Tezepelumab for Severe Asthma: Effectiveness and Value

Midwest Comparative Effectiveness Public Advisory Council (CEPAC)

Public Meeting — November 19, 2021

Meeting materials available at: https://icer.org/asthma-2021/#timeline

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Patient and Clinical Experts

Melanie Carver, Chief Mission Officer, Asthma and Allergy Foundation of America

- *AAFA receives funding from Pharmaceutical manufacturers, PhRMA, and PCMA.*

Tonya Winders, MBA, President & Chief Executive Officer, Allergy & Asthma Network

- *Tonya Winders serves as a speaker & advisor to AstraZeneca, Amgen, GSK, Novartis, Sanofi, Regeneron & ALK Abello. The Allergy & Asthma Network receives funding from healthcare companies for unbranded disease awareness, education, advocacy & research.*

Jonathan Corren, MD, Medicine and Pediatrics, UCLA School of Medicine

- *Dr. Jonathan Corren has received honoraria from AstraZeneca, Genentech, Regeneron, and Sanofi. Dr. Corren has equity interests in Allakos in excess of $10,000, and received research funding from AstraZeneca, Genentech, Novartis, Optinose, Regeneron, and Sanofi, and is an advisory board member and speaker board member for AstraZeneca.*

Michael E. Wechsler, MD, Professor of Medicine, Director of NJH Cohen Family Asthma Institute, National Jewish Health

- *Dr. Michael Wechsler has received consulting fees and honoraria from the following health care companies: AstraZeneca, Amgen, Boehringer Ingelheim, Genentech, GlaxoSmithKline, Novartis, Regeneron, and Sanofi.*

Why are we here today?

“When Julia is having asthma exacerbations it affects her days, her sleep at night. In fact, I always sleep next to her when she is having difficulty breathing so I can be right there to give her her medication… Asthma is the number one reason she misses school.”

The Eisen Story
https://asthma.chestnet.org/patient-testimonials/

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 others in the health care “system”?

The Impact of Rising Health Care Costs

Leonard Edloe
Richmond, Virginia

The Whitman family
Bird City, Alaska

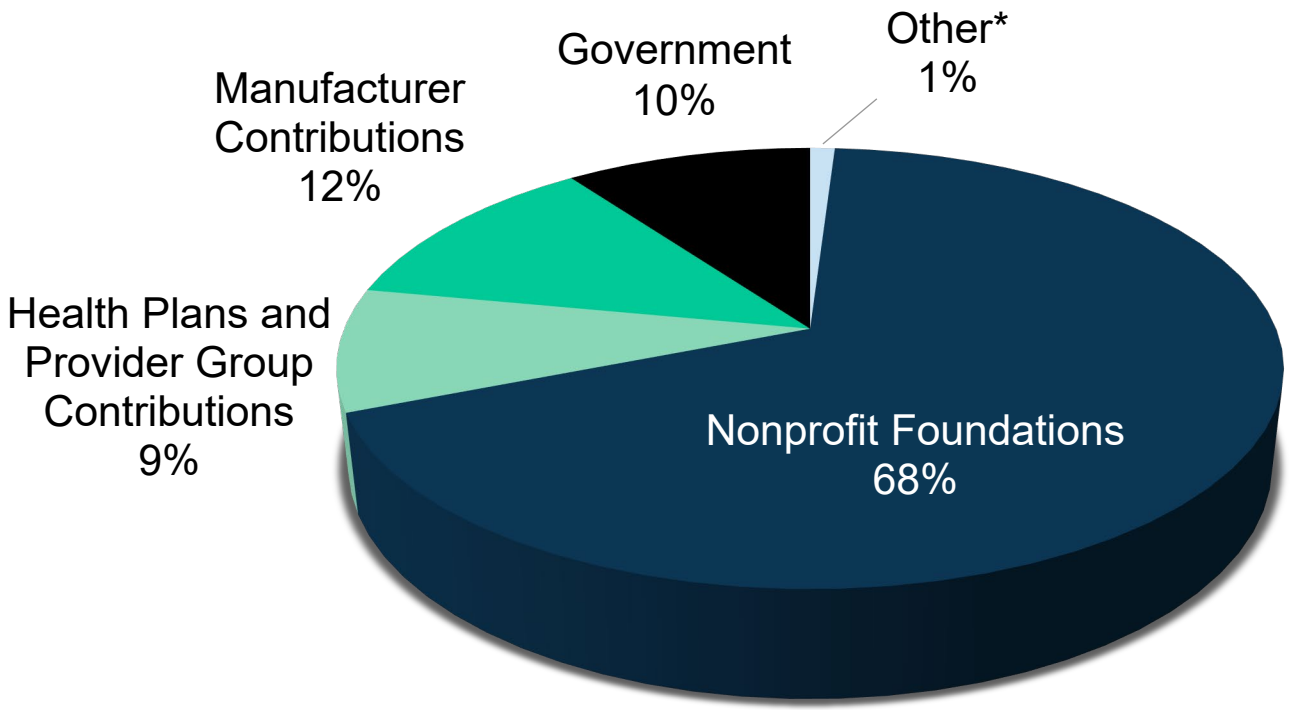
The Maccoux family
Brooklyn Park, Minnesota

Organizational Overview

- Midwest Comparative Effectiveness Public Advisory Council (CEPAC)
- 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
- University of Colorado cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
  - **Kaharu Sumino, MD, MPH**, Associate Professor of Medicine, Washington University School of Medicine
    - No relevant conflicts of interest to disclose, defined as more than $10,000 in health care company stock or more than $5,000 in honoraria or consultancies during the previous year from health care manufacturers or insurers.
  - **Michael E. Wechsler, MD,** Professor of Medicine, Director NJH Cohen Family Asthma Institute, National Jewish Health
    - Dr. Michael Wechsler has received consulting fees and honoraria from the following health care companies: AstraZeneca, Amgen, Boehringer Ingelheim, Genentech, GlaxoSmithKline, Novartis, Regeneron, and Sanofi.
  - How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Agenda

Time (CT)	Activity
10:00am – 10:20am	Meeting Convened and Opening Remarks
10:20am – 11:00am	Presentation of the Clinical Evidence
11:00am – 11:40am	Presentation of the Economic Model
11:40am – 12:05pm	Public Comments and Discussion
12:05pm – 12:45pm	Lunch Break
12:45pm – 2:00pm	Midwest CEPAC Vote on Clinical Effectiveness and Value
2:00pm – 2:10pm	Break
2:10pm – 3:30pm	Policy Roundtable
3:30pm – 4:00pm	Reflections from Midwest CEPAC
4:00pm	Meeting Adjourned

Presentation of the Clinical Evidence

David M. Rind, MD, MSc

Chief Medical Officer

Institute for Clinical and Economic Review

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Key Collaborators

- **Belén Herce-Hagiwara, BA**

  Research Assistant, ICER

- **Serina Herron-Smith, BA**

  Senior Research Assistant, ICER

Disclosures:

We have no conflicts of interest relevant to this report

Asthma

- 25 million Americans, including 5 million children
- 1.6 million ER visits, 180,000 hospitalizations, and 3,500 deaths each year in the US
- Asthma is more than twice as common among Black children as among White children and remains somewhat more common among Black adults
- About half of patients with mild-to-moderate asthma exhibit type 2 phenotype; proportion is higher in severe asthma

Severe Asthma

- Some overlap in definitions
- 5-10% of all asthma
- Global Initiative for Asthma (GINA):

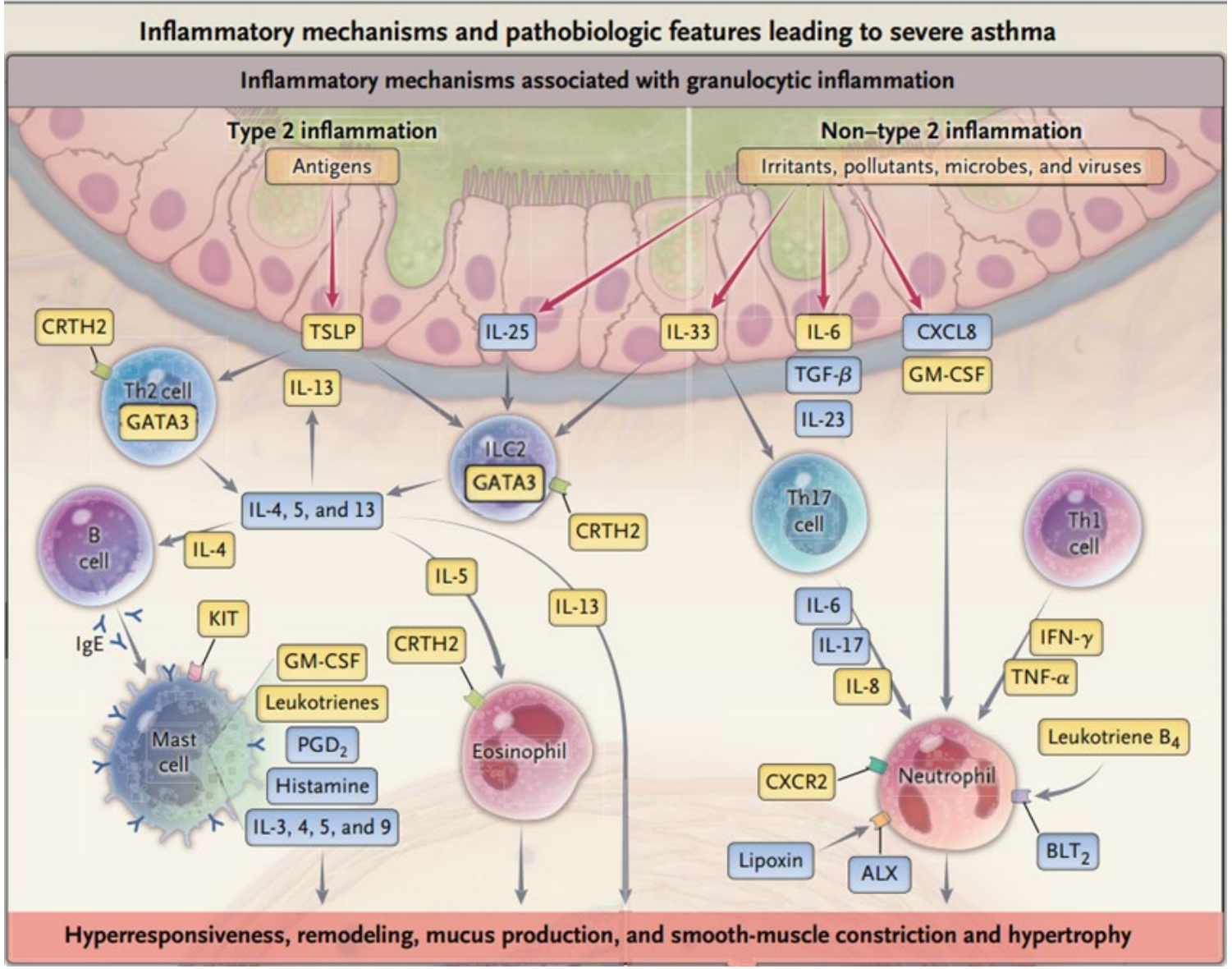
  A subset of difficult-to-treat asthma that is uncontrolled despite adherence with maximal optimized high dose ICS/LABA treatment and management of contributory factors, or that worsens when high dose treatment is decreased

Patient Experience of Severe Asthma

- Most patients report having daily symptoms and are scared and burdened by their symptoms
- Interferes with living the life they want to live
- Burdens family and caregivers
- Fear systemic corticosteroid side effects
- Daily symptom control is more important than reducing asthma exacerbations

Type 2 Phenotype

- Phenotypes not clearly defined and can overlap
- Increases in type 2 helper cells
- Response to antigens/allergens
- Allergic asthma and eosinophilic asthma are generally considered type 2 asthma
  - All the biologics currently available are for allergic asthma (omalizumab) or eosinophilic asthma (mepolizumab, reslizumab, benralizumab, dupilumab)
- Thymic stromal lymphopoietin (TSLP) sits early in pathway



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Tezepelumab

- Monoclonal antibody targeting TSLP
- Subcutaneous injection every four weeks
- FDA decision expected early next year

Scope of Review

- Intervention: Tezepelumab for severe asthma
- Comparators
  - All patients: usual care alone (placebo arm of clinical trials)
  - Eosinophilic asthma : dupilumab + usual care
  - Allergic asthma: omalizumab + usual care
  - Steroid dependent asthma: dupilumab + usual care

Clinical Evidence

Tezepelumab: Clinical Evidence

- Phase 2 (dose finding) “PATHWAY” trial in 550 adults with uncontrolled asthma
- Phase 3 “NAVIGATOR” trial in 1061 adults and adolescents with severe, uncontrolled asthma
- Phase 3 “SOURCE” trial in 150 adults with OCS-dependent asthma; limited reporting to date

Outcomes

- Annualized asthma exacerbation rate (AAER): Primary outcome of most trials, but not most patient-important outcome
- Improvement in daily symptoms (ACQ and AQLQ measure symptoms and QoL) most important to patients; MCID 0.5 points
- Subgroups
  - Most drugs had only worked in eosinophilic asthma so stratification by eosinophil count is particularly important
  - Omalizumab used in allergic asthma so can compare that subgroup as well

Tezepelumab and Dupilumab in All Patients

Drug	AAER Rate Ratio Range vs. Placebo	Difference in ACQ* vs. Placebo	Difference in AQLQ vs. Placebo
Tezepelumab 210 mg	0.29 to 0.44	Δ = 0.29 to 0.33	Δ = 0.20 to 0.34
Dupilumab 200 & 300 mg	0.30 to 0.54	Δ = 0.22 to 0.39	Δ = 0.26 to 0.36

AAER: annualized asthma exacerbation rate, ACQ: Asthma Control Questionnaire, AQLQ: Asthma Quality of Life Questionnaire, mg: milligram
* ACQ-5 used for dupilumab trials. ACQ-6 used for tezepelumab trials.

Tezepelumab and Dupilumab by Eosinophil Count

Drug	Blood Eosinophil Count (cells/µL)	AAER Rate Ratio Range vs. Placebo	Difference in ACQ* vs. Placebo	Difference in AQLQ vs. Placebo
Tezepelumab 210 mg	≥150	0.34 to 0.39	Δ = 0.35 to 0.41	Δ = 0.29 to 0.41
	<150	0.17 to 0.61	Δ = 0.09 to 0.30	Δ = 0.11 to 0.44
Dupilumab† 200 & 300 mg	≥150	0.44	--	--
	<150	0.93 to 1.15	--	--

AAER: annualized asthma exacerbation rate, ACQ: Asthma Control Questionnaire, AQLQ: Asthma Quality of Life Questionnaire, mg: milligram
* ACQ-5 used for dupilumab trials. ACQ-6 used for tezepelumab trials.
† Data from LIBERTY ASTHMA QUEST only, not reported for the phase 2b study

Tezepelumab and Omalizumab in Allergic Asthma

Drug	AAER Rate Ratio Range vs. Placebo	Difference in ACQ-6 vs. Placebo	Difference in AQLQ vs. Placebo
Tezepelumab 210 mg	0.20 to 0.42	Δ = 0.10 to 0.29	Δ = 0.07 to 0.34
Omalizumab*	0.52	NR	Δ = 0.26

AAER: annualized asthma exacerbation rate, ACQ-6: Asthma Control Questionnaire-6, AQLQ: Asthma Quality of Life Questionnaire, mg: milligram; NR: not reported
* Data from prior ICER report

Reduction in Systemic Steroids

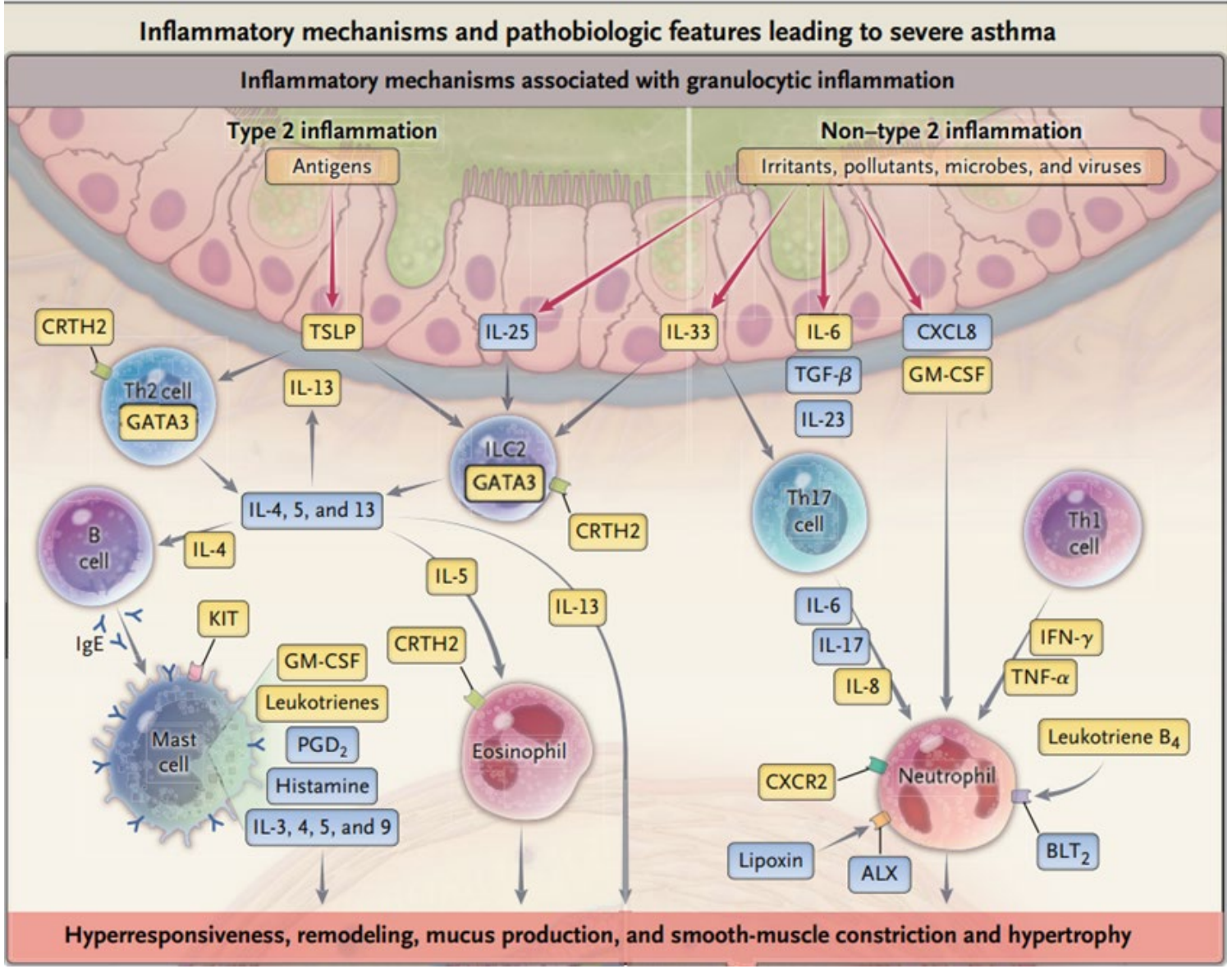
- Tezepelumab (SOURCE trial)
  - Patients were not more likely to reduce their OCS dose at week 48 with tezepelumab than placebo (OR 1.28, 95% CI 0.69 to 2.35)
- Dupilumab (VENTURE trial)
  - Greater reduction in OCS dose with dupilumab than placebo (70% vs. 42%)
  - More patients had a reduction in dose of at least 50% (80% vs. 50%)
  - More patients had a reduction in dose to below 5 mg/day (69% vs. 33%)

Harms

- Adverse events and serious adverse events are rare with all these drugs
- Omalizumab does carry a “black box” warning for anaphylaxis
- Dupilumab and omalizumab have long-term safety data

Controversies and Uncertainties

- Lack of head-to-head trials (particularly with omalizumab, old trials)
- Very high placebo response rates in randomized trials
- Tezepelumab has a new mechanism of action, so concerns about as-yet-unidentified harms
- We do not have data on the subgroup who have neither eosinophilic asthma nor allergic asthma. We asked the manufacturer for data for this subgroup, but these data were not provided
- Very few Black patients in the tezepelumab trials despite severe asthma being more common in this population in the US



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Potential Other Benefits and Contextual Considerations

- Death from asthma is uncommon, but severe asthma has daily symptoms that interfere with nearly all activities and that markedly reduce quality of life
- Asthma disproportionately affects Black Americans, and they may have a more severe disease course
- The ICER Health Improvement Distribution Index for Black Americans with asthma is 1.21

Public Comments Received

- “The MCID concept is meant to compare a change from baseline in an individual patient (or group of patients), not the difference in response between two populations.”
- “While the report recognizes the efficacy of omalizumab for patients with an allergic phenotype, the dupilumab efficacy in this patient population should also be recognized.”
- “ICER’s reliance on the QALY is of great concern, especially when being used in an evaluation regarding asthma patients. As asthma is a chronic disease, the quality of life of patients, as defined by the QALY, is already diminished. This will lead to lower scores, even for drugs that are clinically effective, as patients with chronic diseases often cannot achieve perfect health.”

Summary

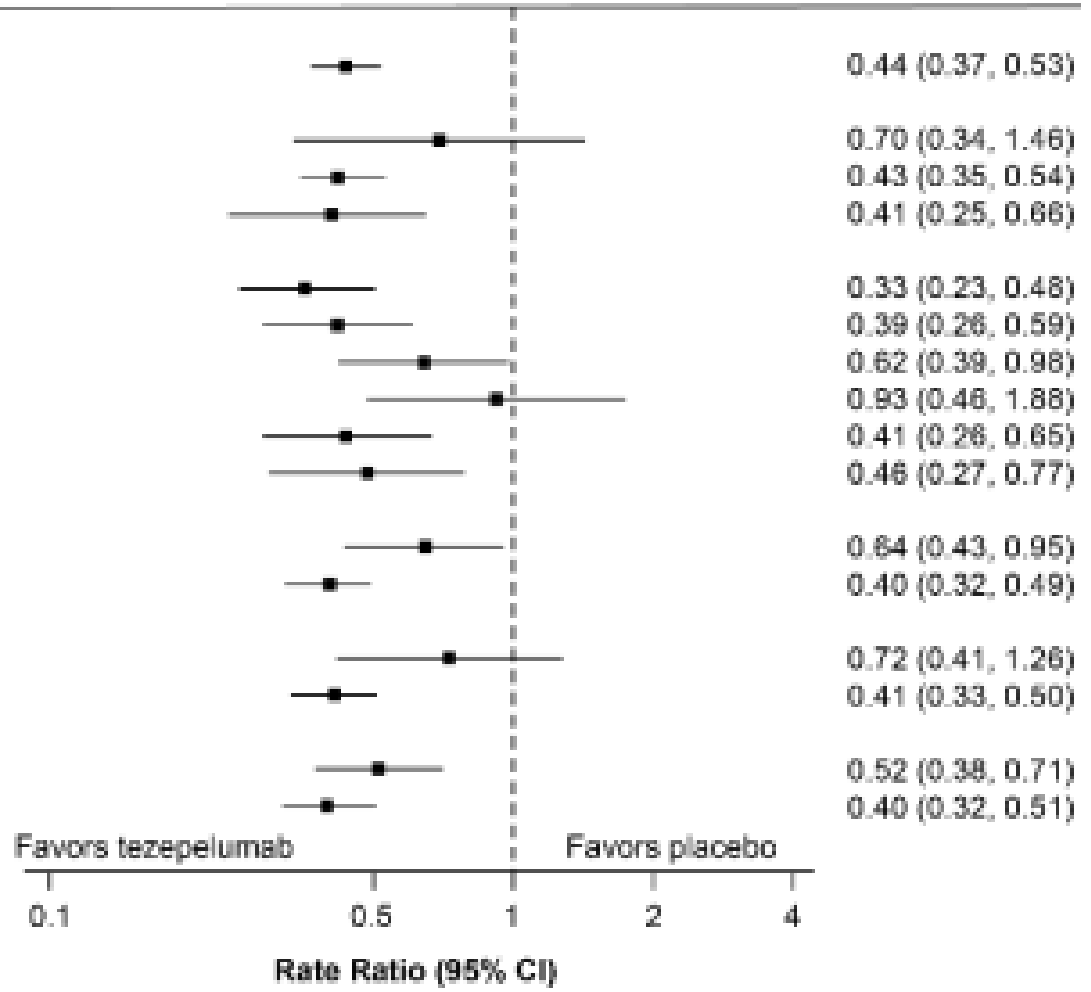
- Tezepelumab is likely effective for a broad group of patients with type 2 asthma and perhaps some with non-type 2 asthma
- This effectiveness, as with other biologics, reflects greater efficacy in reducing exacerbations than improving daily symptoms; therapies that reduce daily symptoms are needed
- We lack long-term safety data, which affects our evidence ratings (as it did for new biologics in the 2018 review)
- Tezepelumab is probably less effective in reducing need for oral corticosteroids than dupilumab

Evidence Ratings

Treatment	Comparator	Population	Evidence Rating
Tezepelumab vs.	Standard of care	All Patients With Severe Asthma	C++
Tezepelumab vs.	Dupilumab	Eosinophilic Asthma	I
Tezepelumab vs.	Omalizumab	Allergic Asthma	I
Tezepelumab vs.	Dupilumab	Steroid-Dependent Asthma	C-

Questions?

	Tezepelumab 210 mg Q4W N/Estimate	Placebo N/Estimate	Rate Ratio (95% CI)
Overall	528/0.93	531/2.10	0.44 (0.37, 0.53)
Age at study entry (years)			
Adolescent (≥12 – <18)	41/0.68	41/0.97	0.70 (0.34, 1.46)
Adult (≥18 – <65)	391/0.99	416/2.27	0.43 (0.35, 0.54)
Adult (≥65)	96/0.76	74/1.87	0.41 (0.25, 0.66)
Geographical region			
Asia Pacific	125/0.99	127/3.00	0.33 (0.23, 0.48)
North America	111/0.84	111/2.15	0.39 (0.26, 0.59)
South America	87/0.92	87/1.49	0.62 (0.39, 0.98)
Central/Eastern Europe	38/1.14	39/1.22	0.93 (0.46, 1.88)
Western Europe plus Australia	86/1.11	85/2.68	0.41 (0.26, 0.65)
Rest of world	81/0.59	82/1.29	0.46 (0.27, 0.77)
ICS dose at study entry			
Medium	131/0.85	132/1.33	0.64 (0.43, 0.95)
High	397/0.95	398/2.38	0.40 (0.32, 0.49)
OCS at baseline			
Present	49/2.12	51/2.94	0.72 (0.41, 1.26)
Absent	479/0.82	480/2.00	0.41 (0.33, 0.50)
Age at asthma diagnosis*			
Child (<18 years old)	197/0.90	202/1.73	0.52 (0.38, 0.71)
Adult (≥18 years old)	331/0.94	329/2.34	0.40 (0.32, 0.51)



Tezepelumab for Severe Asthma: Effectiveness and Value

R. Brett McQueen, PhD

Assistant Professor

University of Colorado Anschutz Medical Campus

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Key Review Team Members

- **Brett McQueen, PhD**, Assistant Professor, University of Colorado Anschutz Medical Campus
- **Eric Gutierrez, MPH**, Statistical Analyst, University of Colorado Anschutz Medical Campus
- **Jon Campbell, PhD**, ICER
- **Noemi Fluetsch, MSc, MPH**, ICER

Disclosures:

Financial support provided to the University of Colorado from the Institute for Clinical and Economic Review (ICER).

University of Colorado researchers have no conflicts to disclose defined as more than $10,000 in healthcare company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.

Objective

- Assess the lifetime cost-effectiveness of tezepelumab plus standard of care (SoC) [e.g., inhaled corticosteroid therapy and at least one additional controller medication] versus SoC alone in patients with severe asthma

Methods in Brief

Methods Overview

- **Time Horizon**: Patient lifetime
- **Setting**: United States
- **Perspective**: Health care sector (direct medical care and drug costs); modified societal
- **Cycle Length**: 2 weeks
- **Discount Rate**: 3% per year (costs and outcomes)
- **Outcomes**: Total and incremental: costs, life years, quality-adjusted life years (QALY), equal value of life years (evLY), percent responder

Model Cohort Characteristics

Baseline Characteristic	Value
Mean (SD) Age in Years	52 (12)
Percent Female	66%
Mean (SD) Weight in kg	78 (18)
Proportion of Patients with Chronic Oral Corticosteroid Use (SoC)	9.6%
Source	NAVIGATOR and PATHWAY (Menzies-Gow, 2021 and Corren, 2017)

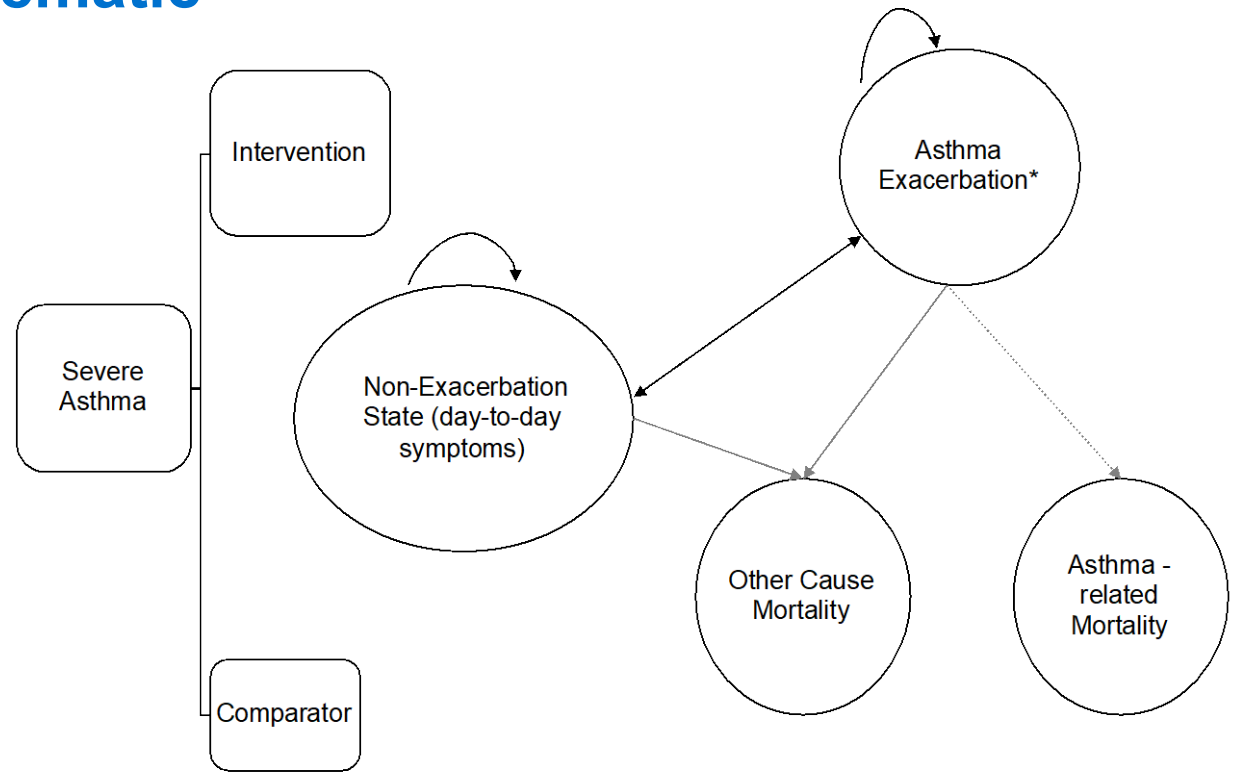
kg: kilogram, SD: standard deviation, SoC: standard of care

Treatment Regimens

Generic Name	Dose	Approval Status
Tezepelumab	210 mg subcutaneous injection every 4 weeks	Decision in early 2022

mg: milligram

Model Schematic



*Exacerbation defined by different subcategories:

1. Mild exacerbation defined by asthma related event that requires an oral steroid burst (but not emergency room or hospitalization) and decrement to quality of life
2. Moderate exacerbation defined by asthma related event that requires admittance to the emergency department (but not a hospitalization) and decrement to quality of life
3. Severe exacerbation defined by asthma related event that requires a hospitalization, decrement to quality of life, and increased risk of mortality

Key Assumptions

- Utility for the non-exacerbation health state based on mapped relationship between the AQLQ and the EQ-5D
  - Utility allowed to be different for tezepelumab plus SoC vs. SoC alone due to potential improvements in day-to-day symptoms
- Increased mortality for severe exacerbations
  - Additional risks of death given oral steroid burst do not impact mortality over and above the severe asthma-related mortality rate
- Chronic OCS and impact on costs and disutility incorporated for doses greater than 5 mg per day
- No switching between biologics

Key Model Inputs: SoC Clinical Inputs

Key Input	Input Value	Source
Annualized Exacerbation Rate, end of study (95% CI)	1.82 (1.58, 2.08)	Averaged across placebo arm of NAVIGATOR and PATHWAY trials
Proportion of Exacerbations Resulting in Steroid Burst (without ED visit or hospitalization)	76.8%	Soong et al. 2020 Figure 1
Proportion of Exacerbations Resulting in ED visit (without hospitalization)	9.1%	Soong et al. 2020 Figure 1
Proportion of Exacerbations Resulting in Hospitalization	14.1%	Soong et al. 2020 Figure 1
Severe Asthma Exacerbation Risk of Death	0.0068	Centers for Disease Control and Prevention

CI: confidence interval, ED: emergency department

Key Model Inputs: Tezepelumab plus SoC Clinical Inputs

Key Input	Input Value for Tezepelumab plus SoC vs. SoC alone RR (95% CI)	Source
Tezepelumab Rate Ratio for Exacerbations Resulting in Steroid Burst (without ED visit or hospitalization)	0.41 (0.33, 0.53)	Pooled PATHWAY and NAVIGATOR trials
Tezepelumab Rate Ratio for Exacerbations Resulting in ED Visit (without hospitalization)	0.20 (0.10, 0.41)	Pooled PATHWAY and NAVIGATOR trials
Tezepelumab Rate Ratio for Exacerbations Resulting in Hospitalization	0.20 (0.10, 0.41)	Pooled PATHWAY and NAVIGATOR trials

CI: confidence interval, ED: emergency department, RR: rate ratio, SoC: standard of care

Key Model Inputs: Costs

Key Input	Mean Input Value	Source
Annual Price for Therapy (Tezepelumab plus SoC)	$27,859 + annual SoC costs	Placeholder based on net pricing of dupilumab
Annual Cost for SoC	$6,494	Whittington et al. 2018
Exacerbation-Related Steroid Burst	$1,604	Suruki et al. 2017
Exacerbation-Related ED Visit	$2,161	Suruki et al. 2017
Exacerbation-Related Hospitalization	$9,442	Suruki et al. 2017
Annual Cost of Long-Term Oral Corticosteroid Use with Adverse Events	$8,326	Lefebvre et al. 2017

ED: emergency department, SD: standard deviation, SoC: standard of care

Key Model Inputs: Utilities

Characteristic	Tezepelumab plus SoC	SoC (Placebo Arm)	Source
Asthma Patient-Reported Outcome Measure	AQLQ	AQLQ	Pooled PATHWAY and NAVIGATOR trials
Asthma Patient-Reported Outcome Mean Change Difference vs. SoC (95% CI)	0.34 (0.17, 0.49)	Reference	Pooled PATHWAY and NAVIGATOR trials
Non-Exacerbation Mean Health State Utility for Biologic plus SoC vs. SoC Alone (95% CI)	0.788 (0.774, 0.801)	0.75	Pooled PATHWAY and NAVIGATOR trials
Steroid Burst	-0.1 (2-week duration)		Lloyd et al. 2007
ED Visit	-0.15 (2-week duration)		Lloyd et al. 2007 and assumption
Hospitalization	-0.20 (2-week duration)		Lloyd et al. 2007
Chronic Oral Corticosteroid Use	-0.023 (annualized for a lifetime duration)		Norman et al. 2013

AQLQ: Asthma Quality of Life Questionnaire, CI: confidence interval, ED: emergency department, SoC: standard of care

Results

Base-Case Results

Treatment	Intervention Cost	Other Non-intervention Costs	Total Cost	QALYs	LYs	evLYs	% Responder†
Tezepelumab plus SoC*	$657,000	$40,000	$697,000	15.00	19.11	15.02	82%
SoC Alone	$122,000	$106,000	$228,000	13.91	18.80	13.91	70%

evLYs: equal value of life years, LYs: life years, QALYs: quality-adjusted life years, SoC: standard of care

*Price is a placeholder based on net pricing of dupilumab

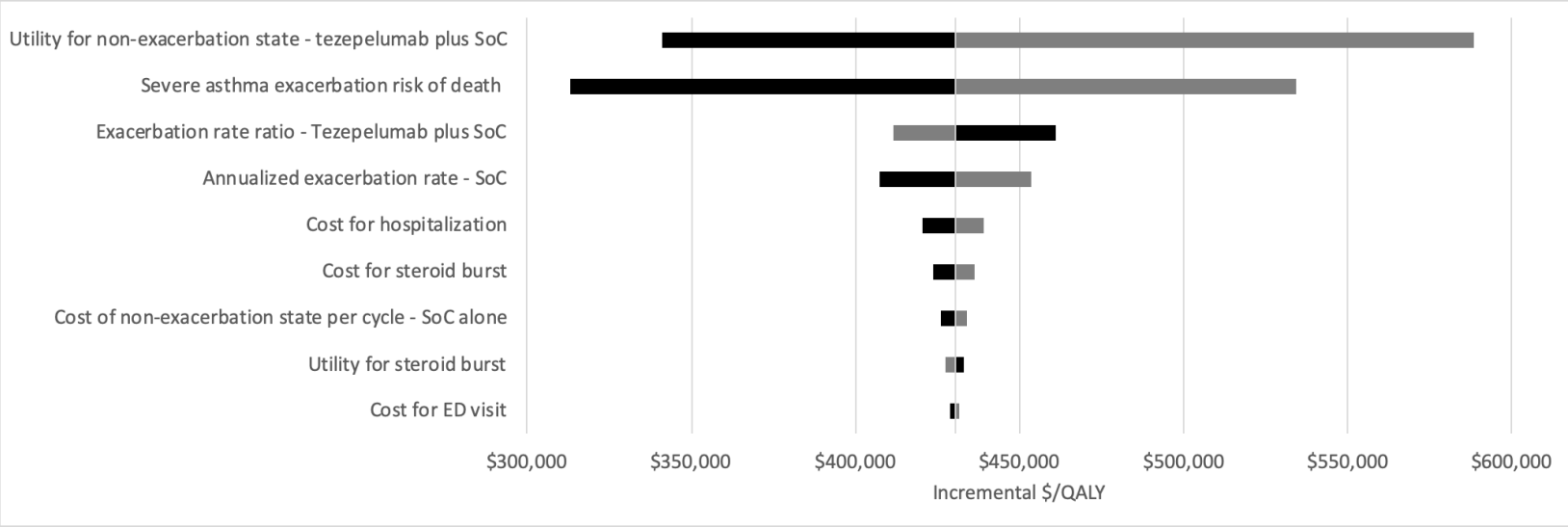
† response defined as change from baseline in Asthma Control Questionnaire-6 score of ≥ 0.5

Base-Case Incremental Results

Treatment	Comparator	Cost per QALY Gained	Cost per evLY Gained	Cost per Responder†
Tezepelumab plus SoC*	SoC alone	$430,000	$422,000	$4.7 million

evLY: equal value of life year, QALY: quality-adjusted life year, SoC: standard of care
*Price is a placeholder based on net pricing of dupilumab
† response defined as change from baseline in Asthma Control Questionnaire-6 score of ≥ 0.5

One Way Sensitivity Analyses



Tezepelumab price is a placeholder based on net pricing of dupilumab; grey shade indicates lower input's impact on the cost-per-QALY estimate whereas black shade indicates higher input's impact.
ED: emergency department, QALY: quality-adjusted life year, SoC: standard of care

- Key drivers of cost-effectiveness estimates include utility for non-exacerbation state for tezepelumab plus Soc and SoC alone, severe asthma exacerbation risk of death, annualized exacerbation rate for SoC alone, and exacerbation rate ratio for tezepelumab plus SoC

Probabilistic Sensitivity Analysis

Drug	Cost-Effective at $50,000 per QALY Gained	Cost-Effective at $100,000 per QALY Gained	Cost-Effective at $150,000 per QALY Gained
Tezepelumab plus SoC*	0%	0%	0%

Drug	Cost Effective at $50,000 per evLY Gained	Cost Effective at $100,000 per evLY Gained	Cost Effective at $150,000 per evLY Gained
Tezepelumab plus SoC*	0%	0%	0%

evLY: equal value of life year, QALY: quality-adjusted life year, SoC: standard of care
*Price is a placeholder based on net pricing of dupilumab

Scenario Analyses: Modified Societal Perspective

Treatment	Comparator	Cost per QALY Gained	Cost per evLY Gained
Tezepelumab plus SoC	SoC alone	$424,000	$416,000

evLY: equal value of life year, QALY: quality-adjusted life year, SoC: standard of care

Limitations

- Placeholder price for tezepelumab
- Lack of evidence on long-term response and discontinuation; assumed full adherence and constant treatment benefits over lifetime
- No difference in direct mortality observed in trials. Future evidence on indirect mortality needed

Comments Received

- Mortality risks from exacerbations occurring directly from and outside of hospital settings
- Request for comparisons to 2018 review
- Changes to clinical and utility inputs for omalizumab and dupilumab, respectively

Conclusions

- Tezepelumab plus SoC provide clinical benefit in terms of gains in QALYs, LYs, and evLYs over SoC alone
- If price is similar to other asthma biologics it would not meet commonly cited cost-effectiveness thresholds

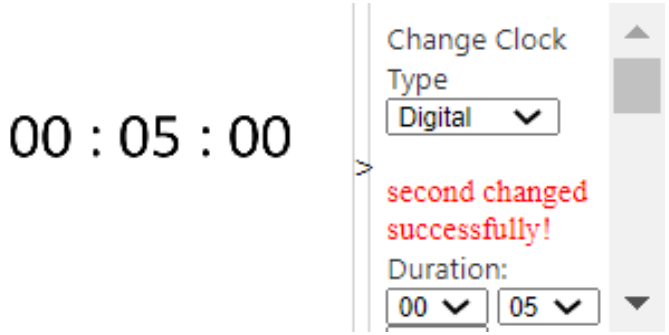
Questions?

Manufacturer Public Comment and Discussion

Andrew Lindsley, MD, PhD, Asset Lead, Medical Director, Amgen

Conflicts of Interest:

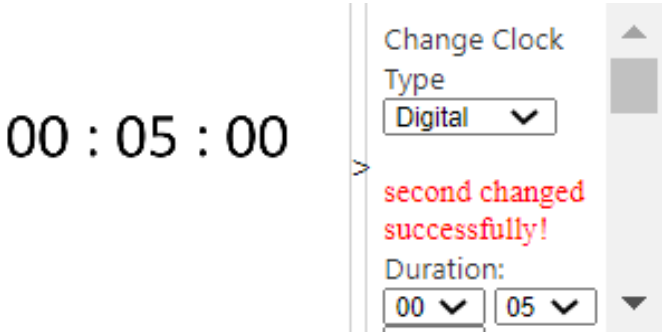
- *Dr. Lindsley is a full-time employee of Amgen.*



Kyle Hvidsten, MPH, Head, Health Economics & Value Assessment, Sanofi

Conflicts of Interest:

- *Kyle Hvidsten is a full-time employee of Sanofi.*

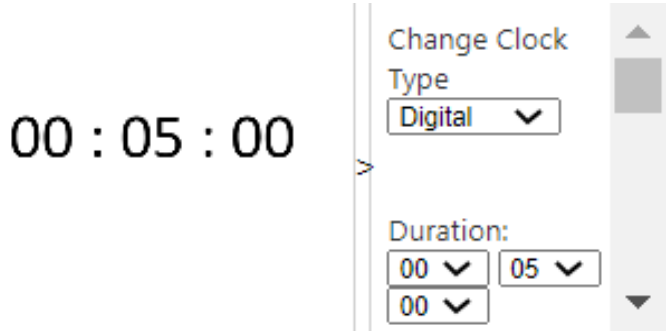


Public Comment and Discussion

Kenneth Mendez, President & CEO, Asthma and Allergy Foundation of America

Conflicts of Interest:

- AAFA receives funding from pharmaceutical manufacturers, PhRMA, and PCMA.
- Kenneth has equity interests in Abbott Labs and AbbVie in excess of $10,000.



Monique Cooper, Patient Advocate, Caregiver

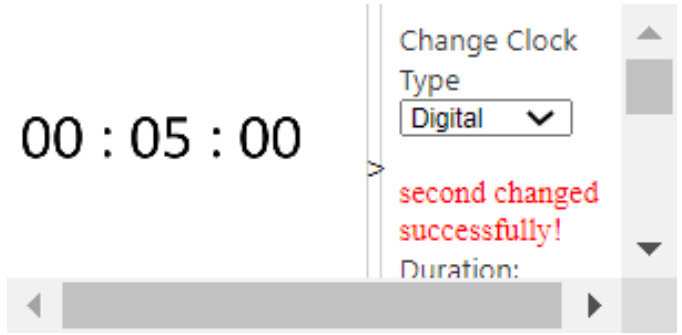
Conflicts of Interest:

- *No financial conflicts to disclose.*

Brenda Young, Patient Expert, Allergy and Asthma Network Volunteer

Conflicts of Interest:

- *No financial conflicts to disclose.*



Lunch

Meeting will resume at 12:45pm

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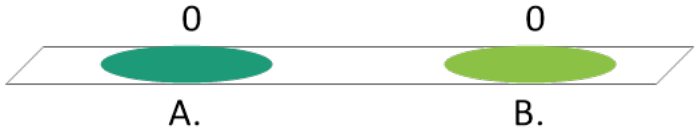
Voting Questions

1. For adults and adolescents with severe asthma, is the evidence adequate to demonstrate that the net health benefit of tezepelumab added to standard-of-care therapy without biologics, is superior to that provided by standard-of-care therapy alone?

A. Yes

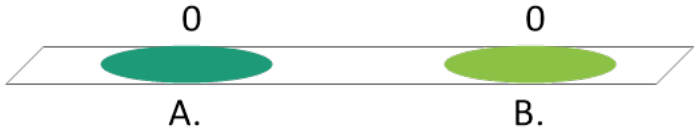
B. No



2. For adults and adolescents with severe eosinophilic asthma, is the evidence adequate to distinguish the net health benefit provided by tezepelumab from that provided by dupilumab?

A. Yes

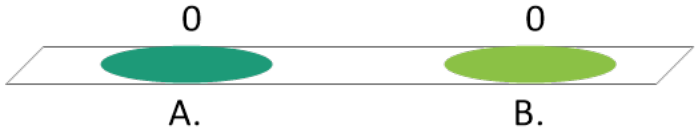
B. No



2a. If the answer to question 2 is yes, which therapy has the greater net health benefit?

A. Tezepelumab

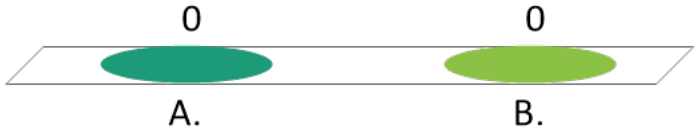
B. Dupilumab



3. For adults and adolescents with severe allergic asthma, is the evidence adequate to distinguish the net health benefit provided by tezepelumab from that provided by omalizumab?

A. Yes

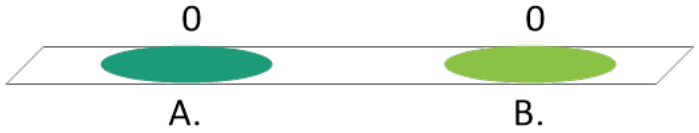
B. No



3a. If the answer to question 3 is yes, which therapy has the greater net health benefit?

A. Tezepelumab

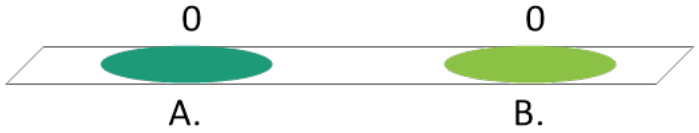
B. Omalizumab



4. For adults with steroid-dependent asthma, is the evidence adequate to distinguish the net health benefit provided by tezepelumab from that provided by dupilumab?

A. Yes

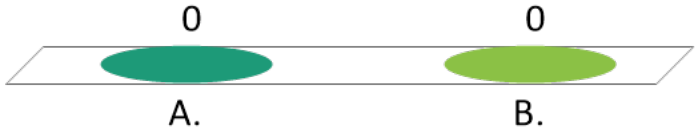
B. No



4a. If the answer to question 4 is yes, which therapy has the greater net health benefit?

A. Tezepelumab

B. Dupilumab



Contextual Considerations and Potential Other Benefits or Disadvantages

5. When making judgments of overall long-term value for money, what is the relative priority that should be given to <u>any</u> new effective treatment for severe asthma, on the basis of the following contextual considerations:

Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability

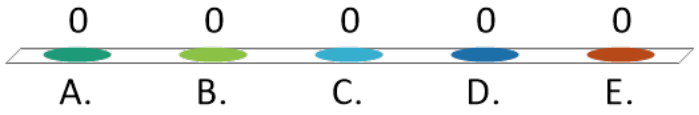
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



6. When making judgments of overall long-term value for money, what is the relative priority that should be given to any new effective treatment for severe asthma, on the basis of the following contextual considerations:

Magnitude of the lifetime impact on individual patients of the condition being treated

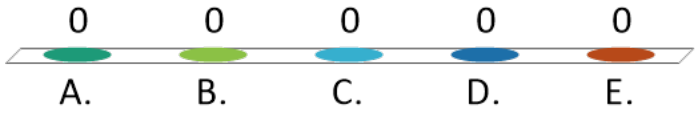
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



7. What are the relative effects of tezepelumab versus standard-of-care alone on the following outcomes that inform judgment of the overall long-term value for money of tezepelumab?

Patients' ability to achieve major life goals related to education, work, or family life

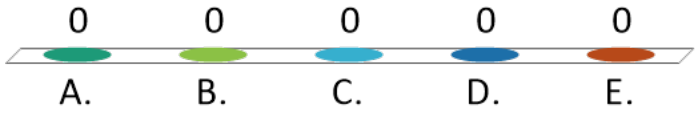
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



8. What are the relative effects of <u>tezepelumab versus standard-of-care alone</u> on the following outcomes that inform judgment of the overall long-term value for money of tezepelumab?

Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life

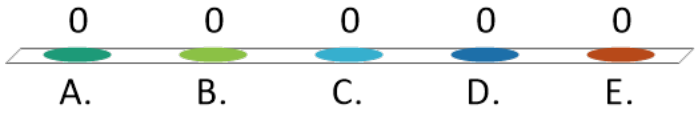
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



9. What are the relative effects of <u>tezepelumab versus standard-of-care alone</u> on the following outcomes that inform judgment of the overall long-term value for money of tezepelumab?

Patients' ability to manage and sustain treatment given the complexity of regimen

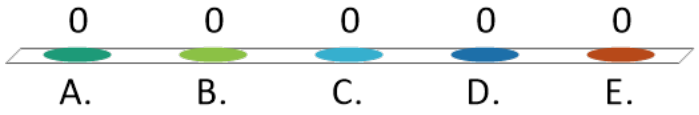
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



10. What are the relative effects of <u>tezepelumab versus standard-of-care alone</u> on the following outcomes that inform judgment of the overall long-term value for money of tezepelumab?

Society's goal of reducing health inequities

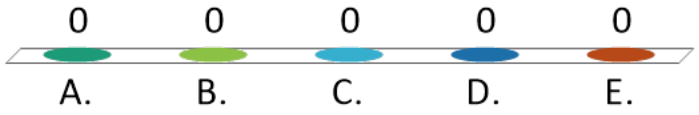
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



Long-term Value for Money

13. 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 tezepelumab versus standard-of-care alone?

A. Low long-term value for money at current prices

B. Intermediate long-term value for money at current prices

C. High long-term value for money at current prices

Break

Meeting will resume at 3:30pm

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Policy Roundtable

Policy Roundtable

Policy Roundtable Participant	Conflict of Interest
Mindy Bauer, PharmD, Associate Director, Clinical Pharmacy, IPD Analytics	Dr. Bauer is a full-time employee of IPD Analytics.
Melanie Carver, Chief Mission Officer, Asthma and Allergy Foundation of America	AAFA receives funding from Pharmaceutical manufacturers, PhRMA, and PCMA.
Kyle Hvidsten, MPH, Head, Health Economics & Value Assessment, Sanofi	Kyle Hvidsten is a full-time employee of Sanofi.
Tony R. Vancauwelaert, MD, FAAFP, Executive Medical Director, Enterprise Medical Operations - Pharmacy, Health Care Services Corporation	Dr. Vancauwelaert is a full-time employee of Heath Care Services Corporation.
Michael E. Wechsler, MD, Professor of Medicine, Director of NJH Cohen Family Asthma Institute, National Jewish Health	Dr. Wechsler has received consulting fees and honoraria from the following health care companies: AstraZeneca, Amgen, Boehringer Ingelheim, Genentech, GlaxoSmithKline, Novartis, Regeneron, and Sanofi.
Tonya Winders, MBA, President & Chief Executive Officer, Allergy & Asthma Network	Tonya Winders serves as a speaker & advisor to AstraZeneca, Amgen, GSK, Novartis, Sanofi, Regeneron & ALK Abello. The Allergy & Asthma Network receives funding from healthcare companies for unbranded disease awareness, education, advocacy & research.
David Zimmer, BS, MBA, Vice President US Value and Access, Amgen	David Zimmer is a full-time employee of Amgen.

Midwest CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around December 16
  - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: https://icer.org/asthma-2021/#timeline

Adjourn

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