

stranded DNA, and/or antiphospholipid antibody positive). Infertility is defined as attempting to conceive for >1 year without conception. Pearson's chi-squared testing was performed for categorical measures and two-sample t-tests for continuous measures.

**Results** Patients and controls were predominantly Black and had a mean of 1.85 live births per individual. Women with SLE had a total of 828 live births with 710 live births in the control group (434 from related controls). Preeclampsia was seen in 74 women with SLE and 21 controls (11 related controls), **table 1**. Low birth weight was seen in 101 women with SLE and 28 controls (17 related controls). Premature gonadal failure was seen in 1.8% of patients with SLE. Infertility was not significantly different between SLE and all controls. A higher proportion of related controls were ANA positive (47.7%) as compared to unrelated controls (30.5%).

Comparing ANA positive to ANA negative controls, there was not a significant difference between proportion of women having a live birth (95.8% vs 97.9%), low birth weight (12.6% vs 11.5%), prematurity (9.2% vs 12.3%), preeclampsia (9.2% vs 8.5%), or infertility 3.3% vs 2.1%).

**Abstract 619 Table 1** Demographic, serologic, and pregnancy outcome characteristics of women with at least one pregnancy, comparing patients with SLE to controls. All p-values are compared to the SLE group

Characteristics	SLE Patients		All Controls		Related Controls	
	n=428	n=271	p value	n=148	p value	
Mean age today years ±SD	55.2 ± 14.3	62.6 ± 14.3	p<0.001	65.1 ± 15.6	p<0.001	
Black%	76.4	99.3	p<0.001	100.0	p<0.001	
High school graduate%	89.9	89.1	p=0.76	84.1	p<0.001	
Insured%	95.4	94.5	p=0.59	94.9	p=0.82	
Tobacco use, ever%	27.0	26.5	p =0.88	28.8	p=0.65	
ANA positive%	97.8	40.1	p<0.001	47.7	p<0.001	
Lupus antibody positive%	83.1	3.6	p<0.001	4.2	p<0.001	
Infertility%	6.1	3.8	p=0.19	3.4	p=0.4	
Any live birth%	88.1	97.4	p<0.001	97.3	p<0.001	
Low birth weight%	28.2	11.1	p<0.001	12.5	p<0.001	
Preeclampsia%	20.3	8.4	p<0.001	8.1	p<0.001	
Premature birth%	30.0	10.8	p<0.001	9.6	p<0.001	

**Conclusion** In a large cohort of predominantly Black women, we note differences in pregnancy outcomes among women with SLE compared to related and unrelated controls. A high rate of ANA positivity was noted in the control groups, increased further in related controls, which is above previously reported general population estimates. Adverse pregnancy outcomes (such as preeclampsia and low birth weight) were seen in those with SLE at a higher rate than controls. In ANA positive controls, there was a trend towards increased rates of adverse outcomes.

Future analysis will evaluate the timing of SLE pregnancy outcomes prior to development of SLE and additional drivers of differences between control groups.

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## CLINICAL MANAGEMENT OF LUPUS IN THE UNITED STATES: A CLAIMS-BASED ANALYSIS

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**Background/Purpose** Systemic lupus erythematosus (SLE) is a chronic autoimmune disease in which clinical symptoms and laboratory measurements are heterogeneous across patients.<sup>1 2</sup> Such clinical heterogeneity complicates diagnosis and management. To characterize the phenotype of lupus patients before and after diagnosis and also determine the most common clinical management paradigms for lupus patients, we investigated claims data with particular attention to the year before and after diagnosis, focusing on patients with general SLE, SLE patients with renal involvement [lupus nephritis (LN)] and patients with only cutaneous manifestations [cutaneous lupus erythematosus (CLE)].

**Methods** Data were acquired using both adjudicated (Closed) and non-adjudicated (Open) commercial databases (from EVERSANA) of patients across the United States. Both databases include claims for diagnoses, procedures, prescriptions, and physician specialties. Analyses were conducted between April 2022 and March 2023. To increase stringency in the identification of lupus patients, cohorts created for LN, SLE, and CLE required two of the specified diagnoses within a six-month period. Altogether, over 100,000 lupus patients were identified by our specifications in the Closed Claims database, and ~38,000 lupus patients in the Open Claims database.

**Results** The cumulative percentages of claims for diagnoses, laboratory testing, procedures and medication generally increased in the year before diagnosis and over the subsequent year. Although we observed differences among the cohorts with respect to concomitant diagnoses and laboratory testing, the basis for diagnosis of patients in each cohort was not always apparent. For example, at index date only 53.4% of SLE patients had received an ANA test and only 43.4% had received an anti-dsDNA test, with comparably low frequencies in LN and CLE. Moreover, at diagnosis, only 8.9% of LN patients had received a kidney biopsy and 23.3% of CLE patients had received a skin biopsy. Subspecialty care by rheumatologists, nephrologists, and dermatologists was associated with increased testing in many instances. Anti-dsDNA and complement testing were increased in patients who had encountered a rheumatologist, kidney biopsies were increased in patients who had encountered a nephrologist, and skin biopsies were increased in patients who had encountered a dermatologist. In addition, there were also differences among cohorts with regard to drug management and emergency department (ED) visits. Of the drug prescriptions examined, at index opioids had the greatest cumulative frequency in LN and SLE, whereas hydroxychloroquine had the highest cumulative frequency in CLE. Among other standard of care drugs, cyclophosphamide was prescribed minimally, mycophenolate mofetil/mycophenolic acid was prescribed more in LN, and methotrexate was prescribed more in SLE. Moreover, when a matched control population was examined, opioid prescription was higher among all lupus cohorts than controls. Notably,

LN patients had a greater frequency of ED visits; LN patients with an encounter with a rheumatologist had fewer ED visits, whereas an encounter with a nephrologist was associated with more ED visits. Finally, cost of care was increased in lupus cohorts in the year before diagnosis and the year subsequently, and was highest in LN.

**Conclusion** The steadily increasing frequency of laboratory tests, emergency department visits, and cost in the year before diagnosis demonstrates the complexity of lupus diagnosis and management. At diagnosis and thereafter, there are major differences between the evaluation and management of lupus patients observed in the general care community reflected within claims databases than those set forth by professional society guidelines.

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**RISK OF DAMAGE PROGRESSION WITH BELIMUMAB VERSUS ORAL IMMUNOSUPPRESSANT USE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS**

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**Background/Purpose** Belimumab was approved for the treatment of non-renal SLE in 2011 and has been previously associated with a lower risk of damage progression when compared with prior ‘usual care.’ We sought to determine the risk of damage progression with belimumab versus alternative SLE immunosuppressants in a contemporary real world setting.

**Methods** We identified all adults with SLE (defined by ≥2 ICD codes >30 days and < 2 years apart) in a United States multi-center electronic health record (EHR) database, Tri-NetX. We identified all patients who initiated belimumab, azathioprine (AZA), methotrexate (MTX), or mycophenolate (MMF) between 3/2011 and 8/2021. We designed and

**Abstract 621 Table 1** Baseline characteristics of belimumab and azathioprine initiators with non-renal systemic lupus erythematosus

	Before overlap weighting			After overlap weighting		
	Belimumab (n=2434)	AZA (n=5644)	Std. Diff.	Belimumab	AZA	Std. Diff.
Age, years, mean (SD)	44.2 (12.6)	44.7 (14.6)	0.0377	44.3	44.3	<0.001
Female, n (%)	2322 (95.4)	5218 (92.5)	0.1236	94.8	94.8	<0.001
Race/Ethnicity, n (%)			0.2828			<0.001
White	1438 (59.1)	2603 (46.1)		54.5	54.5	
Black	587 (24.1)	1869 (33.1)		27.0	27.0	
Asian	51 (2.1)	139 (2.5)		2.3	2.3	
Hispanic	169 (6.9)	593 (10.5)		8.2	8.2	
Other	189 (7.8)	440 (7.8)		8.0	8.0	
Geographic Region, n (%)			0.4104			<0.001
East	808 (33.2)	969 (17.2)		25.4	25.4	
Midwest	300 (12.3)	1011 (17.9)		14.7	14.7	
South	915 (37.6)	2827 (50.1)		42.4	42.4	
West	411 (16.9)	837 (14.8)		17.4	17.4	
Treatment initiation year, median	2018	2017	0.4990	2018	2018	<0.001
Comorbidities, n (%)						
CKD stage ≥3	228 (9.4)	468 (8.3)	0.0379	8.5	8.5	<0.001
CVD	179 (7.4)	549 (9.7)	0.0850	8.1	8.2	<0.001
Heart Failure	59 (2.4)	246 (4.4)	0.1070	2.9	2.9	<0.001
Obesity	200 (8.2)	528 (9.4)	0.0402	8.8	8.8	<0.001
Charlson Comorbidity Index, mean (SD)	1.0 (0.8)	1.0 (0.9)	0.0375	1.0	1.0	<0.001
Tobacco use, n (%)	107 (4.4)	393 (7.0)	0.1111	5.1	5.1	<0.001
SLE Severity Index, n (%)			0.0930			<0.001
Mild	1360 (55.9)	3123 (55.3)		56.2	56.2	
Moderate	802 (32.9)	1772 (31.4)		32.2	32.2	
Severe	272 (11.2)	749 (13.3)		11.7	11.7	
SLE disease duration, n (%)			0.2354			<0.001
≤ 2 years	1435 (59.0)	3938 (69.8)		62.1	62.1	
2-4 years	472 (19.4)	830 (14.7)		18.2	18.2	
≥4 years	527 (21.7)	876 (15.5)		19.7	19.7	