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Characterizing the burden and unmet need of lupus nephritis

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Introduction and objectives

- Lupus nephritis (LN) is an autoimmune disease caused when systemic lupus erythematosus (SLE), also known as lupus, affects part of the kidneys resulting in impaired kidney function.
- It is estimated that 25% of patients with LN develop end-stage renal disease (ESRD). Although kidney dialysis and transplantation have a huge burden both on the patients and healthcare providers, the overall humanistic and economic cost of LN has not been well characterized outside of the US.
- Without country-specific epidemiology and data on the clinical, economic, and humanistic impact of LN, health technology assessment (HTA) agencies, payers, and healthcare providers cannot accurately assess the value of new treatments for LN.
- The objective of this targeted literature review was to characterize the clinical, economic, and humanistic burden of LN and identify any evidence gaps.

Methods

- A targeted review and synthesis of the current literature on epidemiology, clinical, economic, and humanistic burden was conducted to identify relevant articles published between January 2013 and August 2023 in the following scope markets: the US, the UK, Germany, France, China, and Japan. Searches on clinical guidelines, randomized controlled trials related to standard of care, and HTA outcomes were also conducted to understand the landscape situation in LN.

Results

1. LN affects 1 in 100,000 people in the US.[8]

- In total, five relevant studies reporting on the epidemiology (ie, proportion of SLE patients with LN, incidence and prevalence rates in general population) in patients with LN were identified.[2, 6, 8, 17, 20]
- All studies were retrospective cohort studies conducted in the US.
- Three types of datasets were used: Optum, LUMEN, and Medicaid (from different counties). The year of data collection ranged from 1976 to 2019.

Five studies reported the percentage of patients with SLE experiencing LN, which ranged from[1-5]:

20% to 38%

The US incidence of LN is[4]:

1:100,000

Higher-risk groups include:

- Older individuals
- Females
- African Americans

No epidemiological data were identified for LN outside the US

Health inequity:

Despite having a higher incidence rate of LN than many other ethnic groups, Black patients have made up less than 15% of the clinical trial populations in LN.

2. More than 1 in 3 patients with LN develop ESRD within 5 to 10 years.

- Nineteen relevant studies were identified that reported on clinical burden of LN. The geographic split of the studies was: the US (13), the UK (4) and China (3).[1-19]

21%-37%

of patients with LN develop ESRD after 5 to 10 years[5-9]

ESRD necessitates dialysis or renal transplantation, which are both **debilitating for the patient** and **costly for the healthcare provider.**

Ten-year survival:

70%-88%[6, 9, 11]

The 10-year survival rate of LN indicates that, for most patients, LN is a **chronic condition.** Therefore, any burden on healthcare systems or impact on HRQoL **accumulates across the years.**

3. Lupus PRO tools do not capture all the effects of LN on HRQoL.[21]

- **Lupus PRO** was the only disease-specific HRQoL tool identified.
- Only one HRQoL study in patients with LN was identified.[21]
- LN affects HRQoL in domains that are not included in generic or SLE HRQoL tools.
- SLE patients with LN have poorer HRQoL than those without, and depression and anxiety are common.[22]

Key concerns with lupus medications[21]:

1. **"bothersome side-effects of medications"**
2. **"number of medications"**

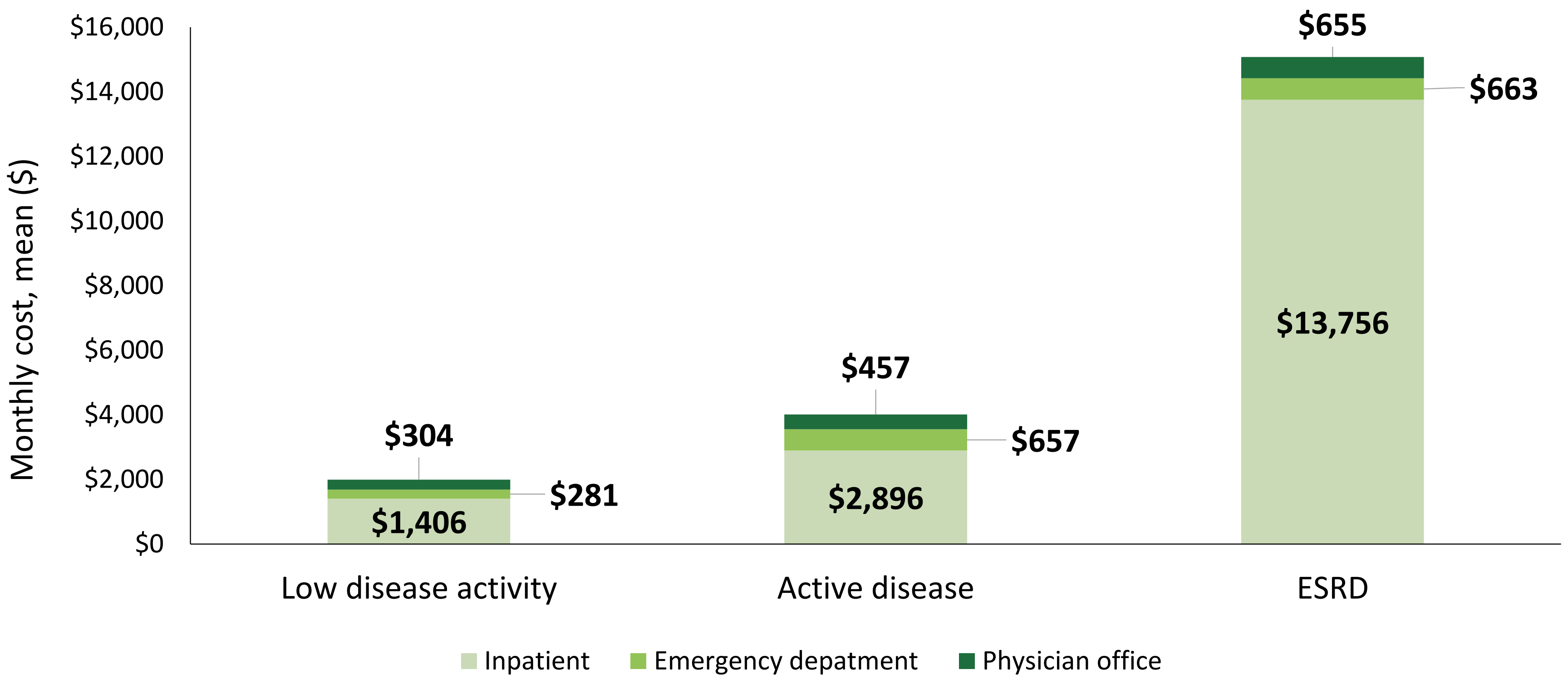
4. ESRD costs US healthcare providers ~$15,000 a month per patient.[2]

- Three relevant retrospective cohort studies reporting cost data for LN were identified.[2, 16-18] All three studies reported US cost data.

Per patient healthcare costs for patients with LN who had varying levels of disease activity in the US were as follows:

- **Low disease activity:** ~$2,000 per month.
- **Active disease:** ~$4,000 per month.
- **ESRD:** ~$15,000 per month.

At all levels of disease activity, the greatest costs were incurred due to **in-patient stays.**



The hidden cost of chronic LN:

1:100,000 US incidence of LN → **70%-88%** of patients with LN survive >10 years → **$240,000** Cost of low activity LN over 10 years, per patient

The cost of ESRD in patients with LN:

1:100,000 US incidence of LN → **21%-37%** of LN develop ESRD within 5 to 10 years → **$15,000** Monthly cost of ESRD, per patient

5. Gap analysis

Epidemiology	USA	NA	China Germany France UK Japan Asian (regional) European (regional) Global
Clinical burden	NA	Patient survival/mortality Hospitalization rates	Pediatric survival/mortality
Humanistic burden	NA	Physical symptoms Emotional impact Quality of life	NA
Economic burden	NA	Total hospitalization costs Direct costs	Indirect costs Pharmacy costs

🟩 **High data availability** 🟩 **Moderate data availability** ☐ **No data available**

Conclusions

- Any treatment that can delay patients with LN progressing to ESRD would save healthcare providers over $10,000 a month per patient, based on US cost data. There are no ex-US cost data available, which means the cost of LN for many healthcare providers is hidden.
- LN has an additional impact on HRQoL compared to SLE, which is not captured due to the lack of a specific PRO tool for LN.
- For HTA agencies and payers to accurately assess the value of new LN treatments, there is an apparent need for more epidemiological and economic data outside of the US and the development of an LN-specific PRO measure.

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Abbreviations: ESRD, end-stage renal disease; HRQoL, health-related quality of life; HTA, health technology assessment; LN, lupus nephritis; NA, not available; PRO, patient reported outcome; SLE, systemic lupus erythematosus; UK, United Kingdom; US, United States.

References: **1.** Khosroshahi, et al. *Arthritis Care Res.* 2023:75(7). **2.** Dall'Era, et al, *Care Spec Pharm.* 2023:29(1). **3.** Rong, et al. *J Hum Hypertens.* 2022:36(2). **4.** Sim, et al. *Mayo Clin Proc.* 2018:93(2). **5.** Duong, et al. *Nephrol Dial Transplant.* 2023:38. **6.** Hocaoğlu, et al. *Arthritis Rheum.* 2023:75(4). **7.** Gisca, et al. *Rheumatology.* 2021:60(4). **8.** Feldman, et al. *Arthritis Rheum.* 2018:70(3). **9.** Sexton, et al. *J Am Soc Nephrol.* 2015:10(2). **10.** Farinha, et al. *Rheumatology.* 2020:59(11). **11.** Pruthi, et al. *Kidney Int.* 2016:89(4). **12.** Ntatsaki, et al. *Clin Rheumatol.* 2018:37(9). **13.** Tian, et al. *Front Med.* 2022:9. **14.** Chen, et al. *BMC Nephrol.* 2020:21(1). **15.** Gõmez-Puerta, et al. *Arthritis Care Res.* 2015:67(10). **16.** Furst, et al. *J Med Econ*. 2013:16(4). **17.** Bell, et al. *Lupus.* 2023:32(2). **18.** Bell, et al. *Cureus.* 2023:15(4). **19.** Feldman, et al. *Arthritis Rheum.* 2015:67(6). **20.** Tedeschi, et al. *Arthritis Rheum.* 2019:71(7). **21.** Jolly, et al. *Lupus.* 2018:27(2). **22.** Mozaffarian, et al., *Patient Preference Adherence.* 2016:10.