Real-world Economic Implications of Achieving Low Disease Activity in Lupus Nephritis

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BACKGROUND

- Lupus nephritis (LN) is a common and severe manifestation of systemic lupus erythematosus (SLE), affecting approximately 50% of SLE patients and leading to end-stage renal disease (ESRD) in up to 30% of patients[1]
- Previous studies have reported higher healthcare costs in patients with SLE that develop LN compared to patients without LN[2,3]
- One of the main goals of LN treatment is to achieve low disease activity to preserve kidney function, with decreases in proteinuria within 6 to 12 months of initiating treatment associated with better long-term outcomes[4,5]
- While the clinical value of achieving low disease activity or clinical remission has been well documented, the impact on healthcare costs are less defined
- The purpose of this analysis was to understand the real-world economic implications of achieving low disease activity compared to active disease or ESRD in a large LN population

METHODS

- This retrospective, observational analysis included US patients ≥18 years of age within Optum's health plan identified with ICD-9 or ICD-10 codes to have SLE and evidence of LN between January 1, 2015, and December 31, 2019, and with ≥2 months of follow-up data
- Low disease activity was defined by the following: evidence of glucocorticoid doses ≤5 mg/day, evidence of mycophenolate mofetil (MMF) doses ≤2 g/day, and no use of cyclophosphamide for ≥6 consecutive months
- Follow-up time that could not be defined as low disease activity was defined as an active disease period, except for periods with evidence of ESRD determined by ≥1 ESRD diagnosis code, evidence of dialysis, treatment with phosphate binders, or evidence of kidney transplant
- Healthcare payer costs for medical and pharmacy services paid during defined periods of low disease activity, active disease, and ESRD were calculated and compared

IDENTIFICATION OF PATIENTS WITH LUPUS NEPHRITIS

Patients were deemed to have LN if they met any of the following conditions:
≥1 inpatient diagnosis (non-diagnostic medical claim) for glomerular disease in SLE (ICD10: M32.14), or
≥2 outpatient diagnoses (non-diagnostic medical claim) for glomerular disease in SLE at least 30 days apart (ICD10: 32.14), or
≥1 inpatient diagnosis or ≥2 outpatient diagnoses (non-diagnostic medical claim) for SLE (ICD9: 710.0 or ICD10: M32), and ≥1 nephrologist visits during study period, or
≥1 inpatient diagnosis or ≥2 outpatient diagnoses (non-diagnostic medical claim) for SLE (ICD9: 710.0 or ICD10: M32), and evidence of cyclophosphamide, cyclosporine, rituximab or tacrolimus, or
≥1 inpatient diagnosis or ≥2 outpatient diagnoses (non-diagnostic medical claim) for SLE (ICD9: 710.0 or ICD10: M32), and evidence of ESRD, or
≥1 inpatient diagnosis or ≥2 outpatient diagnoses (non-diagnostic medical claim) for SLE (ICD9: 710.0 or ICD10: M32), and ≥1 diagnosis (non-diagnostic medical claim) for acute or chronic renal conditions including: - Glomerulonephritis (including lupus glomerulonephritis), acute or chronic renal failure, nephritis or nephrotic syndrome (including lupus nephrotic syndrome), and renal failure or proteinuria (ICD-9 codes 580-586 and 791.0; ICD-10 codes: N00-N08, N17, N18, N19, R80)

LN, lupus nephritis; SLE, systemic lupus erythematosus.

RESULTS

KEY DEMOGRAPHICS

- There were 21,251 patients who met the study criteria for LN diagnosis, with a mean follow-up of 31.0 months (Min, Max; 2.0, 60.1). Patients with commercial insurance (38.1%) were younger (mean age [SD], 47.8 [13.3] years) than Medicare (61.9%) patients (mean age [SD], 67.9 years [11.5])
- Overall, 51.3% (44.9% commercial and 55.3% Medicare) of patients had at least one period of low disease activity. Evidence of active disease was noted in 67.3% of patients (69.6% commercial and 65.9% Medicare), and ESRD was evident in 10.5% of patients (11.5% commercial and 9.9% Medicare)

	Overall n=21,251	Commercial n=8,101	Medicare n=13,150
Age, years			
Mean (SD)	60.3 (15.7)	47.8 (13.3)	67.9 (11.5)
Age category, n (%)			
18-29	861 (4.1)	834 (10.3)	27 (0.2)
30-39	1,636 (7.7)	1,400 (17.3)	236 (1.8)
40-49	2,740 (12.9)	2,023 (25.0)	717 (5.5)
50-64	6,460 (30.4)	3,214 (39.7)	3,246 (24.7)
65-74	5,490 (25.8)	451 (5.6)	5,039 (38.3)
75-84	3,161 (14.9)	138 (1.7)	3,023 (23.0)
≥85	903 (4.3)	41 (0.5)	862 (6.6)
Sex, n (%)			
Female	18,470 (86.9)	7,002 (86.4)	11,468 (87.2)
Male	2,774 (13.1)	1,092 (13.5)	1,682 (12.8)
Unknown	7 (0.0)	7 (0.1)	0 (0.0)
Race, n (%)			
White	11,733 (55.2)	4,624 (57.1)	7,109 (54.1)
Black	3,734 (17.6)	1,373 (17.0)	2,361 (18.0)
Hispanic	3,089 (14.5)	1,286 (15.9)	1,803 (13.7)
Asian	666 (3.1)	397 (4.9)	269 (2.1)
Unknown	2,029 (9.6)	421 (5.2)	1,608 (12.2)
Region, n (%)			
Northeast	1,938 (9.1)	711 (8.8)	1,227 (9.3)
Midwest	3,719 (17.5)	1,763 (21.8)	1,956 (14.9)
South	10,016 (47.1)	3,717 (45.9)	6,299 (47.9)
West	5,542 (26.1)	1,880 (23.2)	3,662 (27.9)
Other/Unknown	36 (0.2)	30 (0.4)	6 (0.1)
Continuous Enrollment during Follow-up Period, months			
Mean (SD)	31.0 (20.2)	27.5 (19.3)	32.5 (20.3)

SD, standard deviation.

CLINICAL CHARACTERISTICS

	Overall n=21,251	Commercial n=8,101	Medicare n=13,150
Quan-Charlson comorbidity index			
Mean (SD)	2.35 (2.01)	1.70 (1.60)	2.80 (2.10)
LN Disease Periods, n (%)			
Low Activity	10,911 (51.3)	3,645 (44.9)	7,266 (55.3)
Active	14,310 (67.3)	5,642 (69.6)	8,668 (65.9)
ESRD	2,240 (10.5)	930 (11.5)	1,310 (9.9)
Comorbidities[a], n (%)			
Connective Tissue Disorder	13,319 (62.7)	5,264 (65.0)	8,055 (61.3)
Hypertension	12,928 (60.8)	3,555 (43.9)	9,373 (71.3)
Any infection[b]	6,491 (30.5)	2,108 (26.0)	4,383 (33.3)
Abdominal/Stomach Cramping	4,216 (19.8)	1,523 (18.8)	2,693 (20.5)
Diabetes	4,080 (19.2)	884 (10.9)	3,196 (24.3)

[a]Most common comorbidities overall.
[b]Includes respiratory infections (influenza, acute bronchitis or pneumonia), bacterial infections, and urinary tract infections.
Quan-Charlson Index is a method of categorizing comorbidities of patient using ICD-10 diagnosis codes; a score of 0 means no comorbidities were found.
ESRD, end-stage renal disease; LN, lupus nephritis; SD, standard deviation.

HEALTHCARE COSTS

- Overall, mean monthly medical costs for periods of active disease were $4,777 compared to $2,523 for periods of low disease activity. Mean monthly medical costs for periods of ESRD were $18,084
- After factoring in pharmacy costs, overall mean monthly total costs for periods of active disease ($6,612) and ESRD ($21,844) were nearly 2-fold and 6-fold higher, respectively, than periods of low disease activity ($3,584)
- Mean monthly medical and total costs were consistently higher in Medicare patients compared to commercial patients across all periods of disease

HEALTHCARE COSTS FOR LOW DISEASE ACTIVITY, ACTIVE DISEASE AND ESRD[a]

	Low Disease Activity			Active Disease			ESRD		
	Overall n=10,911	Commercial n=3,645	Medicare n=7,266	Overall n=14,310	Commercial n=5,642	Medicare n=8,668	Overall n=2,240	Commercial n=930	Medicare n=1,310
Monthly Medical Cost $US	2,523	1,794	2,889	4,777	4,243	5,124	18,084	14,741	20,457
Inpatient	1,406	890	1,665	2,896	2,351	3,251	13,756	10,882	15,796
Emergency department	281	194	325	657	749	597	663	537	753
Physician office	304	322	295	457	499	430	655	533	741
Other outpatient	532	388	605	768	646	847	3,013	2,793	3,169
Monthly Pharmacy Cost $US	1,061	993	1,095	1,835	1,920	1,781	3,760	2,305	4,793
Monthly Total Cost $US	3,584	2,787	3,984	6,612	6,163	6,905	21,844	17,047	25,250

[a]Given differential follow-up time across patients, costs were presented as monthly costs and adjusted to 2020 $US.
ESRD, end-stage renal disease.

LIMITATIONS

- Administrative claims data are subject to a number of limitations including, but not limited to, data coding errors/misspecifications, data entry errors and incomplete data
- Study population included patients with commercial and Medicare coverage captured in the Optum database, and study results may not be generalizable to the overall LN population (mean age of study population ~60 years)
- Costs not captured in the Optum database were not included in this analysis, including patient out-of-pocket costs or indirect costs of LN (e.g., loss of work and productivity)

CONCLUSIONS

- This is the first and largest study in LN to describe the economic impact of achieving low disease activity compared to active disease or ESRD in a large US claims population and to provide data from a real-world perspective
- Overall, more than 65% of patients assessed had evidence of active disease, with a mean duration of 20.5 months, and mean monthly total costs ($6,612) during periods of active disease were nearly twice as high as during periods of low disease activity ($3,584)
- Patients with evidence of ESRD (10.5%, average duration 25.7 months) had mean monthly total costs ($21,844) that were 6-fold higher than those of patients with low disease activity
- Early intervention and rapid management of periods of active disease may help achieve lower disease activity, reducing the associated costs and economic burden of active disease and ESRD as well as improving long-term patient outcomes

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DISCLOSURES

MD, ME, AO, and EF are consultants of Aurinia. TH was an employee of Aurinia during the study. PMO is an employee and stockholder of Aurinia.

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