AN EVALUATION OF THE ECONOMIC IMPACT OF EARLIER SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) DIAGNOSIS USING COMPLEMENT C4D ACTIVATION PRODUCTS IN A MULTIVARIATE ASSAY PANEL (MAP)

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PURPOSE: Diagnosis (dx) of systemic lupus erythematosus (SLE) is made via a combination of clinical and laboratory examinations; the sensitivity and specificity (S&S) of standard diagnostic tests (SDTs) (i.e.: ANA and antibodies to dsDNA, Smith, Ro/SSA, La/SSB, centromere, Jo-1, ScI-70, and CCP), are reported to be 83% & 76%, respectively (Putterman et al, 2014). A multivariate assay panel (MAP) combining biomarkers, complement C4d activation products on erythrocytes & B cells, with SDTs, yields improved dx performance with a S&S of 80% & 86%, respectively (Putterman et al, 2014). We evaluated the payer budget impact of SLE dx using MAP compared to SDTs.

METHODS: We modeled a health plan of 1 million enrollees, with 0.1% suspected of SLE. SLE dx among suspected SLE patients was 9.2% (Djikstra et al, 1999). The MAP arm assumed 80% / 20% of suspected SLE patients were tested with MAP/SDTs, compared to 100% SDT testing in SDT arm. Based on improved MAP performance, the hazard ratio for the assumed dx rate compared to SDTs was 1.74, (71, 87, 90, and 91% of the suspected who develop SLE will be diagnosed in years 1 – 4 compared to 53, 75, 84, and 88% with SDTs). Increased MAP performance relative to SDTs should result in earlier dx of SLE, reduction in disease severity at dx, and a longer period of time in less severe disease states (Oglesby et al, 2014) with associated lower costs. Pre-SLE dx claims-based cost data was used to estimate recurring direct costs for undiagnosed patients, and a weighted average of post-dx direct cost data for mild, moderate, and severe SLE were obtained from the literature (Garris et al, 2013) for SDTs, which was re-weighted to reflect the MAP scenario (Table 1).

RESULTS: Total 4-year pre- and post- dx direct medical cost for suspected SLE patients tested with MAP were $58,919,462 compared to $61,174,818 by SDTs (Table 3). Total 4-year average cost savings per suspected SLE patient tested with MAP were $2,256 (Table 3). Reduced inpatient hospital admissions were the biggest driver of cost savings ($581,728 in yr 1). In a one-way sensitivity analysis, the percentage of SLE dx among those suspected of SLE and specificity of MAP had the largest impact on average annual cost savings (respective savings of $16 and $15 per 1% absolute increase in percentage of SLE among those suspected of SLE and MAP specificity).

CONCLUSION: Incorporating MAP into SLE dx results in total 4-year direct cost savings of $2,255,356 ($2,256 per suspected SLE patient) and year 1 savings of $711 per suspected SLE patient. Further, by facilitating earlier dx of SLE at a less severe disease state, it is anticipated that MAP will enhance patient outcomes.

### Methods

- **Analysis conducted in accordance with the ISPOR task force on budget impact models (Sullivan et al, 2014)**
- **Cost year used is 2017, all costs are inflated by 3% per year to reflect standardized costs in 2017**
- **1 million enrollees in a U.S. Commercial Health Plan is used, 0.1% are suspected of having SLE**
- **2 yr pre-dx data from MarketScan commercial medical and pharmacy longitudinal claims data analysis (Figure 1)**
- **4 yr post-dx data sourced literature; inclusion based on availability of parameters and study design**
- **Clinical and cost parameters included in the base case model are included in Table 1 and Table 2, respectively**

A one-way sensitivity analysis was performed using plausible ranges or each variable (Figure 2); variables were normalized by assessing per unit increase of clinical variable (Figure 3) and per $100 increase of cost variables (Figure 4)

### References


### Limitations

- **Shifts in severity at diagnosis with MAP are assumed, in the future these should be studied in the clinical setting**
- **A number of parameters in the model have been observed directly with the use of MAP testing, but have been estimated based on peer-reviewed published data, which the authors believe to be representative and generalizable**
- **The cost of treating SLE is likely to change given recent approvals of new treatments and a number that are in late stages of clinical development. This model does not accommodate for potential future changes in SLE treatment patterns**