



# Prevalence of Cutaneous Lupus Erythematosus in U.S. Populations Using the FDA Sentinel Distributed Database

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## BACKGROUND

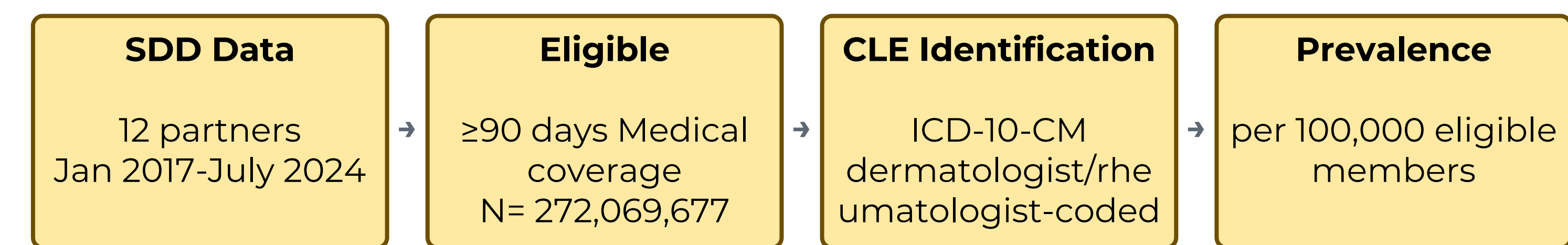
- Cutaneous lupus erythematosus (CLE) is a group of autoimmune skin diseases that can occur alone or with systemic lupus erythematosus (SLE). Key phenotypes include discoid lupus erythematosus (DLE), subacute CLE (SCLE), and other local lupus erythematosus.
- Existing U.S. prevalence estimates for CLE are limited and vary widely by population surveyed, data source, and case definition.
- In claims data, the specialty context of diagnosis coding is an important consideration: diagnoses coded by dermatologists or rheumatologists may provide greater specificity, whereas diagnoses identified without provider-specialty restrictions capture more patients but may be more susceptible to misclassification.
- Updated prevalence estimates can help inform disease-burden assessment and clinical trial planning for therapies in development.

## OBJECTIVES

To estimate the prevalence of CLE phenotypes among pediatric and adult populations in the FDA Sentinel Distributed Database (SDD), which includes commercial and public insurance data, with primary emphasis on diagnoses coded by dermatologists or rheumatologists and comparison with diagnoses identified without provider-specialty restrictions.

## METHODS

- We used claims data from 12 Sentinel Data Partners from January 2017 through July 2024.
- The study included 272,069,677 eligible members with ≥90 days of continuous medical enrollment, allowing gaps up to 45 days.



- CLE phenotypes were identified in outpatient settings using ICD-10-CM diagnosis codes and prespecified algorithms. Prevalence was calculated per 100,000 eligible members.
- Primary estimates used diagnoses coded by a dermatologist or rheumatologist for improved diagnostic accuracy. Estimates based on any outpatient ICD-10-CM diagnosis code, regardless of provider specialty, were included for comparison.

### How CLE phenotypes are defined

#### Individual ICD-10-CM codes

- DLE:** L93.0
- SCLE:** L93.1
- Other local lupus erythematosus:** L93.2

#### CLE/SLE overlap algorithms

- Mixed CLE:** Index on L93.0, L93.1, or L93.2, with ≥1 different CLE code on or after the index date
- SLE without systemic symptoms:** M32.9 on the index date; no M32.0 or M32.1x in the prior 365 days; and ≥1 CLE coded within ±365 days
- DLE preceding SLE:** L93.0 occurring >1 year before M32.9
- Chilblains with SLE:** T69.1 or T69.1XXA/D/S, with M32.9 before or after the index date

## LIMITATIONS

- CLE definitions relied on claims-based codes and algorithms without chart confirmation.
- Specialist-coded definitions may miss valid CLE diagnoses recorded by non-specialists or encounters with missing provider specialty information.
- Provider specialty, race, and Hispanic origin data capture have varied completeness across Data Partners.
- Findings reflect medically insured SDD populations and may not generalize to the full U.S. population.

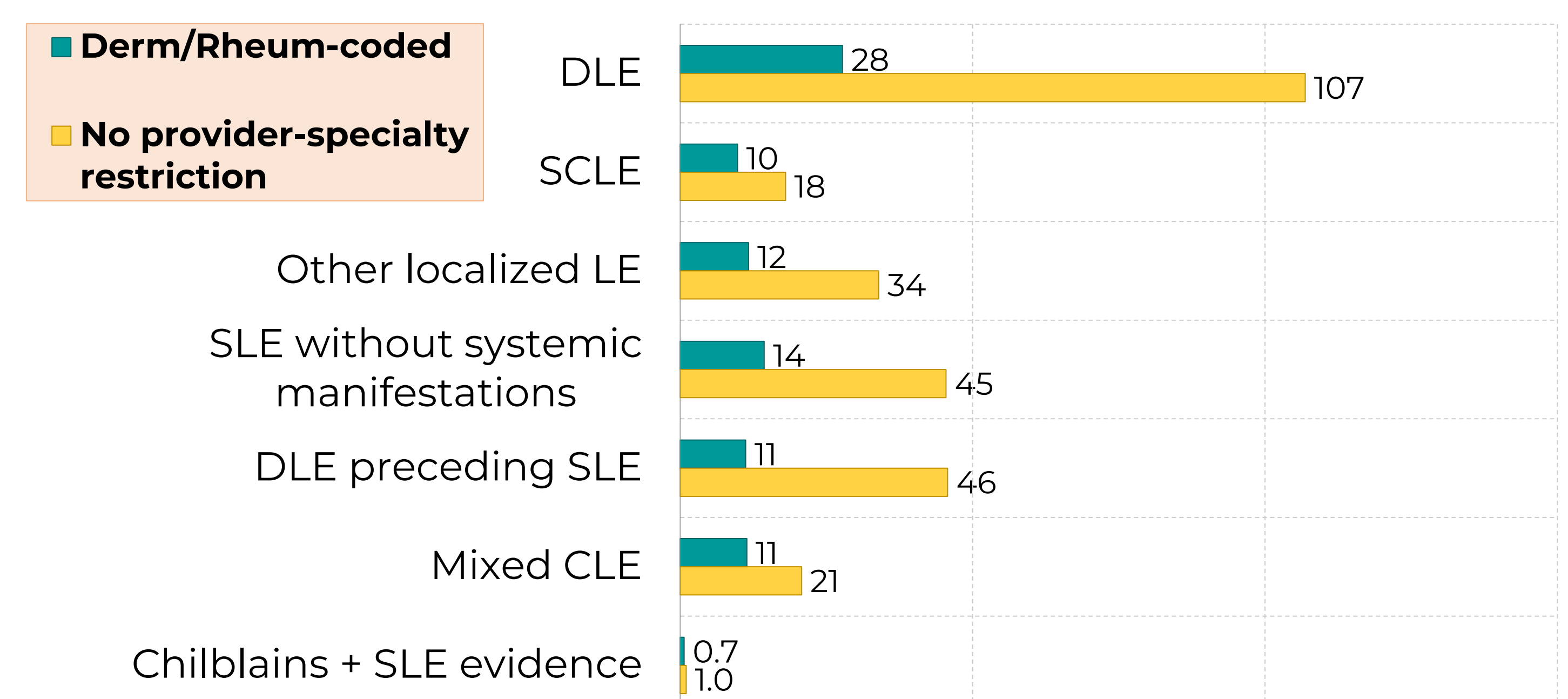
## ACKNOWLEDGEMENTS/DISCLOSURES

- Acknowledgements:** Maria Lewis, Iara Costa, Joy Kolonoski, Diane Emerton, Andrew Petrone, Eric Czernizer, Meg Her and Katie Shapiro. Many thanks are due to the Sentinel Data Partners who provided data used in the analyses.
- Disclosures:** This project was supported by Task Order 75F40124F19014 under Master Agreement 75F40119D10037 from the U.S. Food and Drug Administration (FDA). The contents are those of the authors, and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government. BR, DJC, JCH, VS, and AT are employees of Harvard Pilgrim Health Care Institute, a non-profit organization that conducts work for government and private organizations, including pharmaceutical companies.

## RESULTS

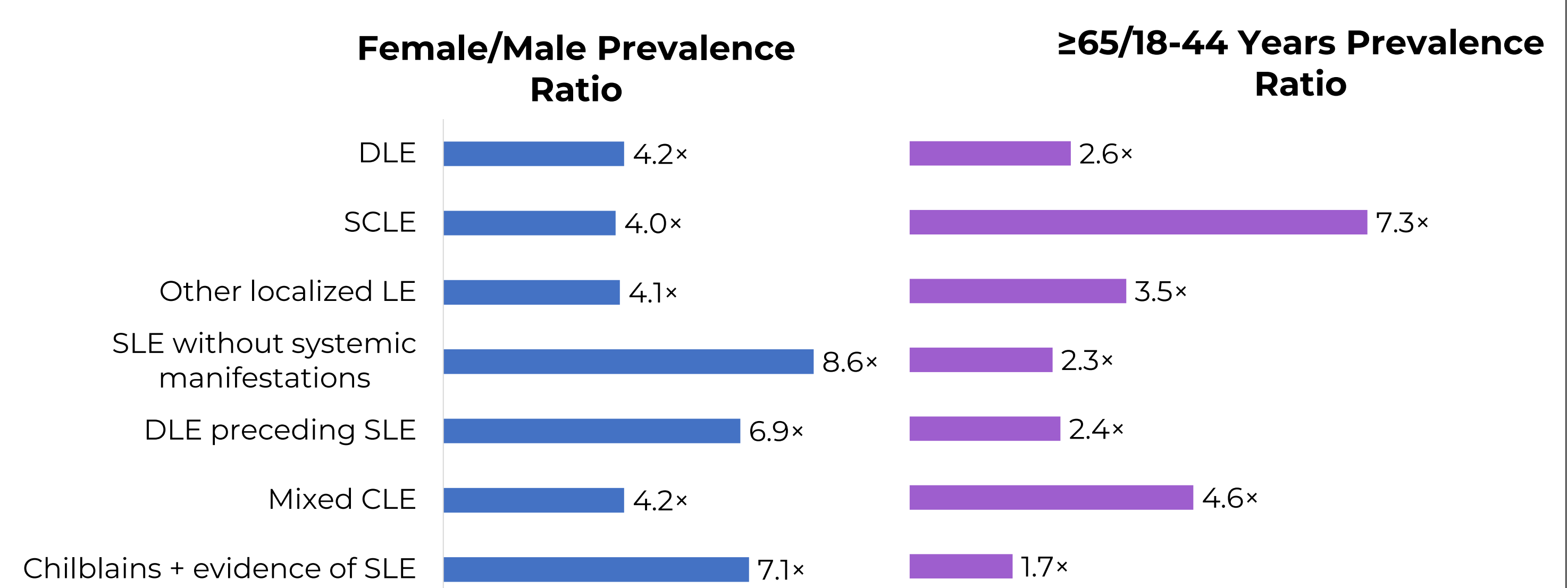
- Using dermatologist- or rheumatologist-coded diagnoses, DLE was the most common CLE phenotype, with a prevalence of 28 per 100,000 eligible members (Figure 1). Specialist-coded estimates ranged from 1 to 28 per 100,000 across CLE phenotypes. Overlap of CLE, especially DLE, with SLE was also common.
- Estimates were consistently higher without provider-specialty restrictions; for DLE, prevalence increased from 28 to 107 per 100,000.

**Figure 1. CLE Prevalence per 100,000 Eligible Members: Dermatologist/Rheumatologist-Coded Diagnoses vs Diagnoses Without Provider-Specialty Restrictions**



- Across CLE phenotypes, prevalence was generally higher among females and adults aged ≥65 years (Figure 2).

**Figure 2. Sex and Age Patterns Across CLE Phenotypes Coded by Dermatologist/Rheumatologist**



- Race patterns varied by phenotype; DLE prevalence was highest among Black individuals and SCLE prevalence among White individuals (Table 1).

**Table 1. CLE Prevalence per 100,000 Eligible Members by Race, CLE Phenotypes Coded by Dermatologist/Rheumatologist**

| Case phenotypes                     | Black/AA | White | AI/AN | Asian | Multi-racial | NH/OP | Uk. | Takeaway                   |
|-------------------------------------|----------|-------|-------|-------|--------------|-------|-----|----------------------------|
| DLE                                 | 67       | 34    | 18    | 21    | 16           | 20    | 15  | Black/AA highest           |
| SCLE                                | 7        | 19    | 4     | 4     | 3            | 3     | 4   | White highest              |
| Other localized LE                  | 17       | 18    | 5     | 8     | 6            | 8     | 6   | Black/AA and White highest |
| SLE without systemic manifestations | 28       | 20    | 15    | 9     | 6            | 8     | 8   | Black/AA and White highest |
| Mixed CLE                           | 17       | 19    | 5     | 6     | 5            | 6     | 5   | White and Black/AA highest |

AI/AN = American Indian or Alaska Native; Black/AA = Black or African American; NH/OP= Native Hawaiian or Other Pacific Islander; Uk=Unknown.

## CONCLUSION

This study provides updated, large-scale CLE prevalence estimates and valuable epidemiological insights for the medically insured U.S. population. Within this large SDD population, prevalence varied by CLE phenotypes and was consistently lower when restricted to dermatologist/rheumatologist-coded diagnoses, highlighting the importance of diagnostic context and algorithm choice.

These findings provide updated prevalence estimates to inform CLE disease-burden assessment and pharmacoepidemiologic studies.