Vera Therapeutics, Otsuka, Alexion, Biogen, Boehringer Ingelheim, Dimerix, Novartis, and Travere*

ICER Speakers

Sarah K. Emond, MPP
President & CEO

Jason H. Wasfy MD, MPhil
Evidence Author; Associate Professor, Harvard Medical School

David Rind, MD, MSc
Chief Medical Officer

R. Brett McQueen, PhD
Lead Modeler & Associate Professor; University of Colorado Anschutz Medical Campus

Why are we here today?

“IgAN is the silent killer as they call it. The diagnosis process is difficult. It's really scary. When you are in a position where everything is perfectly fine, you’re doing everything at the pace you normally would. When you are told there is no solution, your brain works differently. You are still trying to maintain some level of hope.”

-ICER patient interview with individual living with IgAN

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
  - What are the risks and benefits?
  - How do new treatments fit into the evolving landscape?
  - What are reasonable prices and costs to patients, the health system, and the government?
  - What lessons are being learned to guide our actions in the future?

The Impact on Rising Health Care Costs for Everyone

GALLUP®

APRIL 1, 2025

In U.S., Inability to Pay for Care, Medicine Hits New High

Rates among Hispanic, Black adults and those with lower incomes worsen markedly since 2021

Peterson-KFF
Health System Tracker

Health Spending

How much and why ACA Marketplace premiums are going up in 2026

Business Group on Health Survey: 9% Health Care Cost Increase for 2026

https://www.businessgrouphealth.org/newsroom/news-and-press-releases/press-releases/2026-employer-health-care-strategy-survey
https://www.healthsystemtracker.org/brief/how-much-and-why-aca-marketplace-premiums-are-going-up-in-2026/
https://news.gallup.com/poll/658148/inability-pay-care-medicine-hits-new-high.aspx

Organizational Overview

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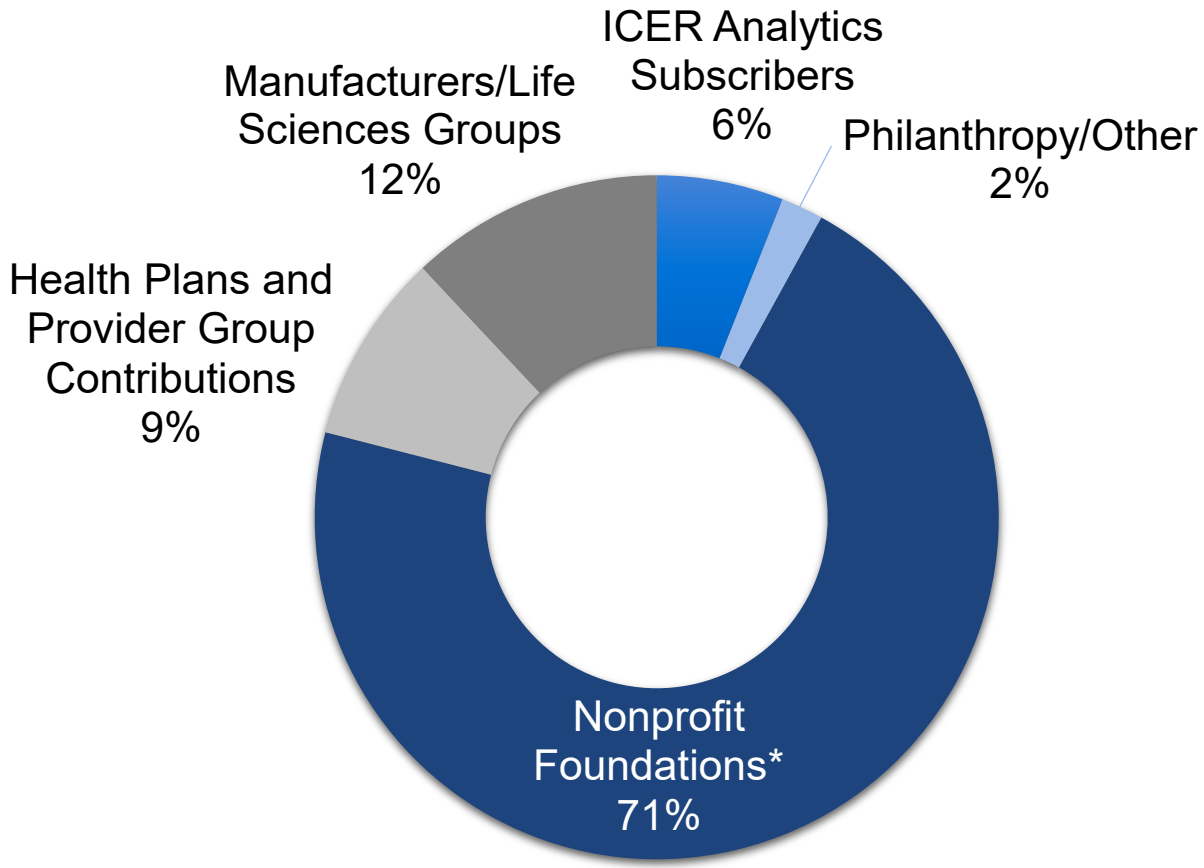
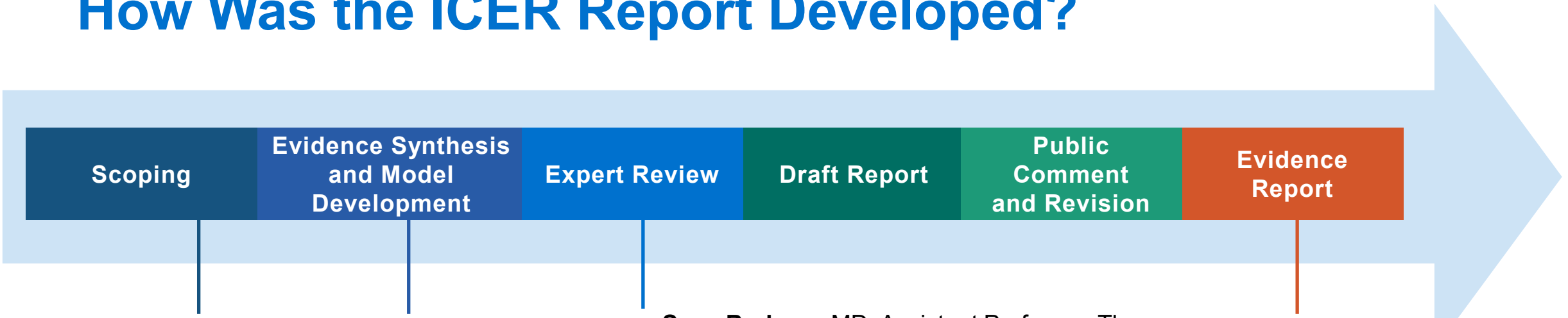
Funding 2026



ICER Policy Summit and non-report activities only

*ICER received significant funding from Arnold Ventures and the Peterson Center on Healthcare, LLC (represented on our "Sources of Funding" page under "Non-profit Foundations").

How Was the ICER Report Developed?



Guidance from patients, clinical experts, manufacturers, and other stakeholders

Evidence analysis in collaboration with **Harvard Medical School** and cost-effectiveness modeling in collaboration with the **University of Colorado**

- **Sean Barbour,** MD, Assistant Professor, The University of British Columbia
- **Jonathan Barratt,** PhD, FRCP, Professor of Renal Medicine, University of Leicester
- **Phil McEwan, PhD,** Chief Executive Officer, Health Economics and Outcomes Research, Ltd.
- **Stuart Miller,** Dir. Of Strategic Partnerships, IgAN Foundation
- **Bonnie Schneider,** Founder and Executive Director, IgAN Foundation

Structured to support **CTAF** voting and policy discussion

Value Assessment Framework: Long-Term Value for Money

Agenda (PT)

9:00 AM	Meeting Convened and Opening Remarks
9:20 AM	Presentation of the Clinical Evidence
10:00 AM	Presentation of the Economic Model
10:35 AM	Manufacturer Feedback on Economic Modeling
10:50 AM	Public Comments and Discussion
11:10 AM	Lunch Break
11:55 AM	CTAF Deliberation and Vote
1:05 PM	Break
1:15 PM	Policy Roundtable Discussion
2:45 PM	Reflections from CTAF
3:00 PM	Meeting Adjourned

Presentation of the Clinical Evidence

Jason H. Wasfy, MD, MPhil

Associate Professor, Director of Cardiology Outcomes Research;

Mass General Brigham and Harvard Medical School

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20 YEARS

Key Team Members

Name	Title
Jason H. Wasfy, MD, MPhil	Evidence Author
Avery McKenna, BS	Research Lead, Evidence Synthesis
Sophia Cassim, BA	Research Assistant, Evidence Synthesis

Disclosures

Financial support provided to JHW from the Institute for Clinical and Economic Review (ICER).

JHW has no conflicts to disclose. AM and SC are employees of ICER and have no conflicts to disclose.

ICER's full policy for managing and disclosing potential conflicts of interest can be found here.

IgA Nephropathy (IgAN)

Disease Background

- **Abnormal IgA deposition** in glomeruli causing inflammation and kidney damage
- An estimated **200,000** people in the US have IgAN, often occurring in **young adults**
- In US, **twice as common in men** than women and more commonly diagnosed in Asian individuals
- Exact **progression** to end-stage kidney disease (ESKD) is **debated**, but many will progress in 15-20 years after diagnosis

IgAN: immunoglobulin A nephropathy, US: United States

Diagnosis

- Some people present with blood in the urine (gross hematuria)
- Diagnosis is confirmed by biopsy; should be considered if suspected and proteinuria is more than or equal to 0.5 g/day
- Pathological information from biopsy informs prognosis

g: gram

Treatment (KDIGO 2025)

Goal 1

Reduce the production of IgA antibodies that eventually deposit in the kidneys

Treatment Options:

- Nefecon for 9 months, unclear safety/efficacy data for longer courses
- Systemic glucocorticoids for 2 months followed by taper over 6-9 months “in settings where Nefecon is not available”

Note: UpToDate provides different guidance, “systemic glucocorticoids first”

Goal 2

Protect glomerular function in the kidneys once deposition of pathogenic IgA has already occurred

Treatment Options:

- ACEi/ARB for goal BP 120/70
- sparsentan for higher-risk
- SGLT2i

Overall Goal: reduce proteinuria to <0.5 g/day, ideally <0.3 g/day

ACEi: angiotensin-converting enzyme inhibitor, ARB: angiotensin receptor blocker, BP: blood pressure, g: gram, IgAN: immunoglobulin A nephropathy, KDIGO: Kidney Disease Improving Global Outcomes, SGLT2i: sodium-glucose cotransporter-2 inhibitor

Insights from Discussions with Patients

- **Delays** in diagnosis, and **difficulty accessing** specialty care even after diagnosis
- Tradeoff between **toxic side effects** of current treatments and preference to **preserve kidney function** longer-term
- Treatments are **immunosuppressive**, raising concerns about infections, and some affect fertility (many women of child-bearing age have IgAN)
- Fear and uncertainty about **disease progression**
- Dialysis is **life-altering**; generally, patients prefer kidney transplant when available

Scope of Review

- For people with IgAN, we evaluated the clinical effectiveness of B-cell directed therapies compared to:
  - systemic glucocorticoids
  - no specific immunomodulatory treatment, and
  - to each other
- All expected to receive renal-protective therapies (e.g., renin-angiotensin inhibitors, endothelin receptor antagonists, SGLT2i)

Main Interventions

- Sibeprenlimab (Voyxact®; Otsuka)
  - APRIL inhibitor (A PRoliferation Inducing Ligand)
  - Accelerated approval November 25, 2025
- Atacicept (Vera Therapeutics)
  - APRIL inhibitor and BAFF (B-cell Activating Factor) inhibitor
  - PDUFA date of July 6, 2026
- Delayed-release oral budesonide (Nefecon; Tarpeyo®; Calliditas Therapeutics)
  - Accelerated approval 2021; Full approval 2023

Outcomes

- We sought information on:
  - Patient-important outcomes including development of ESKD, hospitalization, QOL, serious adverse events (i.e., infection, common glucocorticoid adverse effects)
  - Surrogate measures that predict ESKD
    - Estimated Glomerular Filtration Rate (eGFR)
    - Proteinuria

Clinical Evidence

Key Clinical Trials

Sibeprenlimab

- Phase III VISIONARY
- Phase II ENVISION

Atacicept

- Phase III ORIGIN 3
- Phase II ORIGIN

Nefecon

- Phase III NefIgArd

Systemic Glucocorticoids

- TESTING

These trials generally enrolled:

- People in their late 30's / early 40's
- More men than women (~60%)
- High percentage of Asian participants (23 – 93%)
- Mean eGFR values ranging from 55 – 65 mL/min/1.73m^2
- When measured, mean uPCR values ranging from 1.3 – 1.75 g/g

eGFR: estimated glomerular filtration rate, g/g: gram per gram, mL/min/1.73m²: milliliter per minute per 1.73 meters squared, uPCR: urinary protein to creatinine ratio

Key Clinical Trials

Intervention	Trial Name	N	Treatment Period	Primary Outcome
Sibeprenlimab	**VISIONARY**	510	24 months	Change from baseline in 24h-uPCR at **month 9**
	ENVISION	155	12 months	Change from baseline in 24h-uPCR at **month 12**
Atacicept	**ORIGIN 3**	428	24 months	Change from baseline in 24h-uPCR at **month 9**
	ORIGIN	116	9 months	Change from baseline in 24h-uPCR at ~ **month 6**
Nefecon	**NeflgArd**	364	9 months (15-month follow-up off treatment)	Time-weighted mean eGFR over **24 months**
Systemic Glucocorticoids	**TESTING (Reduced Dose)**	241	6-9 months (median 2.5 years follow-up)	**First occurrence** of a sustained 40% eGFR decrease, kidney failure, or death due to kidney disease.

24h: twenty-four hour, eGFR: estimated glomerular filtration rate, N: total number, uPCR: urinary protein to creatinine ratio

Key Clinical Trials: Systemic Glucocorticoids

TESTING (Reduced Dose)

- Reduced-dose oral methylprednisolone (0.4 mg/kg/day) after adverse events in higher dose
- Conducted in five (mostly Asian) countries
- Baseline proteinuria: 2.48 g/g

STOP-IgAN

- IV methylprednisolone followed by oral prednisolone and in some cases, azathioprine/cyclophosphamide
- Conducted in Germany
- Baseline proteinuria: 1.7 g/g

g/g: gram per gram, IgAN: immunoglobulin A nephropathy, IV: intravenous, mg/kg: milligram per kiligram

Annualized eGFR slope, mL/min/1.73m^2/year

Intervention	Sibeprenlimab		Atacicept		Nefecon		Methylprednisolone	
Trial	Phase II ENVISION		Phase II ORIGIN*		Phase III NeflgArd		TESTING	
Follow-Up	12 months		9 months		2 years (9 mo. on treatment)		2.5 years (6-9 mo. on treatment)	
Arm	Sibe 4 mg/kg	Placebo	Ata 150 mg	Placebo	Nefecon 16 mg	Placebo	Reduced-Dose Methyl-prednisolone	Placebo
N	38	38	33	34	182	182	117	113
Mean Change (SE)	+0.1 (1.6)	-5.9 (1.7)	+2.6 (2.4)	-3.2 (2.4)	-3.06 (NR)	-6 (NR)	-0.7 (NR)	-3.0 (NR)
Difference vs. Placebo (95% CI); p-value	5.96 (1.5, 10.4); NR		5.9 (-0.75, 12.5); NR		2.95 (1.67, 4.58); p<0.0001		2.3 (-0.03, 4.6); p=0.054	

*Exploratory analysis using 9-month data cut-off. Annualized slope from atacicept-treated participants using 96 weeks of data from randomized period and OLE = -0.6.

CI: confidence interval, Ata: Atacicept, eGFR: estimated glomerular filtration rate, kg: kilogram, mg: milligram, mL/min/1.73m^2: milliliter per minute per 1.73 meters squared, mo: month, N: number, NR: not reported, OLE: open-label extension, Sibe: Sibeprenlimab, SE: standard error

Proteinuria

Percent Reduction in 24-Hour uPCR at Month 9					
Intervention	**Trial**	**Arm**	**N**	**Geometric Percent Change, %**	**Difference versus Placebo, % (95% CI); p-value***
Sibeprenlimab	VISIONARY	Sibe 400 mg SC	152	-50.2	51.2 (42.9, 58.2); p<0.0001†
		Placebo	168	+2.1	
Atacicept	ORIGIN 3	Ata 150 mg	214	-45.7	41.8 (28.9, 52.3); p<0.001
		Placebo	214	-6.8	
Nefecon	NefIgArd	Nefecon 16 mg	182	-33.6	30 (19.9, 38.8); NR
		Placebo	182	-5.2	

- 24-Hr uPCR was not measured in TESTING trial. At month 12, the reduced dose cohort had a change in proteinuria of -1.01 grams per day compared to +0.10 in the placebo group (p<0.001)

*Difference values may not align with percent change column due to rounding/statistical analysis from trial , †Placebo-adjusted treatment effect, reports 96.5% CI. Note: Geometric mean percentages calculated using the log-transformed scale. Ata: Atacicept, CI: confidence interval, IV: intravenous, mg: milligram, mg/kg: milligram per kilogram, N: total number, NR: not reported in trial, SC: subcutaneous, Sibe: Sibeprenlimab

Patient Reported Outcomes

- There were no HRQoL outcomes reported in trials for sibeprenlimab, atacicept, or in the key systemic glucocorticoid trial (TESTING)
- In the Phase III NeflgArd trial, there were little-to-no differences in SF-36 between Nefecon and placebo groups at both months 9 and 24

Overall Harms: Phase III and TESTING trials

	Sibeprenlimab	Atacicept	Nefecon	Reduced-Dose Glucocorticoids
Serious Treatment-Related AEs	0.4% vs. 0.4%	0% vs. 0.9%	2% vs. 2%	Not reported
Discontinuation due to AEs	0.4% vs. 1.6%	0.9% vs. 3.7%	9% vs. 2%	Not reported
Serious Infections	1.2% across groups	0% vs. 1.4%	3% vs. 1%	Not reported
Severe Infections Requiring Hospitalizations	None	None	2% vs. 0.5%	4% vs. 2%

Note: Data reported as % in active treatment group versus % in placebo group unless specified otherwise

Harms in Glucocorticoid Trials

Nefecon

- Peripheral edema (17% vs. 4%)
  - One case of serious edema
  - One case of severe edema
- Hypertension (12% vs. 3%)
- Acne (11% vs. 1%)
- One serious case of treatment-related pneumonia
- No deaths were determined treatment-related

Low-Dose Methylprednisone

- New diabetes (2% vs. 0%)
- No major cardiovascular events, fractures or GI bleeds
- No deaths were determined treatment-related (one infection-related death)

Note: Data reported as % in active treatment group versus % in placebo group unless specified otherwise

Subgroup Analyses and Heterogeneity

- Across the three interventions, effect modification was **not observed** for key outcomes by subpopulations defined by:
  - sociodemographic factors (e.g., sex, age, race, ethnicity)
  - risk of progression to ESKD (e.g., by baseline proteinuria levels)

Controversies and Uncertainties

Key Points

- Trial inclusion criteria generally included individuals with baseline uPCR ranging from ≥0.75 to 1.0 g/g. Smaller amounts of proteinuria may still be clinically important.
- Although the safety profile of sibeprenlimab and atacicept seem similar to placebo from trial data, rarer and longer-term side effects are hard to detect until a drug enters widespread clinical practice.
- Pivotal trial for Nefecon only tested 9-month treatment; patients may benefit from extended or repeated courses; an OLE is ongoing
- Experts disagree about role of systemic glucocorticoids (e.g., first line or second line) as well as assessment of side effects

e.g.: for example, g/g: gram per gram, OLE: open label extension, uPCR: urine protein-to-creatinine ratio

Benefits Beyond Health and Special Ethical Priorities

Key Points

- Some currently available immunosuppressive treatments can have substantial toxicities and variable efficacy, resulting in difficult treatment decisions and unmet need for less toxic and more effective therapies.
- Asian individuals in the United States have higher measured prevalence of IgAN.
- Once patients develop ESKD and require renal replacement therapy, caregiver needs increase. As such, new treatment options could allow caregivers more ability to pursue their own education, work, and family life.
- No anticipated improvement in access related to mode of administration.

ESKD: End-stage kidney disease, IgAN: immunoglobulin A nephropathy

Public Comments Received

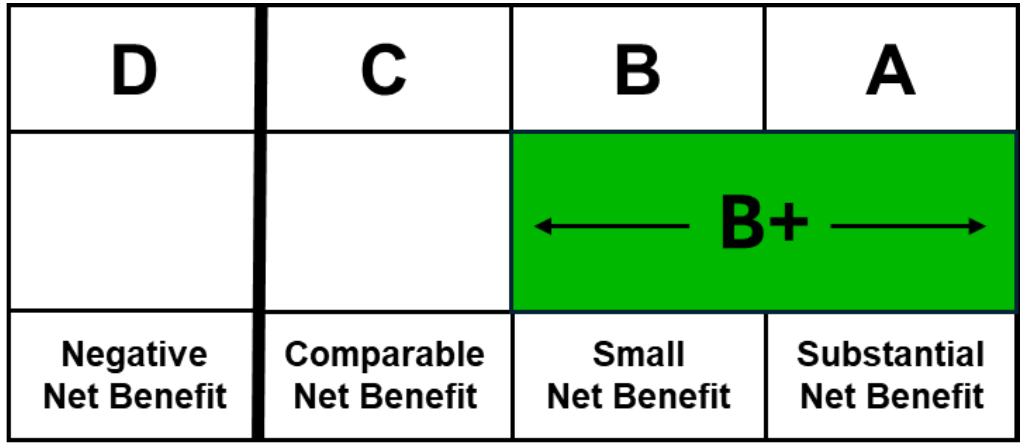
Selection of systemic glucocorticoids as a comparator

External validity of TESTING trial

Differences in trial populations impacts relative efficacy of interventions

Evidence Ratings of Interventions in People with IgA Nephropathy

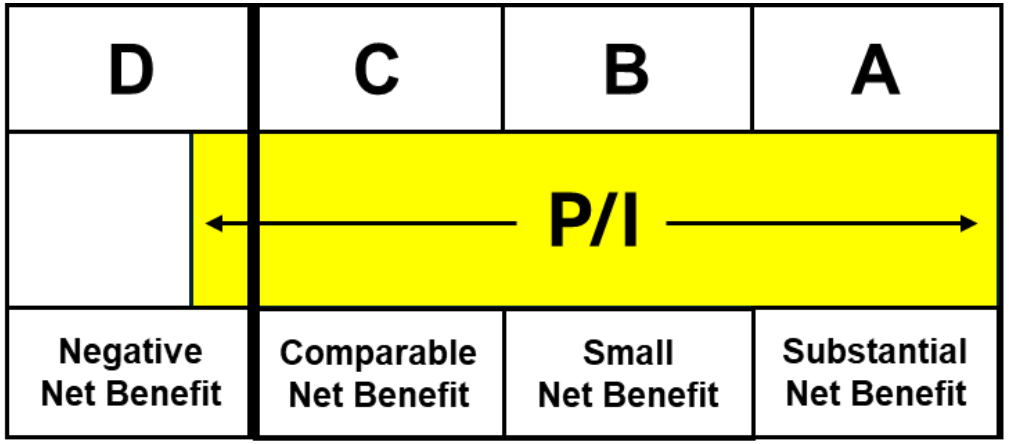
Sibeprenlimab, Atacicept, and Nefecon *each versus* **No Immunomodulatory Therapy**



At least a small net health benefit, and possibly substantially better

Evidence Ratings of Interventions in People with IgA Nephropathy

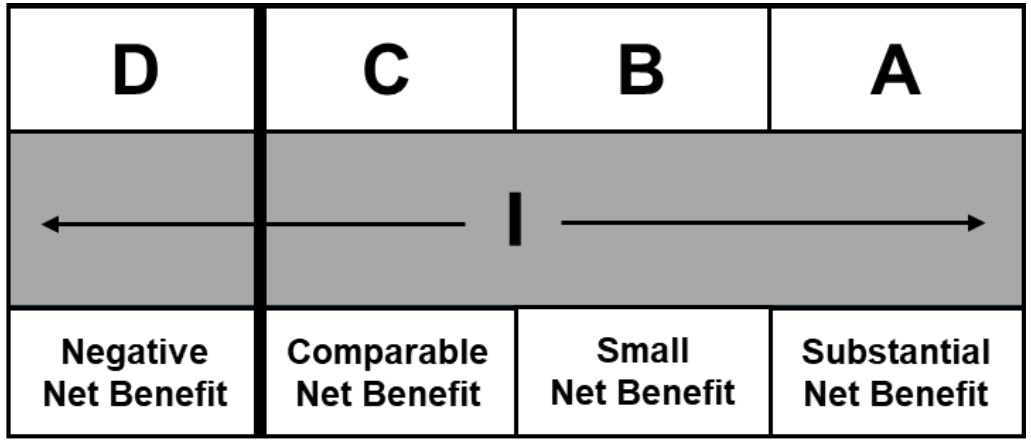
Sibeprenlimab, Atacicept, and Nefecon *each versus* **Systemic Glucocorticoids**



May be somewhat better, but possibly slightly worse

Evidence Ratings of Interventions in People with IgA Nephropathy

Sibeprenlimab, Atacicept, and Nefecon *each versus* **Each Other**



Insufficient evidence

Questions?

Presentation of the Economic Model

R. Brett McQueen, PhD

Associate Professor

University of Colorado Anschutz Medical Campus

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Key Team Members

Team Member	Title
R. Brett McQueen, PhD	Lead Modeler, Associate Professor, University of Colorado Anschutz Medical Campus
Michael J. DiStefano, PhD	Modeler, Assistant Professor, University of Colorado Anschutz Medical Campus
Antal Zemplenyi, PhD	Modeler, Visiting Research Associate, University of Colorado Anschutz Medical Campus
Deepika Paratane, MS, BPharm	Research Assistant, University of Colorado Anschutz Medical Campus
Woojung Lee, PhD	Associate Director of Health Economics and Decision Modeling, ICER
Marie Phillips, BA	Health Econ Research Assistant, ICER

Disclosures

Financial support provided to BM from the Institute for Clinical and Economic Review (ICER). MD, AZ, and DP have no conflicts to disclose. WL and MP are employees of ICER and have no conflicts to disclose.

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Objective

The aim of this analysis was to estimate the cost-effectiveness of atacicept, sibeprenlimab, and Nefecon for IgA nephropathy as compared to systemic glucocorticoids.

Unmet Need

Condition	Absolute evLY Shortfall	Proportional evLY Shortfall
IgA Nephropathy	18.7	59%
Other Example Conditions		
Multiple Sclerosis	18.9	52%
Osteoporosis	2.6	19%

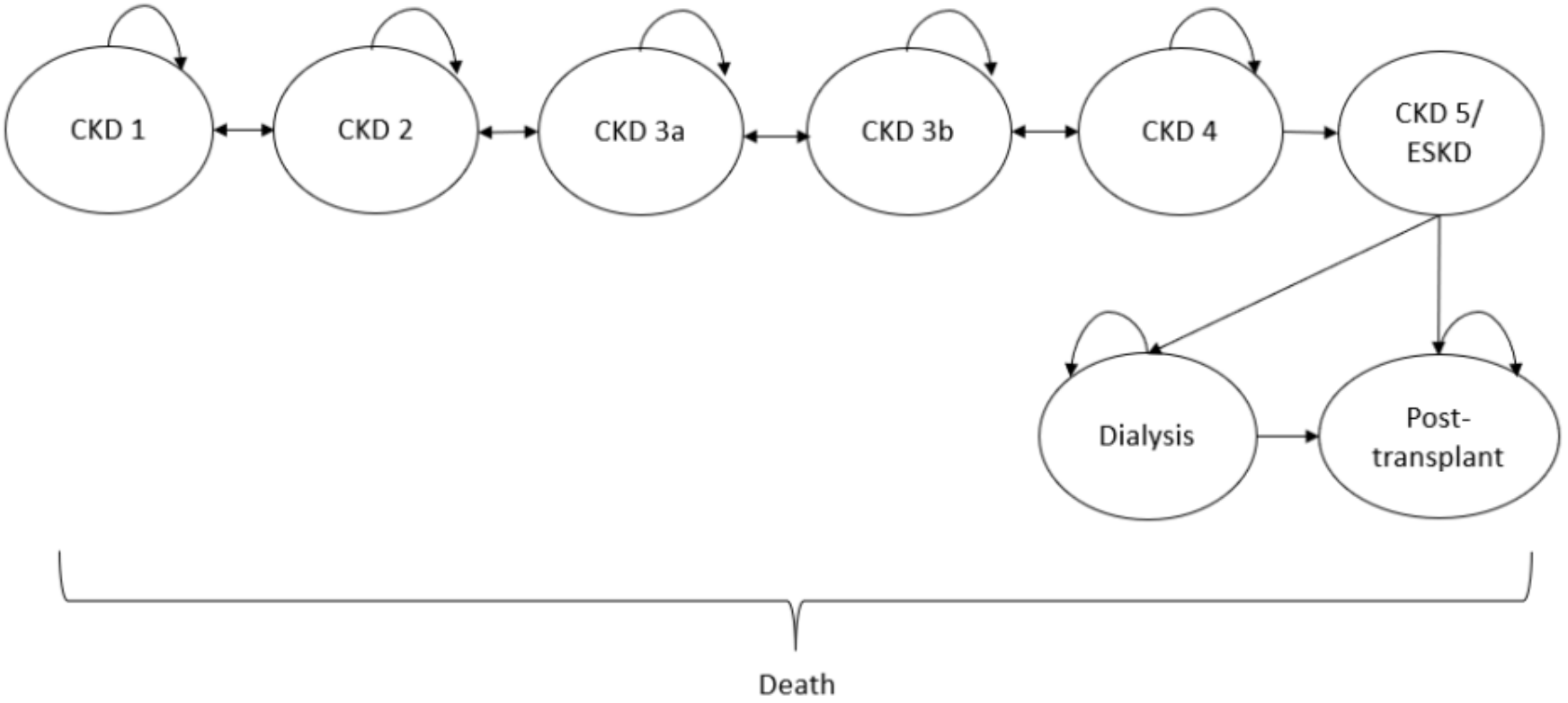
evLY: equal value of life years gained

Methods in Brief

Methods Overview

Domain	Approach
Model	Markov model
Setting	United States
Perspective	Health Care Sector Perspective and Modified Societal Perspective
Time Horizon	Patient lifetime
Discount Rate	3% per year (costs and outcomes)
Cycle Length	1 month
Primary Outcome	Total costs, quality-adjusted life years (QALY), life years (LYs), equal value of life years (evLY), time to ESKD, and incremental cost-effectiveness ratios

Model Schematic



CKD: chronic kidney disease, ESKD: end-stage kidney disease

Model Characteristics

	Model-Wide Baseline Characteristics	Source
Mean Age, Years	43	Lafayette et al. 2023
Female, %	36	Lafayette et al. 2023
Initial State Distribution Across CKD Stage, %	CKD 1: 3% CKD 2: 34% CKD 3a: 39% CKD 3b: 24% CKD 4: 0% CKD 5/ESKD: 0% Dialysis: 0% Post-transplant: 0%	Ramjee et al. 2023

CKD: chronic kidney disease, ESKD: end-stage kidney disease

Key Assumptions

- Treatment with Nefecon was applied for 9 months, with treatment durability lasting 24 months. For atacicept and sibeprenlimab, patients remained on treatment until reaching ESKD.
- Off-treatment transition probabilities derived from the best supportive care arm of the Phase III randomized trial NefIgArd Part B were applied consistently across interventions during periods without treatment, unless data showed otherwise.
- We used slope differences between each intervention and the placebo arm observed in clinical trials to calibrate on-treatment transition probabilities based on transition probabilities derived from the best supportive care arm of the Phase III NefIgArd Part B trial and used in a previous cost-effectiveness model. (Yaghoubi et al.)

Health State Utilities

Health State	Utility	Source
Utility For CKD Stages, Mean	Stage 1: 0.85 (Average US adult) Stage 2: 0.82 Stage 3a: 0.77 Stage 3b: 0.71 Stage 4: 0.70 Stage 5: 0.70	Tang et al. 2020, Pickard et al. 2019
Utility For Dialysis, Mean (95% CI)	0.565 (0.49-0.62)	Liem et al. 2008, Authors' calculation
Post-transplant, Mean (95% CI)	0.81 (0.72-0.90)	Liem et al. 2008
Chronic Oral Corticosteroid Use Disutility	-0.023	Norman et al. 2013

Treatment Costs

Drug	Annual WAC	Net Price
Atacicept (Annual)	n/a	$292,500*
Sibeprenlimab (Annual)	$390,000	$292,500†
Nefecon (9-month Treatment Course Over The Course Of One Year)	$165,113	$133,741†

*Placeholder price
†Estimated net price

IgA Nephropathy-Related Costs

Parameter	Cost	Source
CKD Stage (No Systemic Immunomodulatory Therapy), PPPM (sd)	Stage 1: $1,201 ($2,274) Stage 2: $834 ($2,145) Stage 3: $1,929 ($3,193) Stage 4: $5,965 ($10,463) Stage 5: $11,882 ($18,383)	Lerma et al. 2023, Pesce et al. 2025, Authors' calculation
CKD Stage (Systemic Glucocorticoids), PPPM (sd)	Stage 1: $3,485 ($6,590) Stage 2: $2,419 ($6,223) Stage 3: $5,595 ($9,263) Stage 4: $5,965 ($10,463) Stage 5: $11,882 ($18,383)	Lerma et al. 2023, Pesce et al. 2025, Authors' calculation
Dialysis (Commercial), PPPM (sd)	$18,679 ($8,476)*	United States Renal Data System 2024
Dialysis (Medicare), PPPM	$8,430*	League et al. 2022, American Kidney Fund, Authors' calculation
Transplant Episode, Mean	$446,800†	Ortner & Holzer 2025

*Dialysis health state costs replaced CKD stage health care utilization costs
†Charged amount

Mortality

Mortality Parameter	Value	Source
Standardized Mortality Ratio by eGFR Category (Pre-ESKD) (95% CI)	CKD stage 1 and 2: 0.7 (0.4-1.2) CKD stage 3a and 3b: 1.8 (1.2-2.7) CKD stage 4 and 5: 1.9 (1.1-3.3)	Knoop et al. 2013
Hazard Ratio for All-Cause Mortality Among Those Treated With Glucocorticoids (95% CI)	2.62 (0.52-13.05)	Lv et al. 2022
All-Cause Mortality Among Hemodialysis Patients, Deaths per 1,000 Person-Years	Ages 18-44: 92.1 Ages 45-64: 142.2 Ages 65-74: 221.1 Ages 75+: 318.3	United States Renal Data System 2024
All-Cause Mortality Among Transplant Patients, Deaths per 1,000 Person-Years	Ages 18-44: 13.3 Ages 45-64: 36.1 Ages 65-74: 79.8 Ages 75+: 154.7	United States Renal Data System 2024

CI: confidence interval, CKD: Chronic kidney disease, eGFR: estimated glomerular filtration rate

Results

Base-Case Results

Treatment	Intervention Acquisition Costs*	Intervention-Related Costs†	Non-Intervention Costs‡	Total Costs*	Time to ESKD (Years)	QALYs	evLYs	LYs
Sibeprenlimab	$5,044,000	$0	$840,000	$5,884,000	17.26	14.18	14.78	18.76
Atacicept	$4,986,000	$0	$851,000	$5,837,000	17.06	14.08	14.67	18.64
Nefecon	$128,000	$0	$1,329,000	$1,458,000	7.11	9.59	9.65	13.17
Systemic Glucocorticoids	$0§	$0	$1,393,000	$1,393,000	6.82	9.16	9.16	12.68

*For atacicept, results are based on placeholder price.
†Intervention-related costs include markup costs, administration costs, and costs of monitoring required for the intervention, as specified in clinical trials, guidelines, or package label.
‡Non-intervention costs include health state costs, dialysis and transplant charges, unrelated medical costs, and mortality costs associated with IgA nephropathy.
§Intervention acquisition costs for systemic glucocorticoids are captured in the non-intervention costs and are comparatively small.

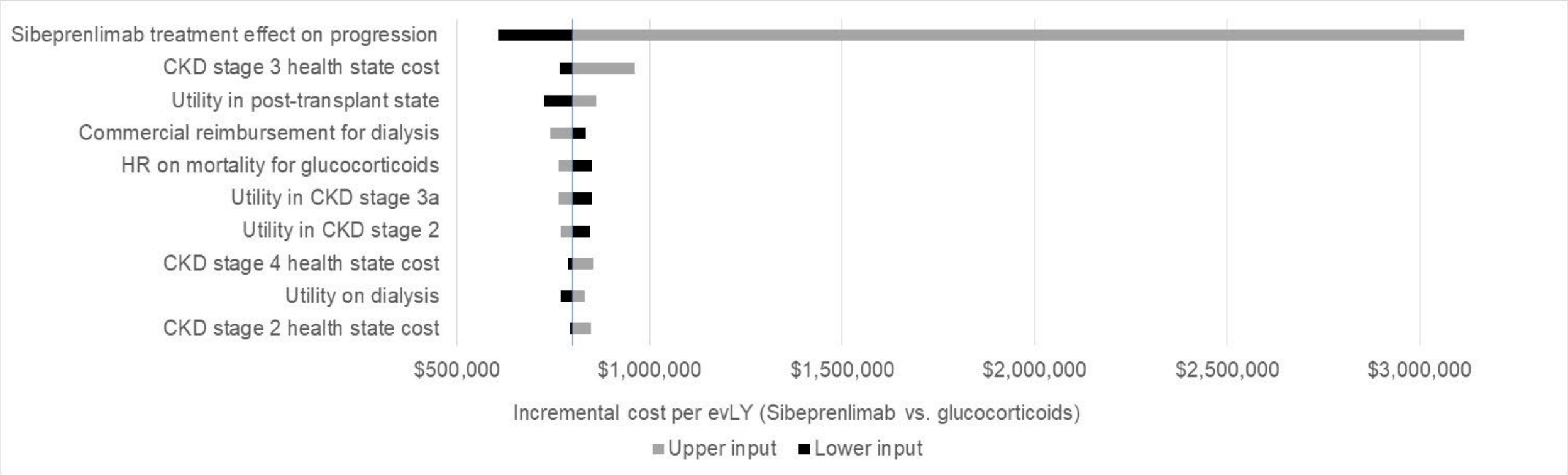
Base-Case Incremental Results

Treatment	Comparator	Cost per QALY Gained	Cost per evLY Gained	Cost per Life Year Gained	Cost per Year of Delayed ESKD Onset
Sibeprenlimab	Systemic Glucocorticoids	$894,000	$799,000	$739,000	$430,000
Atacicept*	Systemic Glucocorticoids	$904,000	$806,000	$746,000	$434,000
Nefecon	Systemic Glucocorticoids	$151,000	$132,000	$131,000	$225,000

*For atacicept, results are based on placeholder price.

ESKD: end-stage kidney disease, evLYs: equal value of life years, QALY: quality-adjusted life year

One Way Sensitivity Analyses



CKD: chronic kidney disease, evLY: equal value of life years, HR: Hazard ratio

Probabilistic Sensitivity Analysis

	Cost Effective at $50,000 per evLY Gained	Cost Effective at $100,000 per evLY Gained	Cost Effective at $150,000 per evLY Gained
Sibeprenlimab	0.0%	0.0%	0.0%
Atacicept*	0.0%	0.0%	0.0%
Nefecon	28%	31%	35%

*For atacicept, results are based on placeholder price.

Scenario Analyses: Cost per evLY

Treatment	Base-Case Results†	Modified Societal Perspective†	No Specific Immunomodulatory Therapy as Comparator	Systemic Glucocorticoid Costs and Disutilities Applied For 2 years (Lower) and Lifetime (Upper)†
Sibeprenlimab	$799,000	$771,000	$799,000	$812,000 (Lower) $779,000 (Upper)
Atacicept*	$806,000	$779,000	$806,000	$820,000 (Lower) $786,000(Upper)
Nefecon	$132,000	$147,000	$176,000	$247,000 (Lower) More effective, less costly (Upper)

*For atacicept, results are based on placeholder price.
†Comparator is systemic glucocorticoids.

Health Benefit Price Benchmark (HBPB)

Annual Prices Using…	Annual WAC	Annual Price at $100,000 Threshold	Annual Price at $150,000 Threshold	Discount from WAC to Reach Threshold Prices
Sibeprenlimab				
QALYs Gained	$390,000	**$61,000**	$75,600	81-84%
evLYs Gained	$390,000	$64,500	**$81,000**	79-83%
Atacicept				
QALYs Gained	$390,000*	**$60,000**	$74,500	81-85%
evLYs Gained	$390,000*	$64,000	**$80,000**	79-84%
Nefecon†				
QALYs Gained	$165,113	**$110,900**	$133,000	19-33%
evLYs Gained	$165,113	$117,500	**$143,000**	13-29%

*Placeholder price; The WAC price of atacicept was assumed to equal that of sibeprenlimab.

†The HBPB for Nefecon reflects the price for one 9-month treatment course over the course of one year.

Note: bolded prices indicate the lower and upper range of the Health Benefit Price Benchmark.

Limitations

- We are uncertain about both treatment duration and treatment durability for the interventions assessed in this analysis.
- While we approximated weighted averages of eGFR for each cohort, we did not have access to patient-level data which impacted our understanding of uncertainty in kidney functioning and its impact on survival and quality of life.
- We used charged amounts for transplant episode costs and ongoing post-transplant care costs. These cost estimates are unlikely to represent the actual amount paid.

Updates to the Evidence Report

- In the Draft Evidence Report, we incorrectly applied on-treatment transitions for systemic glucocorticoids for the lifetime of the model. Updated results reflect treatment duration of 2 years with steroids with adverse effects lasting 4 years.
- Since the publication of the draft report, new price estimates have become available and are used in the economic evaluation. Results for sibeprenlimab and atacicept are changed with the new prices.

Conclusions

- A single course of Nefecon is more expensive but more effective than systemic glucocorticoids, meeting the upper bound of commonly cited cost-effectiveness thresholds.
  - Uncertainty in whether Nefecon would meet commonly cited cost-effectiveness thresholds in scenario and probabilistic analyses.
- Sibeprenlimab leads to life extensions and improvements in quality of life but, at the current estimated net price, far exceeds commonly used cost-effectiveness thresholds.
- The cost-effectiveness of atacicept will depend on its actual price, though would also far exceed commonly used cost-effectiveness thresholds if priced similarly to sibeprenlimab.

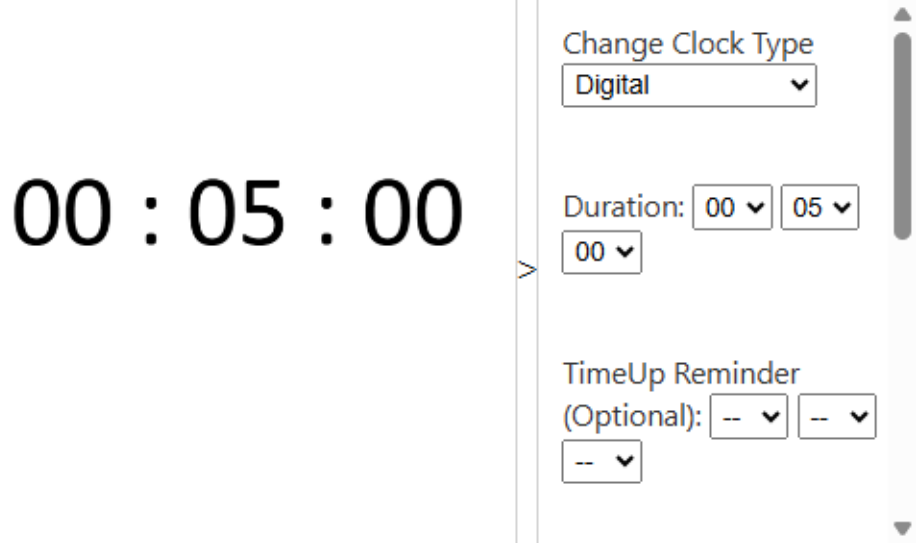
Questions?

Manufacturer Feedback on Economic Modeling

Jay Jackson, PharmD, MPH, BCMAS
Vice President, Health Economics & Outcomes Research,
Vera Therapeutics

Conflicts of Interest:

- *Dr. Jay Jackson is a full-time employee at Vera Therapeutics.*



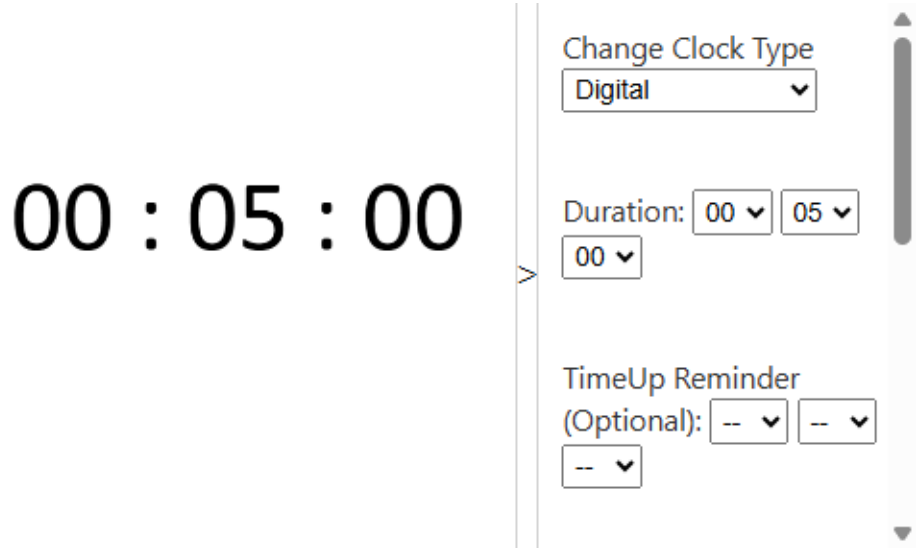
Public Comment and Discussion

Susan Brisendine

Vice President of Partnerships and Innovation at NephCure

Conflicts of Interest:

- *NephCure received 60% of its funding from healthcare companies including; Calliditas, Otsuka, and Vera Therapeutics.*

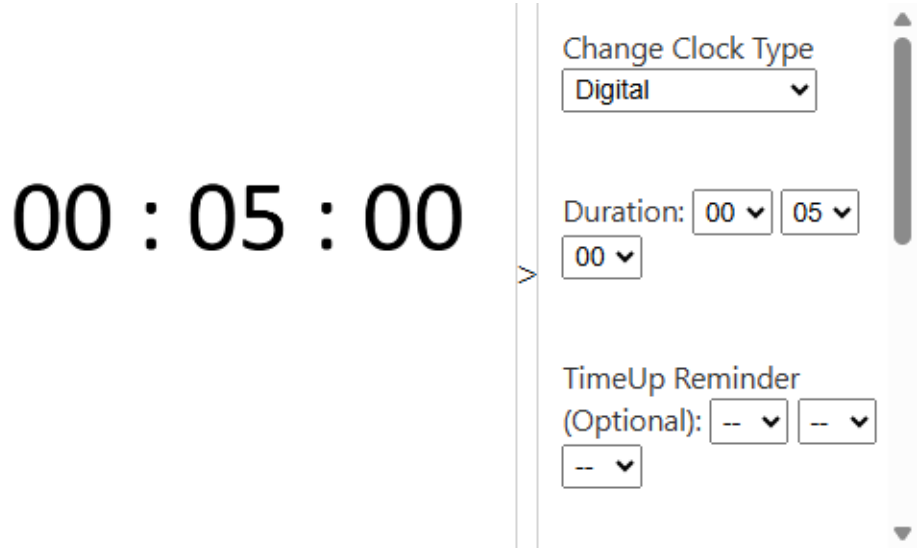


Kirk Campbell, MD

Professor of Medicine and Chief of the Renal-Electrolyte and Hypertension Division at the University of Pennsylvania Perelman School of Medicine

Conflicts of Interest:

- *Dr. Campbell has received funds from Calliditas, Vera Therapeutics, Otsuka, AstraZeneca, and Novartis.*
- *Dr. Campbell serves as volunteer Co-Medical Director and Advisor on Board of Directors with NephCure.*

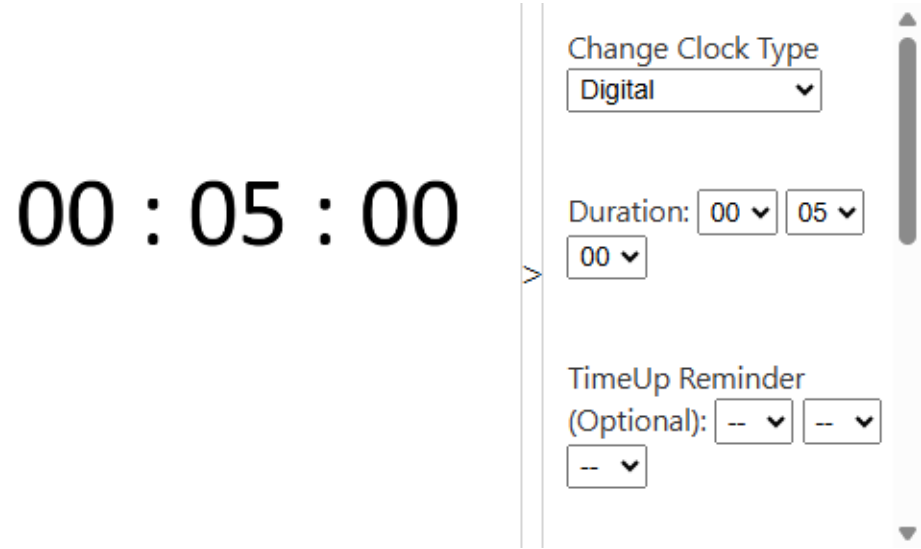


Manufacturer Public Comment and Discussion

Steve Rizk, PharmD, JD
Senior Vice President, Medical Affairs, Veloxis Pharmaceuticals

Conflicts of Interest:

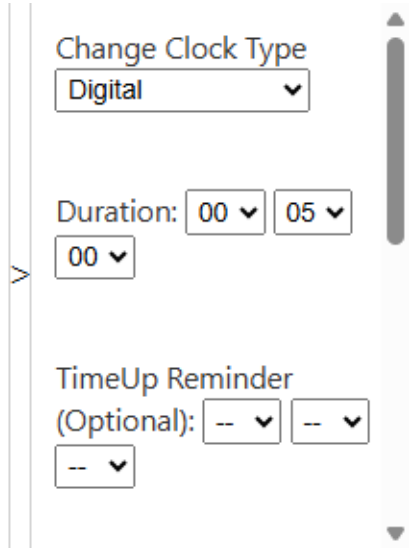
- *Dr. Steve Rizk is a full-time employee of Veloxis Pharmaceuticals and Calliditas Therapeutics.*



Robert Brenner, MD
Chief Medical Officer, Vera Therapeutics

Conflicts of Interest:

- *Dr. Robert Brenner is a full-time employee at Vera Therapeutics.*



Lunch

Meeting will resume at 11:55 AM PT (2:55 PM ET)

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Voting Questions

Patient Population For All Questions: People with IgA Nephropathy (IgAN)

Special Ethical Priorities

To help inform judgements of overall long-term value for money, please answer the following questions:

1. Are there particular obligations to people with this condition because of disease severity and/or unmet need with currently available therapies?

2. Are there particular obligations to people with this condition because it disproportionately affects those from a racial/ethnic group that have not been equitably served by the healthcare system?

3. Apart from issues around disease severity/unmet need and race/ethnicity, are there other particular obligations to people with this condition?

Clinical Evidence

4. Is the current evidence adequate to demonstrate that the net health benefit of sibeprenlimab is greater than that of no specific immunomodulatory therapy?

5. Is the current evidence adequate to demonstrate that the net health benefit of atacicept is greater than that of no specific immunomodulatory therapy?

6. Is the current evidence adequate to demonstrate that the net health benefit of Nefecon is greater than that of no specific immunomodulatory therapy?

7. Is the current evidence adequate to demonstrate that the net health benefit of sibeprenlimab is greater than that of systemic glucocorticoids?

8. Is the current evidence adequate to demonstrate that the net health benefit of atacicept is greater than that of systemic glucocorticoids?

9. Is the current evidence adequate to demonstrate that the net health benefit of Nefecon is greater than that of systemic glucocorticoids?

10. Which intervention has the greater net health benefit?

11. Which intervention has the greater net health benefit?

12. Which intervention has the greater net health benefit?

Benefits Beyond Health

To help inform judgments of overall long-term value for money, please answer the following questions about sibeprenlimab, atacicept, and Nefecon when compared to systemic glucocorticoids:

13. Is sibeprenlimab likely to improve caregivers' quality of life and/or ability to pursue their own education, work, and family life?

14. Is atacicept likely to improve caregivers' quality of life and/or ability to pursue their own education, work, and family life?

15. Is Nefecon likely to improve caregivers' quality of life and/or ability to pursue their own education, work, and family life?

Long-Term Value for Money

16. Given the available evidence on comparative clinical effectiveness and incremental cost effectiveness, and considering benefits beyond health and special ethical priorities, what is the long-term value for money of sibeprenlimab at current pricing?

17. Given the available evidence on comparative clinical effectiveness and incremental cost effectiveness, and considering benefits beyond health and special ethical priorities, what is the long-term value for money of Nefecon at current pricing?

Break

Meeting will resume at 1:15 PM PT (4:15 PM ET)

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Policy Roundtable

Policy Roundtable

Participant	Conflict of Interest
Jonathan Barratt, PhD, FRCP Professor of Renal Medicine, University of Leicester	Dr. Jonathan Barratt has received funds from health care companies including; Calliditas, Vera Therapeutics, Otsuka, AstraZeneca, Argenx, Biogen, Novartis,Vertex, Takeda, Biohaven.
Leslie Fish, PharmD Executive Vice President, Clinical Pharmacy, IPD Analytics	Dr. Leslie Fish is a full-time employee at IPD Analytics.
Lobat Hashemi, PhD Global Head, Health Economics and Outcomes Research, Veloxis Pharmaceuticals	Dr. Lobat Hashemi is a full-time employee at Veloxis Pharmaceuticals and Calliditas Therapeutics.
Jay Jackson, PharmD, MPH, BCMAS Vice President, Health Economics & Outcomes Research, Vera Therapeutics	Dr. Jay Jackson is a full-time employee at Vera Therapeutics.
Anthony “Tony” Pisa Individual Living with IgAN	Tony Pisa is a volunteer Patient Advocate with NephCure.
Samantha Schweisthal Individual Living with IgAN	Samantha Schweisthal is a volunteer Patient Ambassador for the state of Alabama with the IgAN Foundation.
Shikha Wadhwani, MD, MS, FASN Associate Professor of Medicine, Division of Nephrology & Hypertension, University of Texas Medical Branch	Dr. Shikha Wadhwani has received funds from health care companies including; Calliditas, Vera Therapeutics, Otsuka, Alexion, Biogen, Boehringer Ingelheim, Dimerix, Novartis, and Travere.

CTAF Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around March 31st, 2026
    - Includes description of CTAF votes, deliberation, policy roundtable discussion
- Materials available at: https://icer.org/assessment/iga-nephropathy-2025/#overview

Adjourn

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