Helen Trenz | helen.trenz@novartis.com

Quantifying Spillover Impacts: Effect of Novel Therapies for IgA Nephropathy on Patients Awaiting Kidney Transplant

Jaehong Kim,¹ Jacob Fajnor,¹ Jason Shafrin,^{1,2} Briana Ndife,³ Helen Trenz,³ Titte R. Srinivas,³ Ajay Israni⁴

¹Center for Healthcare Economics and Policy, FTI Consulting, Los Angeles, California, USA; ²Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, California, USA; ³Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA;

⁴Department of Internal Medicine, University of Texas Medical Branch, Galveston, Texas, USA

KEY FINDINGS & CONCLUSIONS

- Novel IgAN interventions saved an average of 669 kidneys per year, which reduced overall kidney transplant waitlist size, reduced average transplant wait time by 25 days per waitlist candidate, and generated an additional 0.087 QALYs (monetized benefit: \$13,116) per waitlist candidate
- Within 5 years of model start, IgAN interventions reduced the overall size of the kidney transplant waitlist by 2138 candidates
- Spillover benefits (0.410 QALYs and \$61,485 per patient with IgAN) comprised 23.1% of total IgAN treatment value
- To capture the full societal value of novel IgAN treatments, the spillover benefits of reduced kidney transplant demand should be considered



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INTRODUCTION

METHODS

- novel therapies
- the US ("waitlist")

Spillover Model

- the double queuing model
- Supplementary Table 1

RESULTS

- kidneys per year (**Figure 2**)
- (Figure 3)
- waitlist candidate

Figure 2. Annual Demand for Kidney Transplants by Patients With IgAN



IgAN, immunoglobulin A nephropathy

References

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 IgAN is the most common primary glomerulonephritis worldwide and a leading cause of CKD; up to 50% of patients experience kidney failure within 10 to 20 years of diagnosis¹⁻⁴

 In the US, the OPTN kidney transplant waitlist includes >90,000 candidates with a median transplant wait time of ~4 years^{5,6}

 In recent years, the treatment landscape for IgAN has rapidly evolved.⁷ Novel IgAN therapeutics may reduce kidney transplant demand among patients with IgAN and thereby increase organ availability for other transplant candidates

 This study quantified not only the direct health economic benefits of novel interventions for patients with IgAN but also highlights their substantial impact ("spillover benefits") on the US kidney transplant system by reducing the number of transplant candidates on the kidney transplant waitlist

• This study implemented two health economic modeling frameworks:

- First, a Markov model estimated health benefits accrued among adults with IgAN receiving

- Second, Markov model results were inputted into a double queuing model to quantify the additional value ("spillover benefits") accrued by all candidates in need of a living or deceased donor kidney transplant in

• The overall structure of the spillover model (comprising the Markov model and the double queuing model) is shown in **Figure 1**

• Markov model: The progression-based simulation predicted reduced entry of patients with IgAN to the transplant waitlist due to interventions, using CKD staging and assuming a uniform uptake rate for all interventions (Supplementary Methods, Supplementary Figure 1)

• **Double queuing model:** Accounting for the dynamic interplay between patient demand and organ supply, the relative reduction in patients with IgAN entering the kidney transplant waitlist from the Markov model was applied to the OPTN-reported annual arrival rate of patients with IgAN and incorporated into

• PICOTS criteria for the spillover model are summarized in **Table 1**

• Key inputs for the spillover model are summarized in **Table 2**; the full list of inputs is provided in

• Novel IgAN interventions reduced annual kidney transplant demand by 33.4%, saving an average of 669

• The reduction in kidney transplant demand among treated patients with IgAN reduced the overall waitlist size by 2138 candidates within 5 years of model start and by 3586 candidates in the steady-state equilibrium

The spillover benefits of IgAN interventions for patients on the waitlist are summarized in **Table 3** - Reductions in waitlist size decreased the average transplant wait time by 25 days (0.070 years) per

- Reductions in wait times generated 0.087 QALYs (monetized benefit US\$13,116) per waitlist candidate • Per treated patient with IgAN, novel interventions generated 1.772 QALYs, 23.1% (0.410 QALYs) of which were attributable to spillover benefit (Figure 4)

• Spillover benefits per patient with IgAN were mildly sensitive to treatment utilization (100% dapagliflozin treatment: 21.7% of total value) and modestly sensitive to changes in the annual rate of candidate arrivals to the waitlist (+20%: 19.7% of total value, -20%: 28.0% of total value) (Supplementary Table 2)

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Intervention

Delay in progression of gAN by novel treatments

Criteria

Population

Intervention

Comparator

Outcomes

Timing

Setting

100,000



^aThe transplant waitlist size reached steady-state equilibrium 27 months earlier in the intervention arm vs the comparator arm (first quarter of year 33 vs second quarter of year 35, respectively). Steady-state equilibrium was defined as the point when quarterly change in waitlist size relative to both (i) the previous quarter and (ii) the average waitlist size over the remaining period (until year 70) was less than 0.01%. US, United States.

Table 3. Spillover Benefits per Kidney Transplant Candidate

Outcomes

Wait time for

LY, life-year; QALY, quality-adjusted life-year; US. United States



Individuals in the US of any age awaiting kidney transplant FDA-approved therapeutics that reduce proteinuria (iptacopan, atrasentan)^{8,9} or slow eGFR decline

- (sparsentan, delayed-release budesonide, dapagliflozin)¹⁰⁻¹² in patients with IgAN, in addition to supportive care and systemic corticosteroids
- Supportive care (ACEi/ARB, blood pressure management, lifestyle changes, CVD management) and systemic corticosteroids. Patients with kidney failure were assumed to receive dialysis
- **Clinical outcomes:** Reduction in kidney demand (average number of kidneys saved annually); arrival rate of treated patients with IgAN to the waitlist; average number of patients with CKD on the waitlist; average transplant wait time; LYs
- Health economic outcomes: QALYs; monetized value of additional health gains; share of treatment value attributable to spillover effects
- Lifetime horizon of 70 years; 3-month cycle length
- Societal perspective

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; FDA, US Food and Drug Administration; IgAN, immunoglobulin A nephropathy; LY, life-year; PICOTS, population, intervention, comparator, outcomes, timing, and setting; QALY, quality-adjusted life-year; US, United States.

Figure 3. US Kidney Transplant Waitlist Size Over Time^a

	Intervention [A]	Comparator [B]	Difference [A-B]	
r kidney transplant (years)	2.423	2.493	-0.070	
	12.134	12.072	0.063	
	7.786	7.698	0.087	
QALYs (US\$)	1,167,847	1,154,730	13,116	

Abbreviations

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; FDA, US Food and Drug Administration; HR, hazard ratio; IgAN, immunoglobulin A nephropathy; KDIGO, Kidney Disease: Improving Global Outcomes; LY, lifeyear; OPTN, Organ Procurement and Transplantation Network; PICOTS, population, intervention, comparator, outcomes, timing, and setting; QALY, quality-adjusted life-year; US, United States.

Disclosures

Table 2 Key Snillover Model Innuts

lable Z. Rey Spillovel Model Inputs			
Parameter	Value		
No. of organ arrivals per year	27,332		
No. of total waitlist arrivals per year	44,561		
No. of patients with IgAN arriving to waitlist per year	2004		
Time to candidate removal (years)	5.239		
US IgAN prevalence (%)	0.033		
US IgAN incidence (%)	0.003		
Treatment efficacy (HR) ^a	0.526		
Quality of life			
CKD 1, CKD 2, CKD 3a, CKD 3b	0.670		
CKD4	0.550		
ESKD	0.540		
LYs ^b			
With transplant	14.66		
Without transplant	7.96		
QALYs ^b			
With transplant	11.39		
Willingness to pay for a QALY (US\$)	150,000		

^aThe Markov model used a mean disease progression delay calculated from observed reductions in eGFR decline or meta-regression estimates of eGFR decline from available proteinuria reduction data.⁸⁻¹² ^bLiterature values discounted at a rate of 3.5%. Values were undiscounted assuming a uniform distribution of LYs and constant universal discounting method.

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HR, hazard ratio; IgAN, immunoglobulin A nephropathy; LY, life-year; QALY, quality-adjusted life-year; US, United States.

Scenario Analysis

• The study considered several scenarios of interest, including variations in (i) treatment utilization; (ii) cost-effectiveness threshold; (iii) waitlist size; (iv) average candidate time on waitlist; and (v) annual waitlist candidate arrival rate

Figure 4. Share of Treatment Value Attributable to Spillover Benefits per Patient With IgAN



IgAN, immunoglobulin A nephropathy; QALY, quality-adjusted life-year; US, United States.

Limitations

Modeled efficacy was not specific to individual treatments

• The model did not consider that patients with IgAN may experience additional health improvements from novel interventions due to reduced kidney transplant wait times in the IgAN population; therefore, the measured spillover effect is a conservative estimate

Waitlist survival outcomes were based on the median patient

JK, JF, and JS are employees of FTI Consulting, Los Angeles, California, USA. **BN**, **HT**, and **TRS** are employees of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA. AI is an employee of University of Texas Medical Branch, Galveston, Texas, USA, and has received consulting fees from Novartis and Vera Pharmaceuticals.

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