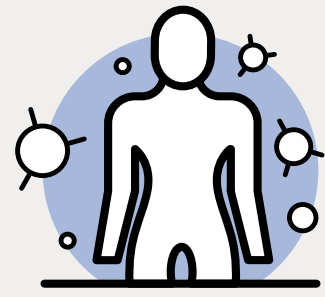


The Cost-effectiveness of Belimumab for the Treatment of Patients with Systemic Lupus Erythematosus in China

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*At the time of the study

Introduction



- Systemic lupus erythematosus (SLE) is a highly heterogeneous condition with manifestations across multiple organs, often leading to irreversible damage¹
- Belimumab is approved for the treatment of patients with SLE in over 75 countries²
 - Intravenous (IV) belimumab (10 mg/kg) has been approved in China since 2019²
- Although the cost-effectiveness of belimumab has been established in Western countries,^{3–5} it has not been thoroughly evaluated in China
 - This economic evaluation of belimumab in China was submitted to inform a policy decision in the 2020 National Reimbursement Drug List (NRDL) negotiation that added belimumab to the NDRL⁶
 - This analysis uses updated belimumab pricing for 2022



Objective

To investigate the cost-effectiveness of IV belimumab plus standard therapy (ST), compared with ST alone, for the treatment of SLE in China from the national health insurance (payer) perspective, using a micro-simulation model

Methods

- This study (GSK Study 213264) adapted the global cost-effectiveness model (CEM) developed for submission to the UK National Institute for Health and Care Excellence³ to the Chinese context (**Table 1**, **Figure 1**, and **Figure 2**)

Table 1. Summary of CEM settings

Model parameters	Details
Model structure	Micro-simulation CEM
Perspective	Chinese national health insurance payer
Study population	Adults with active, autoantibody-positive SLE* receiving ST
Data inputs†	Demographics, efficacy, direct costs, utilities
Short-term efficacy data	Implemented from a belimumab trial in North East Asia (NEA; GSK Study 113750; NCT01345253)
Long-term outcomes	Modelled using longitudinal statistical models from the Hopkins Lupus Cohort, calibrated using long-term organ damage outputs based on observed outcomes of belimumab-treated patients from a propensity score-matched analysis ⁷
Primary outcomes (discounted 5%)	Life-years, QALYs, total direct costs, ICER, ICUR

*SELENA-SLEDAI score ≥ 8 , or low complement levels, or anti-dsDNA positive; †China-specific costs, epidemiology data, and locally adjusted utilities were based on a targeted literature review and a key opinion leader survey
dsDNA, double-stranded deoxyribonucleic acid; ICER, incremental cost-effectiveness ratio; ICUR, incremental cost-utility ratio; SELENA-SLEDAI, Safety of Estrogens in Lupus Erythematosus National Assessment-SLE Disease Activity Index; QALYs, quality-adjusted life-years

Figure 1. Schematic SLE patient flow used in the CEM

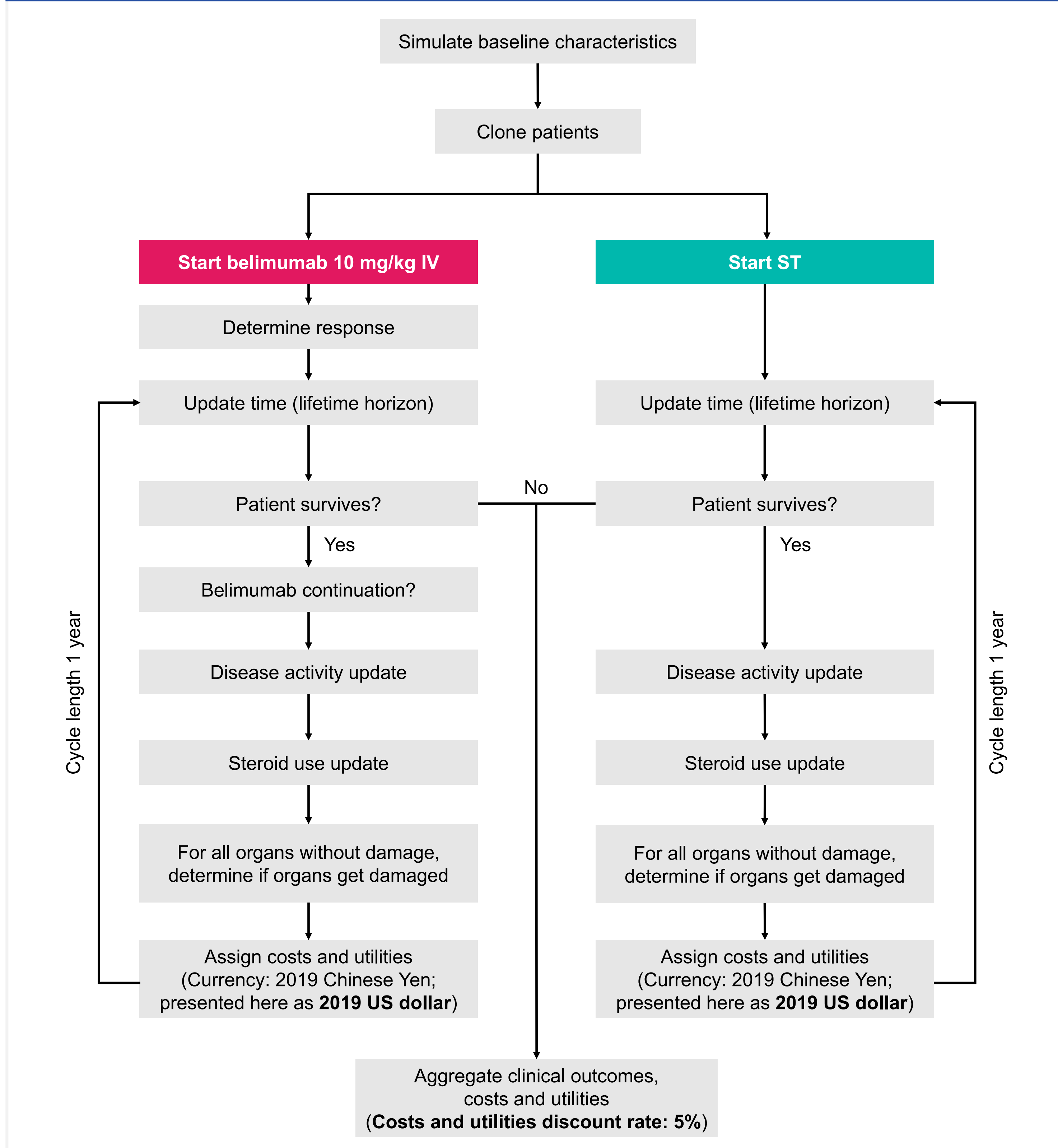
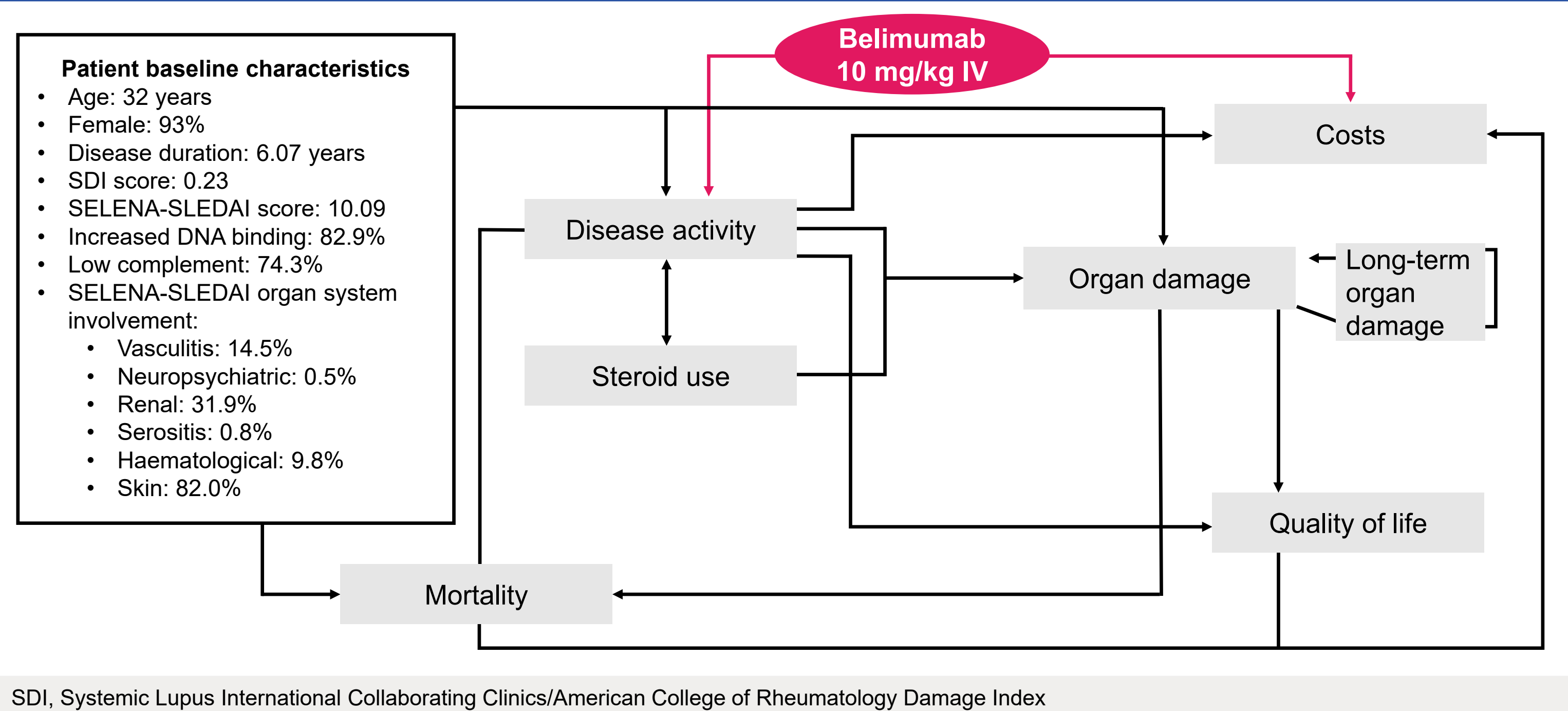


Figure 2. Modelled interdependencies between SLE-related variables



SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index

Results

Patient population

- Of the 677 patients included in the NEA trial, 97.6% (n=661) had a SELENA-SLEDAI score ≥ 8 or low complement levels or were anti-dsDNA positive; these patients informed the CEM population
 - In NEA, 76.6% of patients were from China

Life years, QALYs and SLE outcomes

- Over a lifetime horizon, patients treated with belimumab plus ST had a discounted life expectancy increase of 0.37 and discounted QALY increase of 0.58 versus ST alone (**Table 3**)

Table 3. Life-years, QALYs, and SLE outcomes over a lifetime horizon

	ST	Belimumab (plus ST)	Difference (Belimumab – ST)
Age at death, years	64.9	66.1	1.2
SDI score at death	4.1	4.0	–0.1
AMS score	4.8	4.5	–0.3
Average monthly steroid dose (mg)	220.6	214.3	–6.3
Life-years (discounted 5%)	14.54	14.92	0.37
QALYs (discounted 5%)	8.48	9.06	0.58

AMS, Adjusted Mean Systemic Lupus Erythematosus Disease Activity Index

- In the model, the benefit associated with belimumab was driven by decreased risk of organ damage (**Table 3** and **Table 4**), which reduced organ damage costs (**Table 5**)

Table 4. Organ damage occurrence and duration over a lifetime horizon

	Difference in organ damage occurrence until death (%) (Belimumab – ST)	Difference in duration of organ damage (years) (Belimumab – ST)
Organ damage		
Cardiovascular	–2.0	–0.51
Diabetes	0.3	0.05
Gastrointestinal	0.5	0.12
Malignancy	0.8	0.21
Musculoskeletal	–1.1	–0.10
Neuropsychiatric	–0.2	–0.06
Ocular	0.4	0.11
Peripheral vascular	–0.3	–0.04
Premature gonadal failure	0.1	0.02
Pulmonary	–2.4	–0.56
Renal	–2.8	–0.64
Skin	0.0	0.01

Total direct costs, ICUR and ICER

- Total discounted direct costs were \$3,748 (**Table 5**)
 - Organ damage costs were the greatest expense in both groups
- The ICUR per QALY gained was \$6,437; the ICER per life-year gained was \$10,043 (**Table 5**)

Table 5. Summary of discounted costs over a lifetime horizon

Discounted costs	ST	Belimumab (plus ST)	Difference (Belimumab – ST)
SLE treatment (including ST)*	\$9,350	\$9,513	\$162
Belimumab therapy	\$0	\$9,059	\$9,059
Belimumab administration	\$0	\$13	\$13
Total organ damage costs	\$53,067	\$47,581	–\$5,487
Total direct costs	\$62,418	\$66,166	\$3,748
ICUR			\$6,437
ICER			\$10,043

*Excluding organ damage treatment costs and cost of belimumab therapy

Conclusions

- In our model, over a patient's lifetime, belimumab plus ST reduced long-term damage of many organs, thus contributing to reduced organ damage costs, improved quality of life, and reduced mortality
- The ICUR of \$6,437 is 0.63× China's 2019 gross domestic product per capita (\$10,147) and is within three times China's 2019 gross domestic product per capita
 - This measure has been previously used by the World Health Organization as a cost-effectiveness threshold⁸ and is frequently used in CEM studies in China
- These findings suggest that belimumab plus ST is more cost-effective than ST alone for the treatment of SLE in China, providing economic evidence to policymakers for belimumab use in patients with SLE in China

Disclosures

MT is an employee of OPEN Health Group and has worked as a consultant for GSK. EL, DC, and ZT are employees of GSK and hold stocks and shares in the company. YA is a former employee of GSK and holds stocks and shares in GSK. XH is an employee of GSK.

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References

- Bruce IN, et al. *Ann Rheum Dis*. 2015;74(9):1706–13.
- Levy RA, et al. *Lupus*. 2021;30:1705–21.
- NICE. Belimumab Technology Appraisal Guidance. 2021. Available from: <https://www.nice.org.uk/guidance/ta752/resources/belimumab-for-treating-active-autoantibodypositive-systemic-lupus-erythematosus-pdf-82611372078277#page=14&zoom=100,0,670> [Accessed August 2022].
- Pierotti F, et al. *PLOS ONE*. 2015;10(10):e0140843.
- Vallejo-Aparicio LA, et al. *Value Health*. 2014;17(7):A530.
- Eversana. China Issues 2020 National Reimbursement Drug List. 2021. Available from: <https://www.eversana.com/2021/01/04/china-2020-national-reimbursement-drug-list/> [Accessed September 2022].
- Asukai Y, et al. *Value Health Reg Issues*. 2020;22:S65.
- Woods B, et al. *Value Health*. 2016;19:929–35.

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