IgA Nephropathy (IgAN) In Adults: A Retrospective Analysis Of US Prevalence And Impacts Of Proteinuria And Kidney Function Decline On Healthcare Resource Utilization (HRU) And Costs

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Baseline characteristics

The prevalence cohort consisted of 9,984 patients; mean age 44.9 years (91.9% aged \geq 18 years), 42.8% female and 74.1% Caucasian. Mean proteinuria was 0.6 g/day, mean eGFR was 60.9 mL/min/1.73 m², and 45.8% of patients were in CKD stages 3-5 (**Table**) • Among patients of all ages, the average annual estimated standardized prevalence of IgAN in the US (2016-2020) was 328.97 per 1,000,000 based on US Census Bureau data (Table 2) 1). Among patients with available data, 64% had proteinuria ≥ 1 g/day, which is associated with a high risk of progression.
 Table 2. Standardized prevalence

The HRU/Cost cohort consisted of 813 adult patients (aged \geq 18 years) with linked clai data; mean age 47.4 years, 37.3% female and 74.9% Caucasian. Mean proteinuria wa 0.6 g/day, mean eGFR was 57.7 mL/min/1.73 m², and 49.4% of patients were in CKD stages 3-5 (Table 1).

Table 1. Baseline demographic and clinical characteristics

	Prevalence (n=9,984)	HRU/Cost (n=813)		
Age, Mean (SD), years	44.9 (17.8)	47.4 (13.7)		
Age, n (%)				
≥18 years	9,178 (91.9)	813 (100.0)		
Gender, n (%), Female	4,271 (42.8)	303 (37.3)		
Ethnicity, n (%), Not Hispanic	8,228 (82.4)	668 (82.2)		
Race, n (%)				
Caucasian	7,401 (74.1)	609 (74.9)		
Asian	958 (9.6)	82 (10.1)		
African American	481 (4.8)	32 (3.9)		
Insurance type, n (%)				
Commercial	5,726 (57.4)	554 (68.1)		
Medicare	2,235 (22.4)	146 (18.0)		
Medicaid	1,372 (13.7)	92 (11.3)		
Proteinuria, g/day, mean (SD)	0.6 (2.0)	0.6 (1.9)		
eGFR, mean (SD)	60.9 (43.3)	57.7 (35.9)		
CKD stage, n (%)				
Stage 1	1,881 (18.8)	136 (16.7)		
Stage 2	1,279 (12.8)	133 (16.4)		
Stage 3	1,733 (17.4)	173 (21.3)		
Stage 4	890 (8.9)	76 (9.3)		
Stage 5/ESKD	1,947 (19.5)	153 (18.8)		
Unknown	2,254 (22.6)	142 (17.5)		
Charlson Comorbidity Index, mean (SD)	1.2 (1.7)	1.3 (1.5)		
Any CV event, n (%)	262 (2.6)	22 (2.7)		

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In the US, IgAN is the most common primary glomerular disease in young Caucasian adults and if not controlled, results in progression to End Stage Kidney Disease (ESKD) or End Stage Renal Disease (ESRD), also called chronic kidney failure (CKF)¹⁻⁵

- KDIGO guidelines recognize proteinuria ≥1 g/day as indicative of a high risk of progression and recommend reduction to <1 g/day as a therapeutic goal⁶
- Few studies have reported estimates of US prevalence, or the HRU/costs associated with IgAN

Objectives

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- Estimate the prevalence and profile of patients with IgAN in the US population
- Describe IgAN patient characteristics
- Estimate all-cause HRU and costs for patients with IgAN stratified by proteinuria level (<1.0 g/day vs \geq 1.0 g/day) and chronic kidney disease (CKD) stage

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Study design and data source

- Descriptive, retrospective analysis based on Optum[®] de-identified Market Clarity and proprietary Natural Language Processed (NLP) Data
- The Optum[®] de-identified Market Clarity Dataset deterministically links medical and pharmacy claims with electronic health record (EHR) data from providers across the care continuum
- Study period: January 01, 2006 March 31, 2021
- Identification period: July 01, 2006 March 31, 2021 (index identification period)
- Baseline period: 6 months prior to index
- Index date: first IgAN NLP term within the identification period
- All costs were normalized/discounted and adjusted to 2020 USD using the Consumer Price Index and presented as per patient per month (PPPM) values
- Cost estimates include those incurred for ESKD care; ESKD defined as: first evidence of CKD stage 5 (eGFR <15 mL/min/1.73 m² or ICD-10: N18.5), kidney transplant procedure, dialysis

Prevalence of IgAN in the United States

ked claims uria was in CKD	Year	Standardized prevalence per 1,000,000 US population (95% CI)
/Cost 813) (13.7)	2016	269.99 (243.40, 300.00)
	2017	313.43 (283.76, 346.71)
	2018	345.23 (312.10, 382.54)
100.0)	2019	333.67 (300.59, 371.00)
37.3)	2020	382.53 (342.39, 428.39)
82 2)		

Unadjusted HRU/costs among adults with IgAN by baseline proteinuria level

- Among adult patients with proteinuria data at baseline (Figure 1), 57.6% had proteinuria ≥ 1.0 g/day at baseline, which is associated with a high risk of progression⁶
- High-risk proteinuria in adult patients was associated with a higher mean PPPM number of outpatient visits (2.80 vs. 2.02 P=0.110) and pharmacy claims (3.27 vs 2.70; P=0.200) compared with proteinuria <1.0 g/day, although the differences were not statistically significant (Figure 1)
- Mean total costs PPPM were significantly higher for adult patients with high-risk proteinuria (≥ 1 g/day, \$2,638 vs <1 g/day, \$1,496; P=0.049) (Figure 1)

Unadjusted HRU/costs among adults with IgAN by baseline **CKD** stage

- Higher CKD stage at baseline was associated with a significantly higher number of outpatient visits and pharmacy claims PPPM for adult patients (both P<0.001) (Figure 2)
- Mean total cost (PPPM) increased significantly with higher CKD stage in adult patients (P<0.001) (Figure 2)

Statistical analysis

• Categorical and continuous variables were summarized using descriptive statistics. Standardized prevalence was estimated using direct standardization method. HRU/costs by proteinuria and CKD stage were assessed using generalized linear models.

Inclusion criteria (prevalence and **HRU/cost cohorts**)

- Patients with ≥ 2 NLP term entries with "iga nephropathy", "immunoglobulin a nephropathy", "berger's disease", "berger's nephropathy", "iga glomerulonephritis", or "immunoglobulin a glomerulonephritis", within 180 days at least 30 days apart
- Patients with negation terms in relation to the IgAN SDS term were excluded (negation terms: 'deny', 'failed', 'ignore', 'n/a', 'negative', 'question' 'reject', 'rule out', 'uncertain', 'unspecified')

Inclusion criteria (HRU/cost cohort)

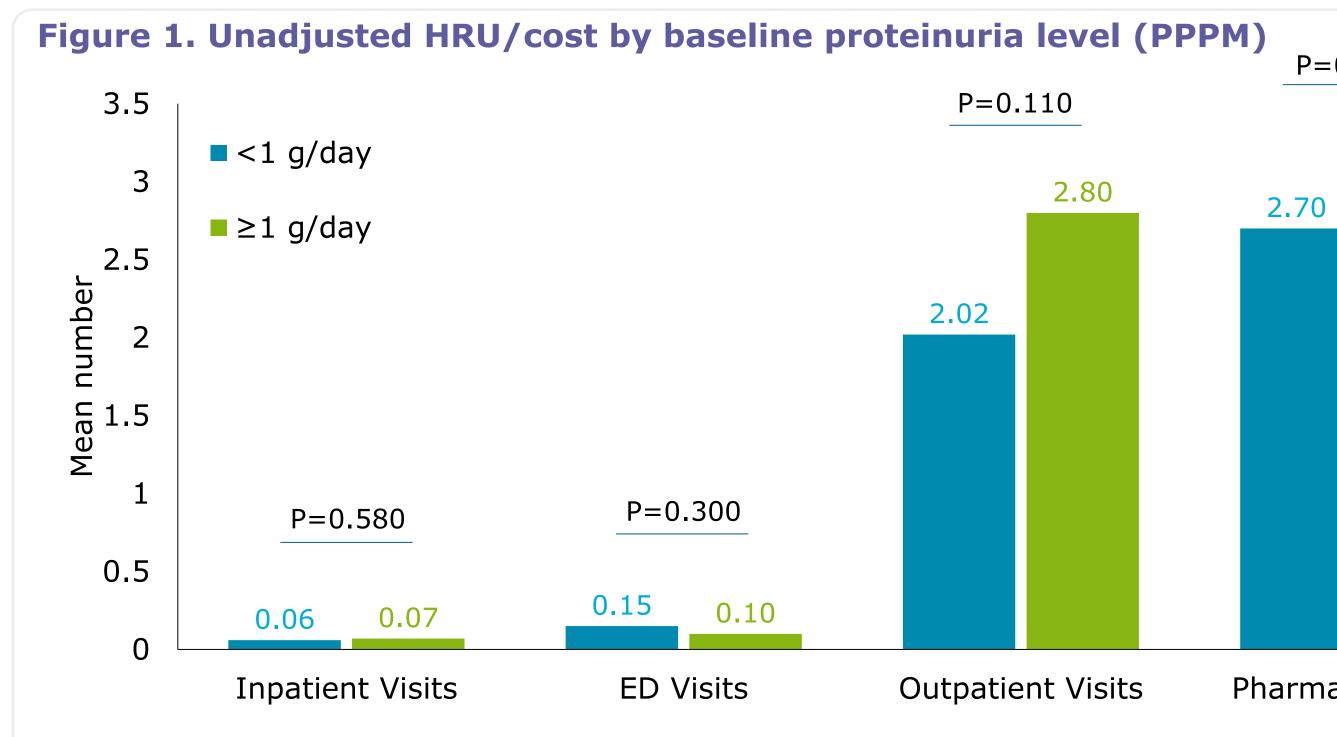
Exclusion criteria (HRU/cost cohort)

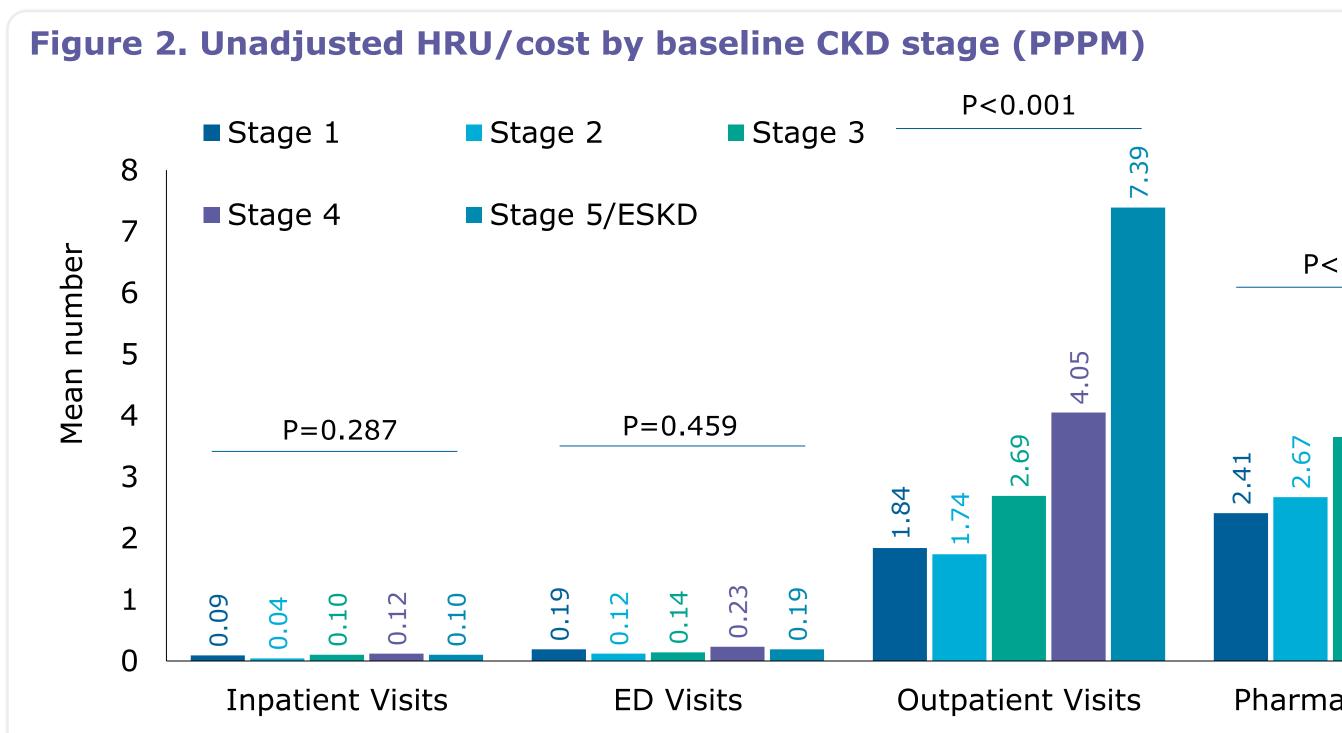
- Cancer diagnosis pre- or post-index Pregnancy pre-index
- COVID-19 pre- or post-index

Methods updates since abstract submission

- Study period extended from March 31, 2020 to March 31, 2021
- Denominators for prevalence calculations updated to align with method used for patient identification (i.e., only including patients with activity captured by EHR)

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 >6 months pre-index continuous enrollment (baseline) >6 months post-index continuous enrollment (follow-up) • Patients with linked Optum Market Clarity claims data

Proteinuria stratifications changed from UP/C to 24-hour urine protein excretion

Limitations

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- of-pocket costs to patients were not included

proteinuria	Mean (SD)
<1 g/day n=87 (42.4%)	\$1,496 (\$2,649)
≥1 g/day n=118 (57.6%)	\$2,638 (\$4,831)
P value	0.049

Pharmacy Claims

			Baseline CKD stage	Total Cost, Mean (SD)
<0.0	01		1 n=136 (20.3%)	\$1,662 (\$3,146)
		4.92	2 n=133 (19.8%)	\$1,451 (\$3,360)
3.65	3.88		3 n=173 (25.8%)	\$2,491 (\$4,196)
			4 n=76 (11.3%)	\$4,983 (\$8,305)
			5/ESKD n=153 – (22.8%)	\$8,539 (\$12,495)
асу	Clai	ms	P value	<0.001

A substantial proportion of patients with IgAN have higher severity of proteinuria (≥ 1 g/day) which is associated with higher HRU and a significantly greater cost burden (P=0.049)

Advancing CKD stage from stage 1 to stage 5/ESKD is associated with significant increases in HRU and total costs (P<0.001)

This study was limited to data in the Optum Market Clarity database and may not be representative of the US population

Optum applies standard pricing algorithms to account for differences in pricing across health plans and provider contracts with resulting cost information designed to reflect allowed payments for all provider services across regions

Missing data or errors in detection of IgAN-related terms in patient records may introduce bias into the analyses including potential underestimation of US prevalence. Patients with IgANrelated terms may have more severe disease and bias results.

The cost data provide a partial view of economic burden as out-

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CONCLUSIONS

Increasing prevalence of IgAN was observed between 2016 and 2020, which may indicate better disease awareness

HRU and costs are higher for patients with higher severity of proteinuria and worsening kidney function

Treatments that reduce proteinuria and slow the rate of decline in kidney function have the potential to reduce the resource intensity and economic burden of IgAN

DISCLOSURES

Mark Bensink is the Managing Director of BenofitConsulting which received consulting fees from Travere Therapeutics, Inc.; Kamlesh M **hakker** has a consulting contract with Travere Therapeutics, Inc. and does not have any equity interest in Travere Therapeutics, Inc.; Edgar **Lerma** received consulting fees from Travere Therapeutics, Inc; Juan Carlos Velez received consulting fees fr.om Travere Therapeutics, Inc.; Richard Lieblich received consulting fees from Travere Therapeutics, Inc.; Martin Bunke is a consultant for Travere Therapeutics, Inc.; Kaijun **Wang** is an employee and stockholder of Travere Therapeutics, Inc.; **Diana Amari, Anusorn** Thanataveerat, David Oliveri, Andrew Rava, and David Cork are employees of Genesis Research which received compensation from Travere Therapeutics, Inc. for conducting this study.

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ABBREVIATIONS

CI, confidence interval; CKD, chronic kidney disease; CKF, chronic kidney failure; ED, emergency department; eGFR, estimated glomerular filtration rate; EHR, electronic health record; ESKD, end-stage kidney disease; HRU, healthcare resource utilization; IgAN, IgA nephropathy; KDIGO, Kidney Disease Improving Global Outcomes; NLP, natural language processed; PPPM, per-patient-per-month; SD, standard deviation; UP/C, urine protein/ creatinine ratio; USD, United States Dollars

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