Belimumab and Voclosporin for Lupus Nephritis: Effectiveness and Value

Public Meeting — March 26, 2021

Meeting materials available at: https://icer.org/assessment/lupus-nephritis-2021/

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Patient and Clinical Experts

Kathleen Arntsen, BA, President & CEO, Lupus and Allied Diseases Association, Inc.

- *LADA receives funding from health care related organizations, including Aurinia and GSK, but members associated with LADA are not compensated.*

Christele Felix, BS, Chief Operating Officer, LupusChat

- *No financial conflicts of interest to disclose.*

Meggan Mackay, MD, MS, Investigator and Professor of Medicine, The Feinstein Institutes for Medical Research, Northwell Health

- *Dr. Mackay participates in industry-sponsored clinical trials for lupus nephritis and is reimbursed for sujects recruited and followed.*

Brad Rovin, MD, Professor of Medicine and Pathology, Ohio State University Wexner Medical Center

- *Dr. Rovin is involved in several trials of novel therapeutics for lupus nephritis and is a consultant on the medical/scientific advisory boards to design trials for these therapeutics. His organization receives less than 25% funding from pharmaceutical companies for clinical trials.*

Why are we here today?

"People should know that lupus is never the same for everyone. Lupus is insidious; its thievery is endless. The effects to my daily life are profound from lupus. I no longer teach. I no longer have the physical ability to do the things that I used to. I have lists to remember things and multiple calendars. If I overdo it one day, I pay for it for three. I have learned to do things in pieces, pacing is key."

Tricia J., Lupus Patient

Why Are We Here Today?

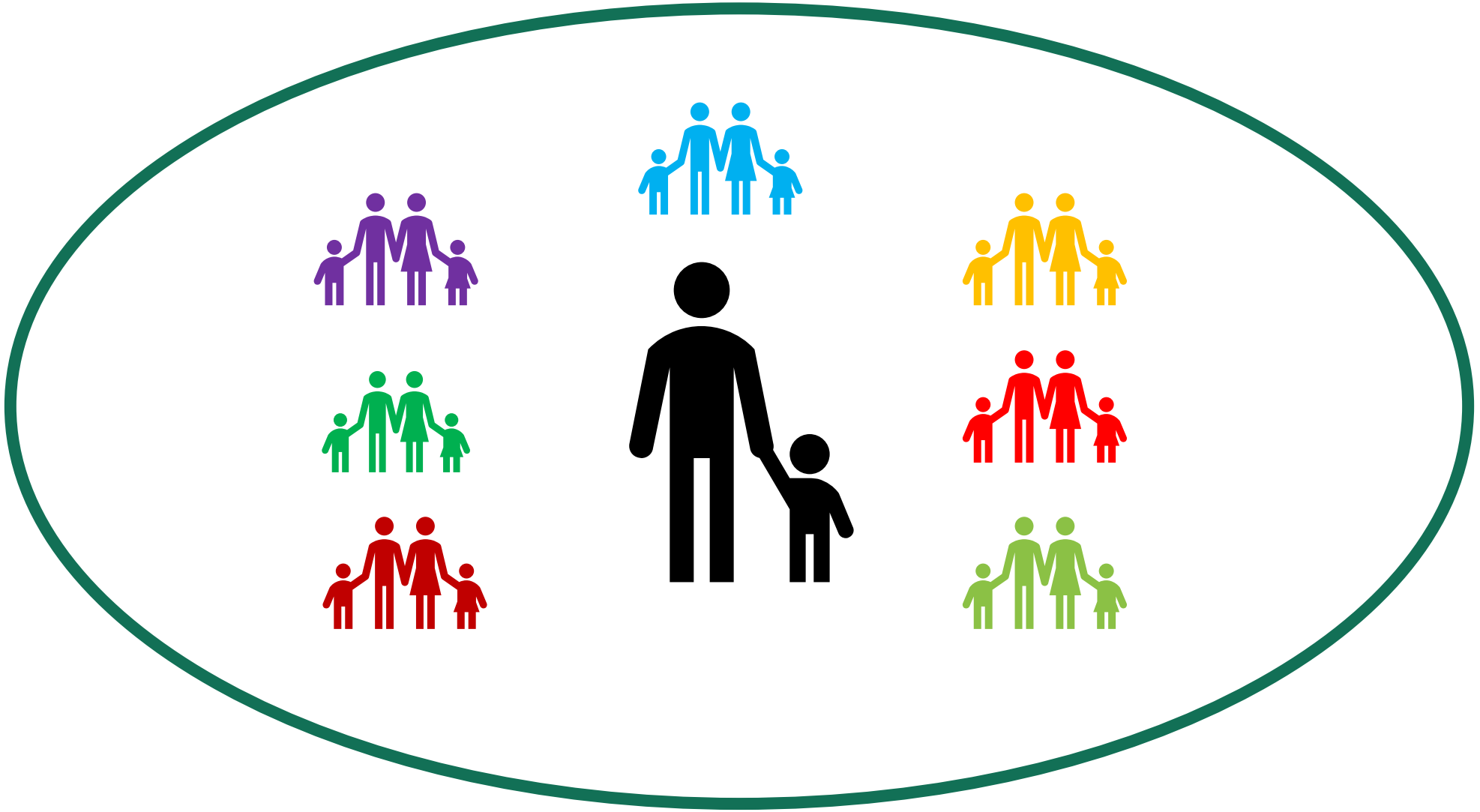
- What happens the day these treatments are approved by the FDA?
- Patients can have difficulty accessing drugs
  - Coverage eligibility
  - Costs (out-of-pocket and insurance premiums)
- What happens to patients and others in the health care “system”?

When There Isn't Enough Money For Health Insurance

Leonard Edloe,
Richmond, Virginia

The Whitmans,
Bird City, Alaska

Luke Breen,
Minneapolis, Minnesota

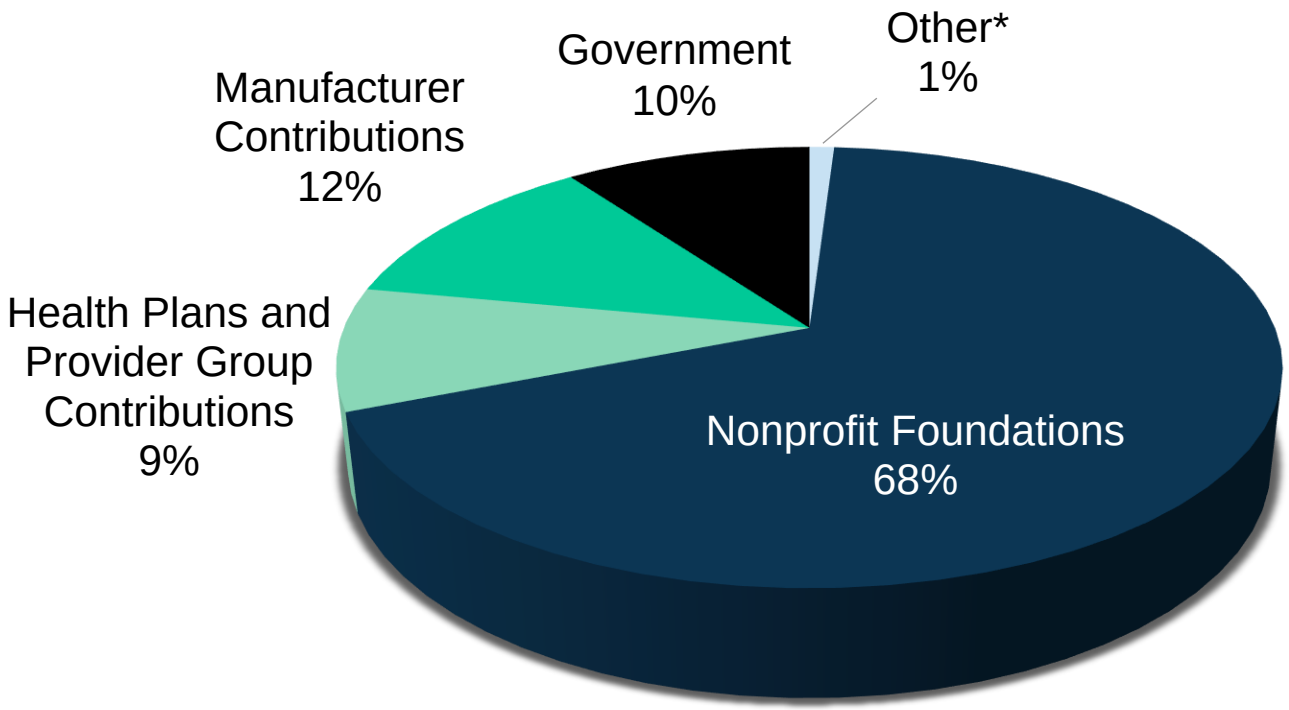


Organizational Overview

- New England Comparative Effectiveness Public Advisory Council
- The Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2021

https://icer.org/who-we-are/independent-funding/



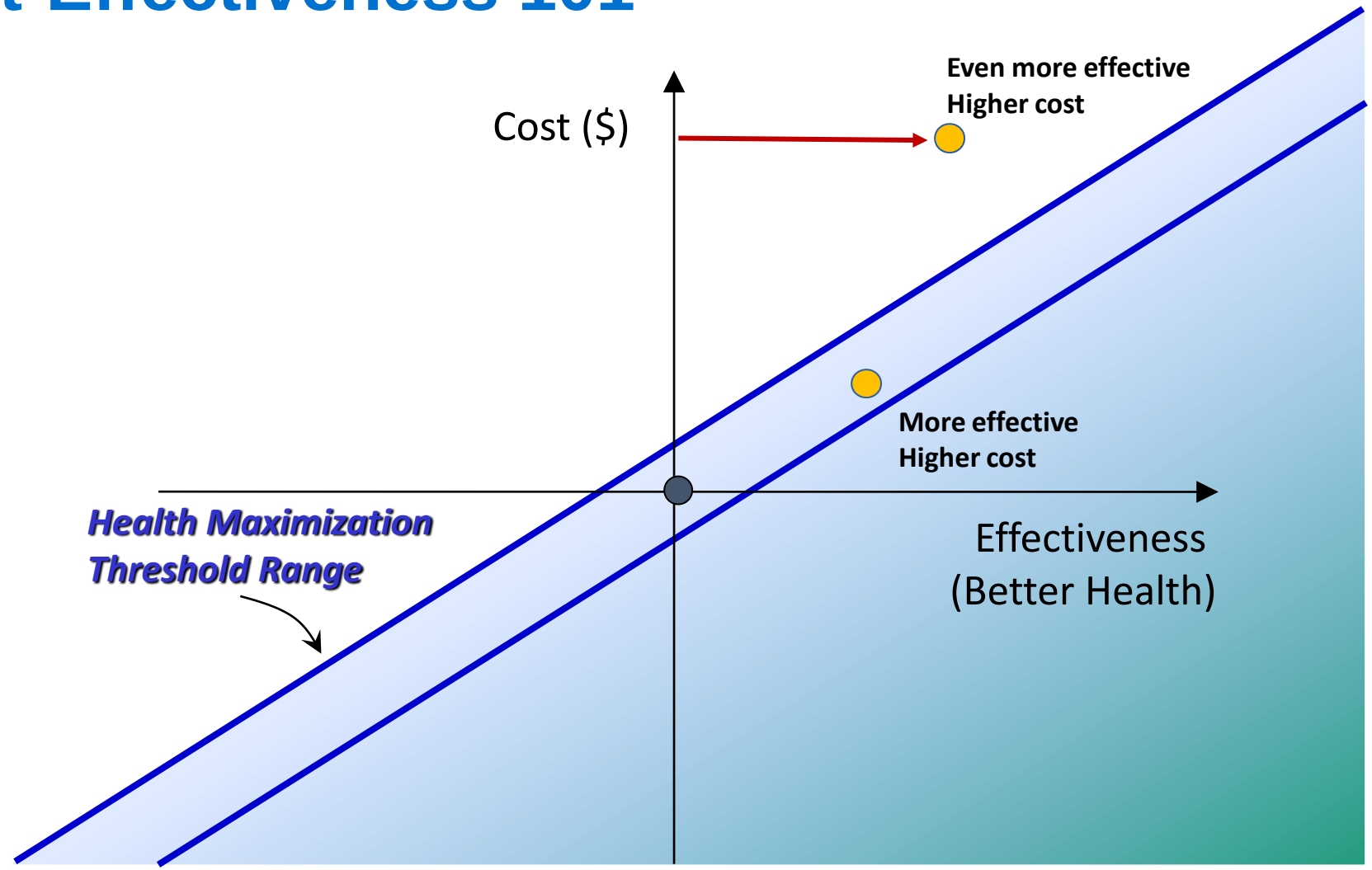
*Individual / matching contributions and speech stipends

How was the ICER report developed?

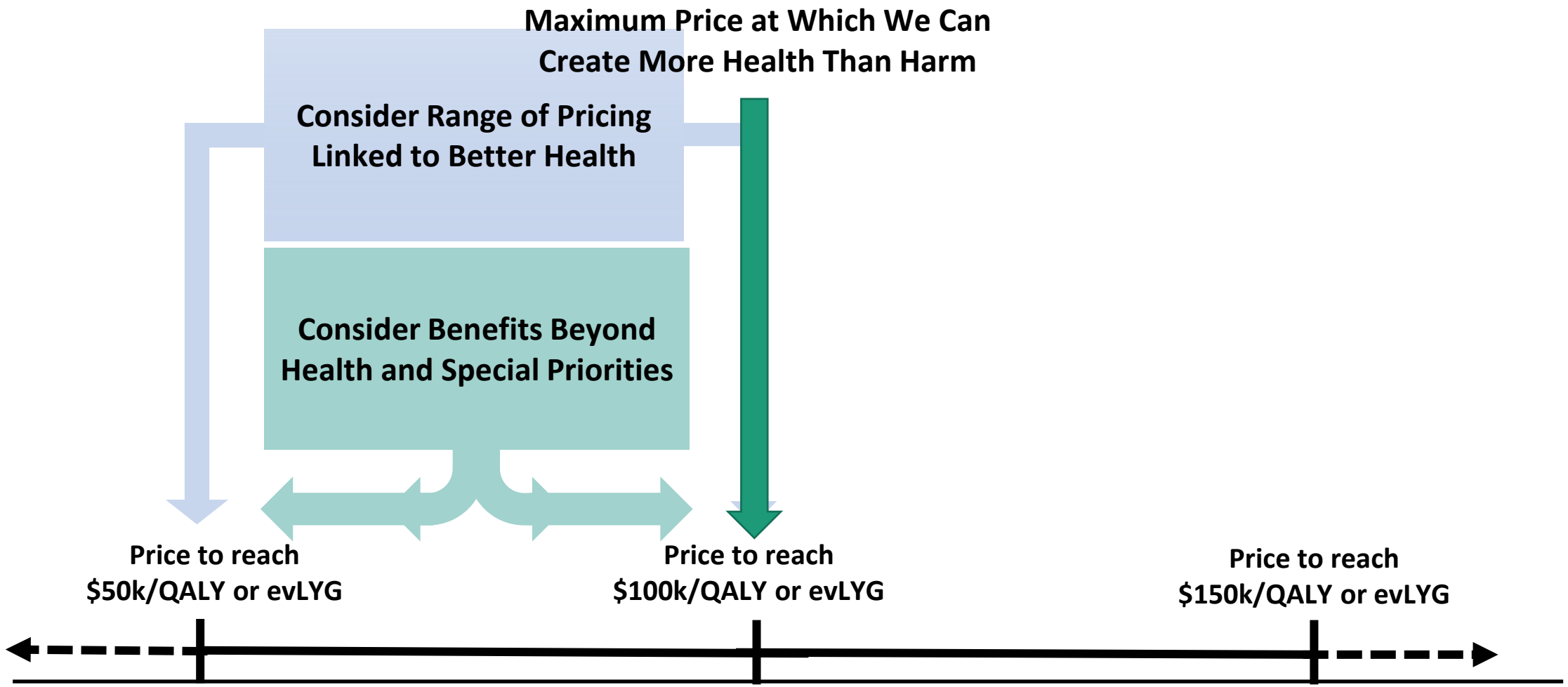
- Scoping with guidance from patient groups, clinical experts, manufacturers, and other stakeholders
- Internal ICER staff evidence analysis
- The University of Sheffield, School of Health and Related Research (ScHARR) cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
  - Kathleen Arntsen, BA, President and CEO, Lupus and Allied Diseases Association, Inc.
  - Michael Ward, MD, MPH, Chief, Clinical Trials and Outcomes Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases
- How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Cost-Effectiveness 101



Integrating Elements of Long-Term Value for Money



Agenda

Time (ET)	Activity
10:00 am—10:20 am	**Meeting Convened and Opening Remarks** *Steven D. Pearson, MD, MSc, ICER*
10:20 am—10:40 am	**Presentation of the Clinical Evidence** *Jeffrey A. Tice, MD, University of California, San Francisco*
10:40 am – 11:10 am	**Presentation of the Economic Model** *Olena Mandrik, PhD, MSc, The University of Sheffield*
11:10 am – 11:40 am	**Public Comments and Discussion**
11:40 am—12:20 pm	**Lunch**
12:20 pm—1:25 pm	**New England CEPAC Deliberation and Vote**
1:25 pm—1:45 pm	**Break**
1:45 pm—3:00 pm	**Policy Roundtable**
3:00 pm—3:30 pm	**Reflections from New England CEPAC and Closing Remarks**
3:30 pm	**Meeting Adjourned**

Presentation of the Clinical Evidence

Jeffrey A. Tice, MD

Division of General Internal Medicine

University of California San Francisco

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Key Collaborators

- **Serina Herron-Smith, BA**, Research Assistant, ICER
- **Belen Herce-Hagiwara, BA**, Research Assistant, ICER

Disclosures:

We have no conflicts of interest relevant to this report

Background

- Systemic Lupus Erythematosus (SLE)
  - 300,000 to 1.5 million in US
  - 90% female
- Lupus nephritis (LN) in about 50%
  - Most common cause of death and disability in SLE
  - Typically presents between the ages of 20 and 40 years
  - Proteinuria (UPCR) followed by loss of kidney function (eGFR)
  - Blacks and Hispanics have more severe, progressive disease

Impact on Patients

- End stage renal disease (ESRD) requiring dialysis or kidney transplant, to avoid dying
- Side effects of treatments (steroids, immunosuppressive therapies)
- Fatigue
- Cost of treatment
- Child-bearing
- Work

Standard of Care and Management of LN

- Induction
  - High dose corticosteroids plus mycophenolate mofetil (MMF) or cyclophosphamide
- Maintenance
  - MMF
- < 50% achieve sustained remission
- ESRD in 11% at 5 years and 17% at 10 years with current therapy

Belimumab (Benlysta)

- B-lymphocyte stimulator inhibitor
  - 10 mg/kg IV every 2 weeks x 3, then
  - 10 mg/kg IV every 4 weeks
- FDA approved for SLE 3/10/11, expanded to LN on 12/16/20

Voclosporin (Lupkynis)

- Calcineurin inhibitor
  - 23.7 mg by mouth twice daily
- FDA approval 1/22/21

Outcomes for Belimumab

- **Primary**
  - Primary efficacy renal response (PERR) at two years
    - UPCR ≤ 0.7 AND eGFR ≥ 60 mL/min/1.73 m^2
- **Secondary**
  - Complete renal response at two years
    - UPCR ≤ 0.5 AND eGFR not more than 10% below baseline

- No reported results on fatigue or other measures of quality of life

Outcomes for Voclosporin

- **Primary**
  - Complete response (CR) at one year
    - UCPR of ≤ 0.5 AND eGFR ≥ 60 mL/min/1.73 m^2
- **Secondary**
  - Partial response: ≥50% decrease in UPCR

- No results on fatigue or other measures of quality of life

Insights from Discussions with Patients

- Must highlight the white / non-white disparities for patients with LN. For example, Black patients progress to ESRD at almost 9 times the rate of white patients.
- Each patient has a unique constellation of co-morbidities, demographics, living circumstances, and baseline medications
- Given the young age of onset of LN, the disease has a huge negative impact on patients' ability to work, to have children, and to advance in their careers
- COVID impact: the need to travel to a medical center for an infusion represents an even greater burden

Clinical Evidence

Key Clinical Trials

Interventions	Trials	N	Baseline Characteristics Across Trials
Belimumab	BLISS-LN	448	Mean age: 33 years Sex: 88% female Race: 50% Asian, 33% white, 14% Black
Voclosporin	AURA-LV AURORA	534	Mean age: 33 years Sex: 87% female Race: 38% Asian, 37% white, 8% Black

Results: Complete Response at One and Two years

Outcome	One Year	Two years
Belimumab CRR§	32.5%	30.0%
Placebo CRR	25.5%	19.7%
Voclosporin CR*	42.3%	-
Placebo CR	23.3%	-

§ CRR: Complete renal response at one year estimated from Figure 1 in the manuscript.

* CR: Complete response from meta-analysis. Two-year data are not available.

Harms in the Phase 3 Trials

Intervention, Trial	Arms	N	SAEs	D/C due to AEs	Mortality	Serious Infections
Voclosporin AURORA	Voclosporin	178	21%	11%	0.6%	10%
	Placebo	178	21%	15%	2.8%	11%
Belimumab BLISS-LN	Belimumab	224	26%	13%	3%	14%
	Placebo	224	30%	13%	2%	17%

Voclosporin carries a black box warning for serious infections and malignancies that may lead to hospitalization or death based on the experience with similar immunosuppressant therapies.

Controversies and Uncertainties

- How one-to-two-year renal response outcomes from the trials translate into long term outcomes such as ESRD, dialysis, and mortality
- How long to continue the therapies
- The impact of these therapies on fatigue and other measures of quality of life
- The impact of these therapies in non-White populations
- Whether voclosporin has less toxicity than other calcineurin inhibitors

Potential Other Benefits and Contextual Considerations

- LN typically impacts young adults and is the major cause of premature mortality for patients living with SLE
- Voclosporin is an oral drug
- LN disproportionately impacts non-white patients. Subgroup analyses suggest that both belimumab and voclosporin may be more effective in Black patients
- Belimumab may have other benefits beyond its impact on renal function

Public Comments Received

- Abstract ACR 2020: A higher proportion of patients receiving belimumab in the BLISS-LN trial achieved low SLE disease activity (SLEDAI-S2K score <4, 28% versus 19%)
- Belimumab is available in a sub-cutaneous formulation, which may supplant the IV formulation
- Voclosporin has a black box warning

Summary

- Belimumab significantly increases the CRR and PERR at two years compared with standard therapy alone without increases in adverse events. Two years is too short to provide high certainty of the magnitude or duration of long-term benefit.
- Voclosporin significantly increases the CR and PR at one year compared with standard therapy alone without increases in adverse events. One year is too short to provide high certainty of the magnitude or duration of long-term benefit.

ICER Evidence Ratings for Belimumab and Voclosporin

Treatment	Comparator	Evidence Rating
Adults with LN		
Belimumab + MMF/Corticosteroids or Cyclophosphamide/Corticosteroids	MMF/Corticosteroids or Cyclophosphamide/Corticosteroids	B+
Voclosporin+ MMF/Corticosteroids	MMF/Corticosteroids	B+

B+: Moderate certainty that the intervention is incremental or better than the comparator

Questions?

Belimumab and Voclosporin for Lupus Nephritis: Effectiveness and Value

Olena Mandrik, PhD, PharmD, MSc

Research Fellow

The University of Sheffield

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Key Modeling Team Members

- **James Fotheringham, MD,** NIHR Clinician Scientist, Consultant Nephrologist, Sheffield Kidney Institute/University of Sheffield
- **Praveen Thokala, PhD,** Senior Research Fellow, University of Sheffield

Disclosures:

Financial support was provided to the University of Sheffield from the Institute for Clinical and Economic Review.

The University of Sheffield researchers have no conflicts to disclose

Objective

Estimate the cost effectiveness of belimumab and voclosporin for patients with lupus nephritis, with each drug compared to the standard of care as represented by the comparator arm in its own pivotal trial(s)

Methods in Brief

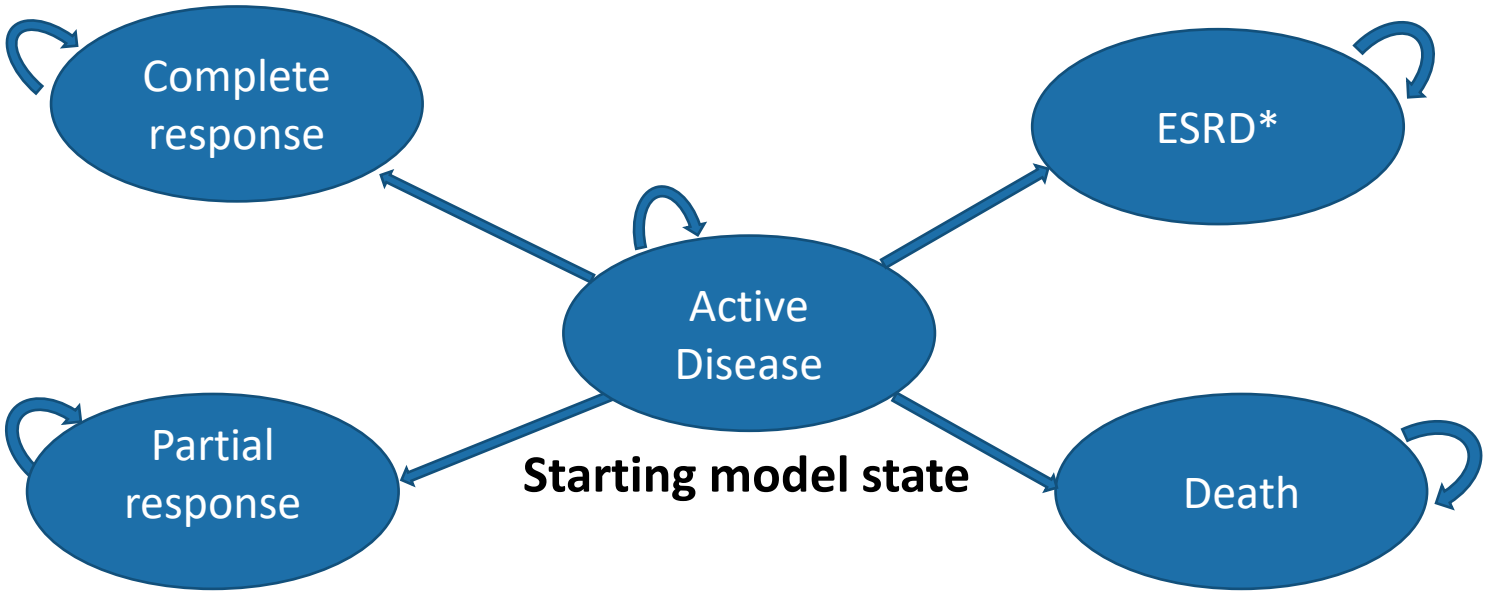
Methods Overview

- **Model**: Short term trial-based Markov model and long-term extrapolation using partitioned-survival modeling
- **Setting**: United States
- **Perspective**: Health care sector perspective
- **Time Horizon**: Lifetime horizon
- **Discount Rate**: 3% per year (costs and outcomes)
- **Cycle Length**: 1 month
- **Primary Outcome**: Cost per quality-adjusted life year (QALY) gained; cost per life year (LY) gained, cost per equal value of life years gained (evLYGs)

Model Characteristics

- **Target Population**
  - Mean age – 36 years;
  - Females – 92%
  - Race/Ethnicity - Black: 53%, Others: 47%
- **Model structure**
  - Short-term model – 3 years
  - Long-term model – lifetime

Short-Term Model Based on Trial Data



Patients maintain their ‘end of follow up’ health state until the end of the short term model

*ESRD: end-stage renal disease

Key Model Assumptions: Short-Term Model

- Patients in Complete and Partial Response states discontinue treatment at the end of the short-term model (unless serious adverse event occurs)
- Patients in Active Disease state discontinue treatment at 18 months
- Tapered steroid use decreases costs and increases quality of life

Key Model Inputs: Belimumab (BLISS-LN trial)

Arm	Complete Renal Response, %	Partial Renal Response, %	End-Stage Renal Disease, %	Death, %
Belimumab	30.0	17.5	0.0	0.4
Placebo	19.7	17.0	0.4	0.9

Efficacy at 104 weeks

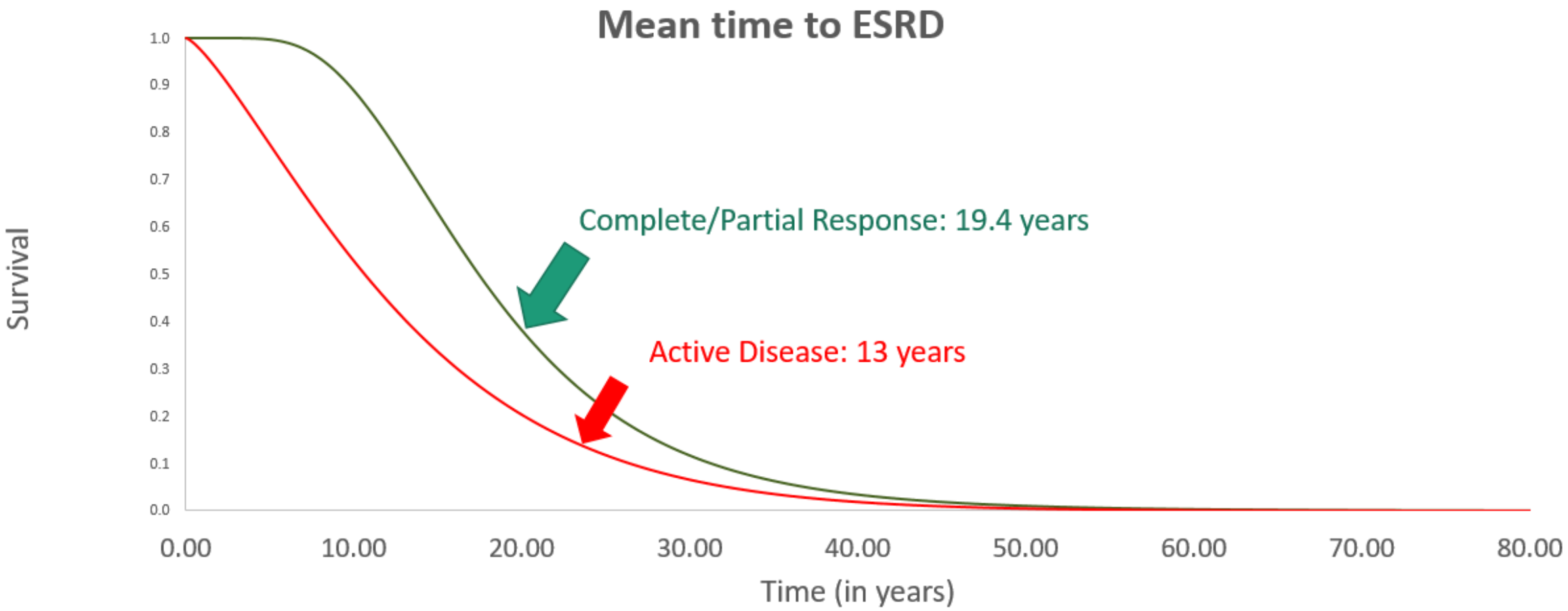
Key Model Inputs: Voclosporin (AURORA and AURA-LV Trials)

Arm	Complete Renal Response*, %	Partial Renal Response**, %	ESRD***, %	Death¥, %
Voclosporin	43.2	26.6	0.0	0.6
Placebo	23.3	28.4	0.0	2.8

Efficacy at 52 weeks

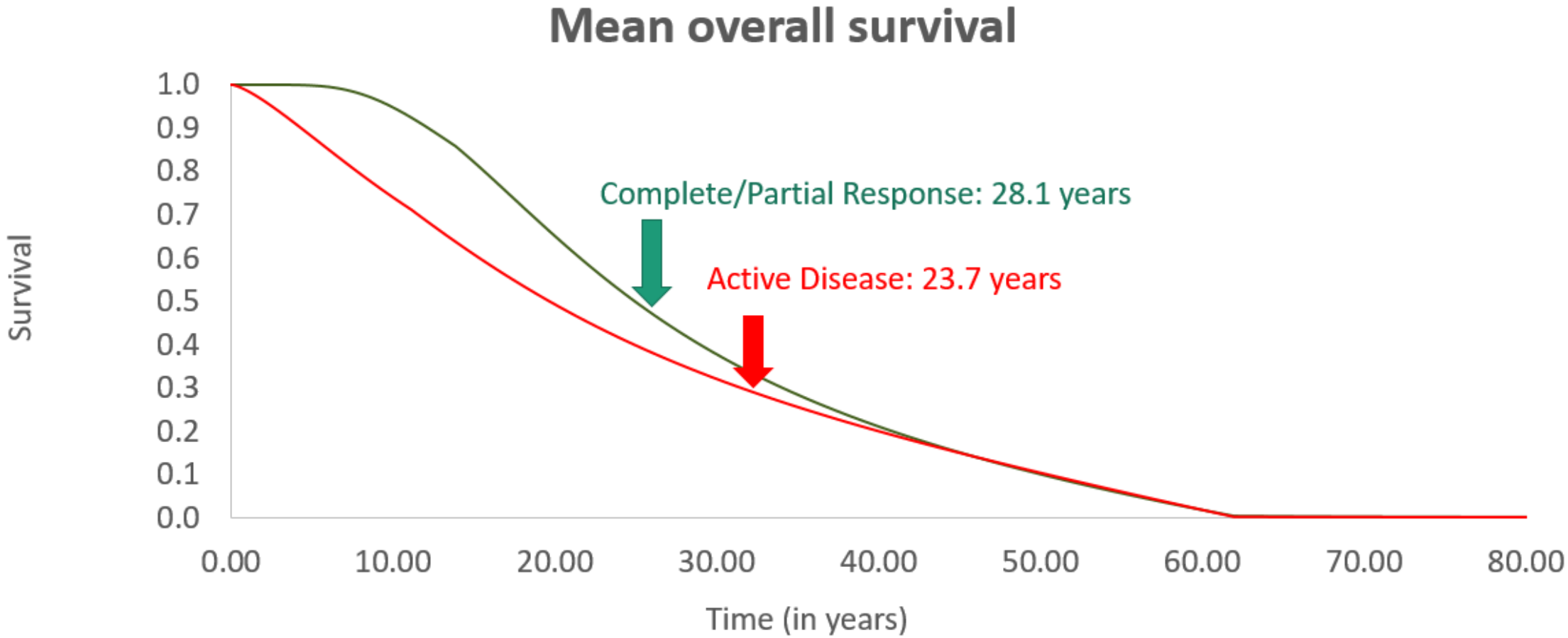
* Meta-analysis of AURA-LV and AURORA trials
** Calculated from Meta-analysis of AURA-LV and AURORA trials
*** Assumed as zero
¥ AURORA trial

Long-Term Model Schematic



Data: Davidson et al (2018); Chen et al (2008)

Long-Term Model Schematic



Data: Davidson et al (2018); Chen et al (2008)

Key Model Assumptions: Long-Term Model

- Patients in Active Disease, Complete and Partial Response at the end of the short-term model transition independent of the previous treatment received
- Patients in Complete and Partial Response are assumed to have the same overall and ESRD free survival
- Time in Active Disease before progressing to ESRD is 1.2 years (for patients in response states)

Key Model Inputs: Treatment-Related Costs

Treatment	Monthly Costs
Belimumab loading dose (1st month)	$9,811*
Belimumab	$3,560*
Voclosporin	$7,686**

* Estimated using average sales price; IV dose; average weight of patients in the US
** Estimated using mean weighted daily dose, price per wallet and assumed discount of 22.5%

Key Model Inputs: Costs of Health States

Health State	Annual Health Related Costs	Indirect (Non-Medical) Costs***
Complete Response	$7,871*	$5,140
Partial Response	$8,185*	$5,140
Active Disease	$42,510 *	$14,777
End Stage Renal Disease	$120,920**	$24,157

Sources:
* Bartels-Peculis et al (2020); Hanly et al (2016); Barber et al (2019); Li et al (2009).
** Medicare (data provided by the Lupus Research Alliance)
*** Cloutier et al. (2020); Garris et al. (2013); Bureau of Labor Statistics (2020)

Key Model Inputs: Quality of life

Health State	Value
Complete Response	0.80
Partial Response	0.71
Active Disease	0.62
End Stage Renal Disease	0.55

Sources: Bexelius et al, 2013; Mohara et al, 2014

Increment in Quality of Life for Low-Dose Steroids: 0.025
Increment in Quality of Life for Treatments with No Steroids: 0.09

Results

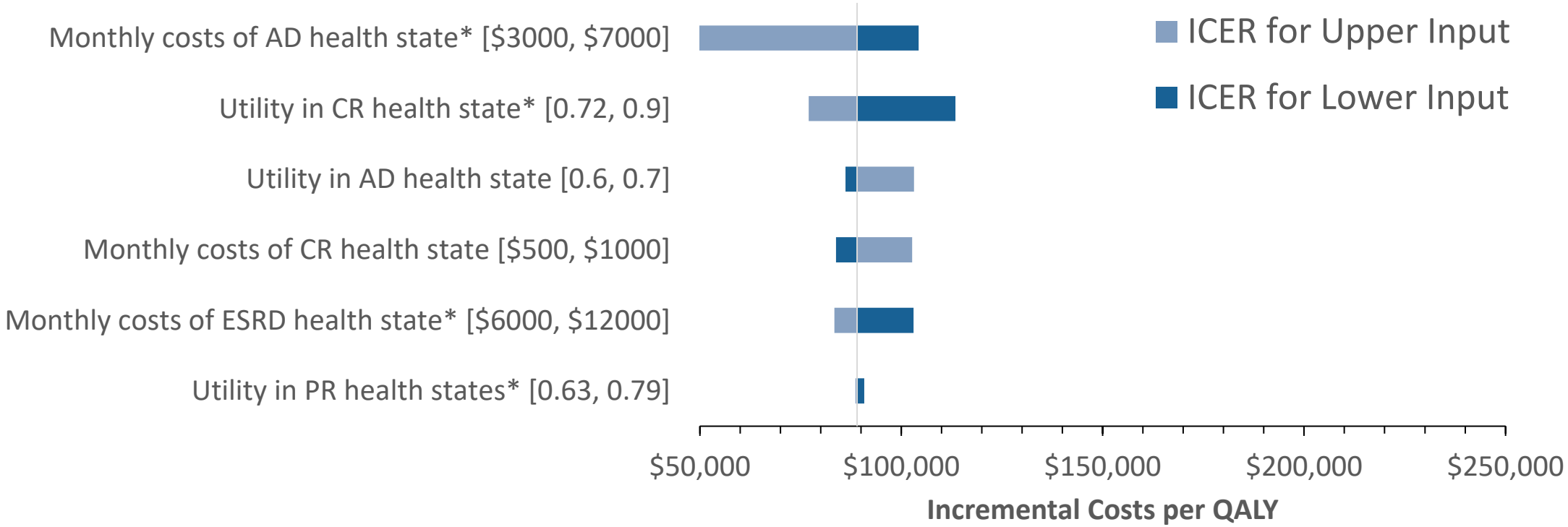
Base-Case Results: Belimumab

Treatment	Drug Cost	Total Cost	QALYs	Life Years	evLYGs
Belimumab	$ 93,500	$930,000	11.7	17.9	11.7
Standard Care-Belimumab	-	$886,300	11.2	17.5	11.2

Treatment	QALYs	Life Years	evLYGs
Incremental Cost-Effectiveness Ratios	$89,700	$113,900	$77,800

QALYs: quality-adjusted life years; evLYGs: equal value of life years gained

One Way Sensitivity Analyses: Belimumab



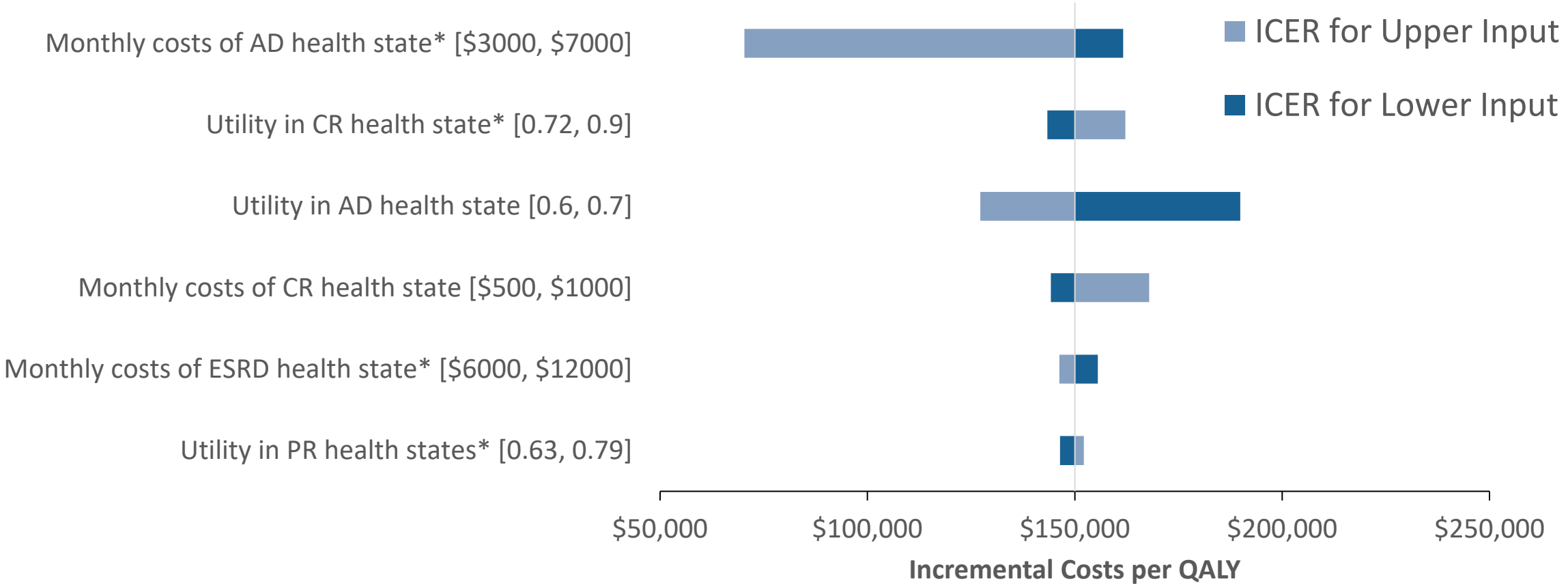
Base-Case Results: Voclosporin

Treatment	Drug Cost	Total Cost	QALYs	Life Years	evLYGs
Voclosporin	$215,300	$928,500	12.6	18.4	12.8
Standard Care-Voclosporin	-	$784,400	11.7	17.6	11.7

Treatment	QALYs	Life Years	evLYGs
Incremental Cost-Effectiveness Ratios	$149,300	$174,300	$131,500

QALYs: quality-adjusted life years; evLYGs: equal value of life years gained

One Way Sensitivity Analyses: Voclosporin



Probabilistic Sensitivity Analysis

Threshold	Belimumab	Voclosporin
$50,000 /QALY	25%	0.3%
$100,000/QALY	52%	11%
$150,000/QALY	69%	49%
$200,000/QALY	79%	79%
$250,000/QALY	86%	93%
$300,000/QALY	90%	98%

QALY: quality-adjusted life year

Deterministic Scenario Analyses

Treatment	Base-Case Results	Societal Perspective	Lower Survival in Response States	Lower Utilities in Response States	Increased Time Spent in AD Prior to ESRD
Belimumab	$89,700	$66,100	$170,000	$115,000	$108,300
Voclosporin	$149,300	$132,000	$237,400	$185,900	$173,100

Results presented as cost per quality adjusted life year (QALY)
AD – active disease

Deterministic Scenario Analyses (continued)

Treatment	Base-Case Results	Treatment Discontinuation at 6 Months for Active Disease	Alternative Costs of Health States Calculation *
Belimumab	$89,700	-	$142,500
Voclosporin	$149,300	$121,800	$195,200

Results presented as cost per quality adjusted life year (QALY)

* Based on cost ratios between ESRD and other health states, data in confidence

Limitations

- Lack of high-quality data on racial/ethnic subgroups
- Uncertainty around:
  - Long-term disease progression
  - Duration of active disease state in the long-term model
  - Duration of therapy and long-term clinical effect of the therapies

Comments Received

- Comment 1: Differential treatment duration for responders and non-responders
  - Change: Duration of treatment in response states – 3 years; duration of treatment in active disease state – 18 months
- Comment 2: Costs of ESRD state
  - Change: Costs of ESRD state sourced from Medicare-covered patients

Conclusions

- **Belimumab**: Incremental cost-effectiveness ratio is $89,700 /QALY
- **Voclosporin**: Incremental cost-effectiveness ratio is $149,300 /QALY
- There is a larger uncertainty in cost effectiveness of voclosporin than in cost effectiveness of belimumab.

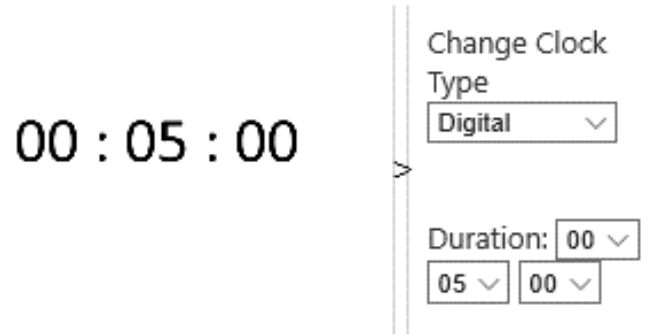
Questions?

Manufacturer Public Comment and Discussion

Bernard Rubin, DO, MPH, Medical Director GlaxoSmithKline

Conflicts of Interest:

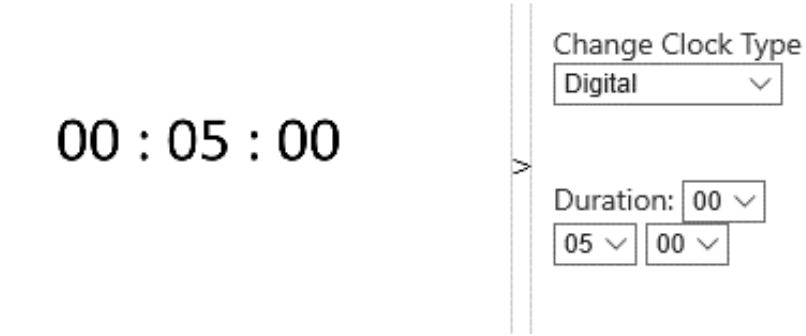
- *Dr. Rubin is a full-time employee of GlaxoSmithKline.*



Eric Turowski, MBA, Vice President of Market Access Aurinia Pharmaceuticals, Inc.

Conflicts of Interest:

- *Eric is a full-time employee of Aurinia Pharmaceuticals, Inc.*

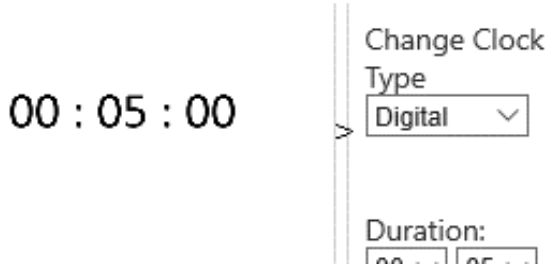


Public Comment and Discussion

Dina Thachet, BS, CCLS, Patient Advocate
Lupus and Allied Diseases Association, Inc.

Conflicts of Interest:

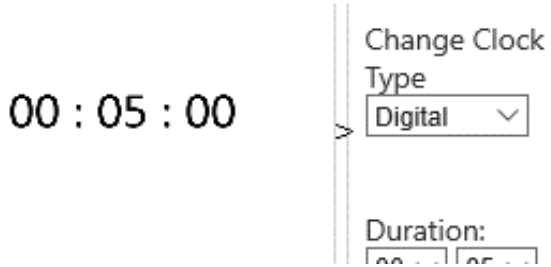
- *No financial conflicts of interest to disclose.*



Toni Grimes, MS, Patient with Lupus
Lupus Foundation of America

Conflicts of Interest:

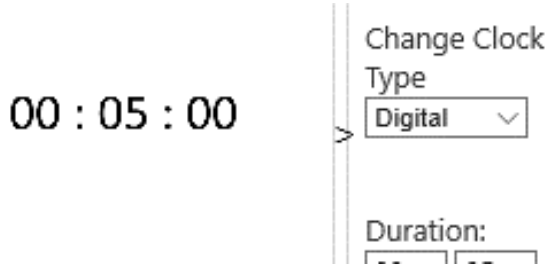
- *No financial conflicts of interest to disclose.*



Tammy Boyd, JD, MPH, President & CEO
Black Women's Health Imperative

Conflicts of Interest:

- *No financial conflicts of interest to disclose.*



Lunch

Meeting will resume at 12:20 pm ET

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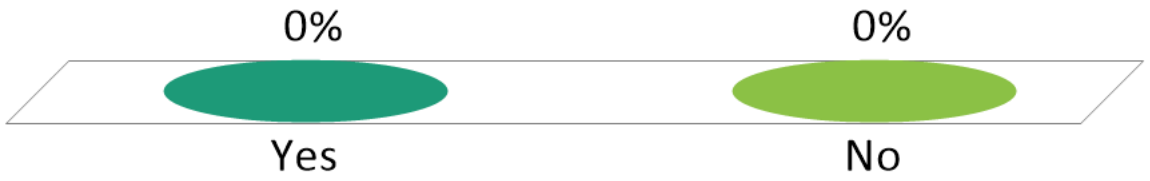
Voting Questions

Clinical Evidence

1. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **belimumab (Benlysta) plus standard induction therapy** is superior to that provided by **standard induction therapy alone?**

A. Yes

B. No



2. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **voclosporin (Lupkynis™) plus standard induction therapy** is superior to that provided by **standard induction therapy alone?**

A. Yes

B. No

Potential Other Benefits and Contextual Considerations

When making judgements of overall long-term value for money, what is the relative priority that should be given to *any* effective treatment for lupus nephritis, on the basis of the following contextual considerations?

1. Contextual Consideration: **Short-term risk of death for patients without treatment**

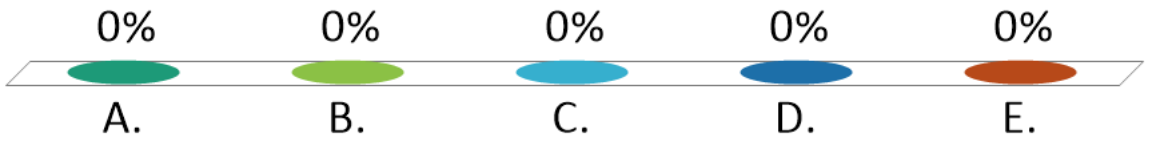
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



2. Contextual Consideration: **Magnitude of the lifetime impact on individual patients of the condition being treated**

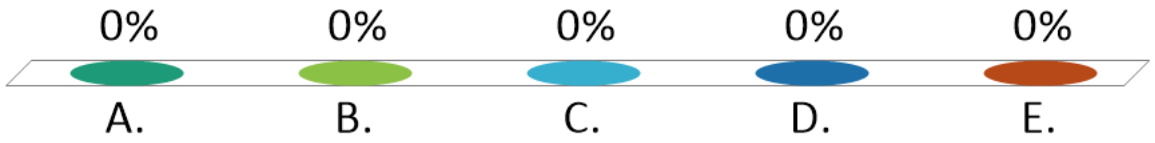
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



3. Contextual Considerations: **Other (as relevant)**

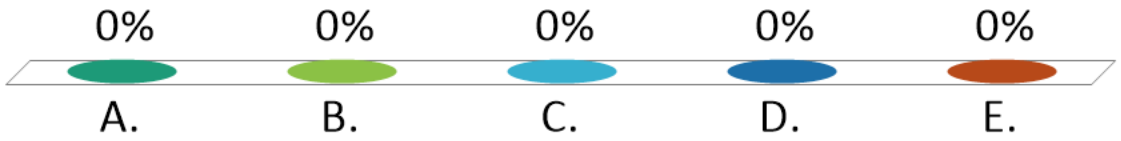
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



What are the relative effects of belimumab versus standard induction therapy for lupus nephritis on the following outcomes that inform judgement of the overall long-term value for money of belimumab?

1. Belimumab: **Patients' ability to achieve major life goals related to education, work, or family life**

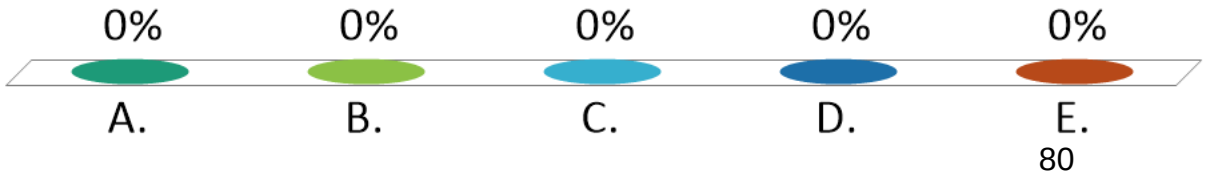
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



2. Belimumab: **Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life**

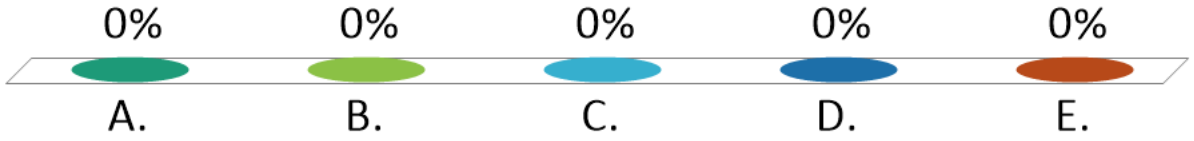
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



3. Belimumab: **Health inequities**

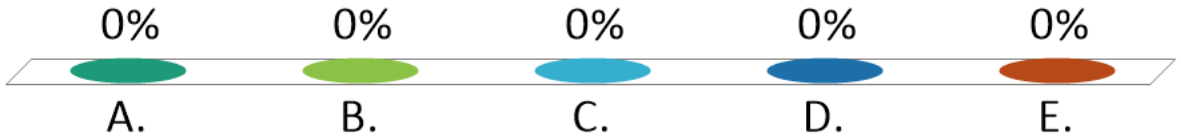
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



4. Belimumab: **Preservation of kidney function improves the chances for patients to have children**

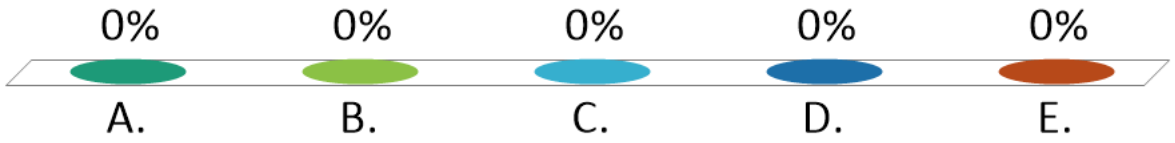
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



What are the relative effects of voclosporin versus standard induction therapy for lupus nephritis on the following outcomes that inform judgement of the overall long-term value for money of voclosporin?

5. Voclosporin: **Patients' ability to achieve major life goals related to education, work, or family life**

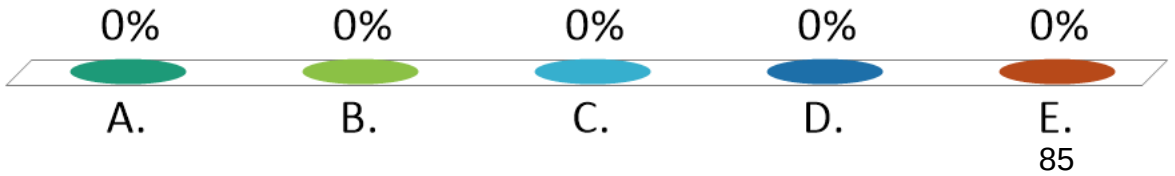
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



6. Voclosporin: **Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life**

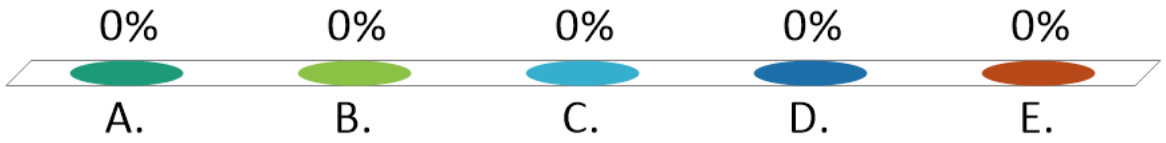
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



7. Voclosporin: **Health inequities**

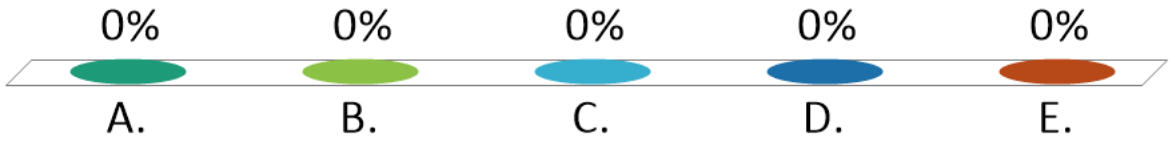
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



8. Voclosporin: **Preservation of kidney function improves the chances for patients to have children**

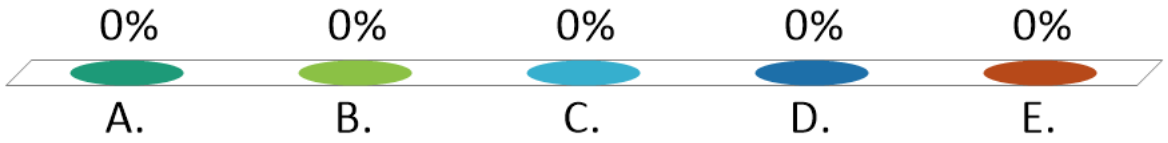
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

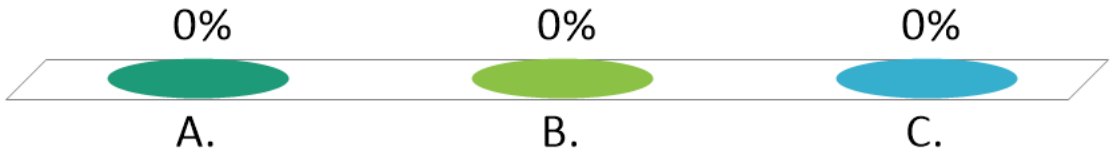
E. Major positive effect



Long-Term Value for Money

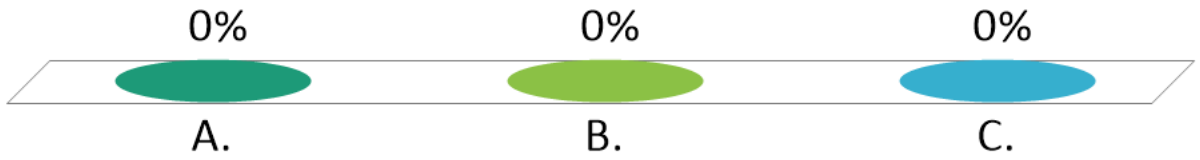
1. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with **belimumab** versus standard induction therapy?

A. Low long-term value for money at current price
B. Intermediate long-term value for money at current price
C. High long-term value for money at current price



2. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with **voclosporin** versus standard induction therapy?

A. Low long-term value for money at assumed price
B. Intermediate long-term value for money at assumed price
C. High long-term value for money at current assumed price



Break

Meeting will resume at 1:45 pm ET

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Policy Roundtable

Policy Roundtable

Policy Roundtable Participant	Conflict of Interest
Kathleen Arntsen, BA, President & CEO, Lupus and Allied Diseases Association, Inc.	LADA receives funding from health care related organizations, including Aurinia and GSK, but members associated with LADA are not compensated.
Linda Goler Blount, MPH, President & CEO, Black Women's Health Imperative	No financial conflicts of interest to disclose.
Christele Felix, BS, Chief Operating Officer, LupusChat	No financial conflicts of interest to disclose.
Meggan Mackay, MD, MS, Investigator and Professor of Medicine, The Feinstein Institutes for Medical Research, Northwell Health	Dr. Mackay participates in industry-sponsored clinical trials for lupus nephritis and is reimbursed for subjects recruited and followed.
Jay McKnight, PharmD, BCPS, Vice President, Pharmacy Clinical and Specialty Strategies, Humana Pharmacy Solutions	Dr. Jay McKnight is a full-time employee of Humana.
Simrat Randhawa, MD, MBA, Senior Vice President, Medical and Clinical Affairs, Aurinia Pharmaceuticals, Inc.	Dr. Simrat Randhawa is a full-time employee of Aurinia Pharmaceuticals, Inc.
Brad Rovin, MD, Professor of Medicine and Pathology, Ohio State University Wexner Medical Center	Dr. Brad Rovin is involved in several trials of novel therapeutics for lupus nephritis and is a consultant on the medical/scientific advisory boards to design trials for these therapeutics. His organization receives less than 25% funding from pharmaceutical companies for clinical trials.
Bernard Rubin, DO, MPH, Medical Director, GlaxoSmithKline	Dr. Bernard Rubin is a full-time employee of GlaxoSmithKline.
Emily Tsiao, PharmD, Clinical Pharmacist, Premera Blue Cross	Dr. Emily Tsiao is a full-time employee of Premera Blue Cross.

New England CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on April 16th
  - Includes description of New England CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: https://icer.org/assessment/lupus-nephritis-2021/

Adjourn

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