
Ensifentrine for Chronic Obstructive Pulmonary Disease: Effectiveness and Value

Public Meeting — June 14, 2024

Meeting materials available at: <https://icer.org/assessment/copd-2024/>



Patient Experts

Valerie Chang, Executive Director, Hawaii COPD Coalition

- *Hawaii COPD Coalition receives annual sponsorships from a BCBS insurer and exhibit fees from pharmaceutical companies for the annual COPD Education Day. The COPD Foundation receives greater than 25% of funding from health care companies.*

Phyliss DiLorenzo, Patient Expert, COPD Foundation Board Member

- *No personal conflicts to disclose. The COPD Foundation receives greater than 25% of funding from health care companies.*

Clinical Experts

Dr. Stephanie Christenson, MD, MAS, Associate Professor, Division of Pulmonary, Critical Care, Allergy, and Sleep Medicine, UCSF

- *Dr. Christenson reports grant support from the NIH, American Lung Association, COPD Foundation, and Department of Defense; consulting and advisory board fees from AstraZeneca, Sanofi, Regeneron, GSK, Verona Pharma, Glenmark Pharmaceuticals, Axon Advisors, Apogee Therapeutics, Amgen, Devpro Pharma, Kymera Therapeutics, and Genentech; Non-branded speaking fees from AstraZeneca, GSK, Sanofi, Regeneron, Amgen, Medscape, Horizon CME; writing fees from UpToDate.*

Dr. Juan Rojas, MD, MS, Director of Clinical Informatics & Data Science, Division of Translational & Precision Medicine, and Assistant Professor, Department of Internal Medicine, Division of Pulmonary, Critical Care, & Sleep Medicine, Rush University

- *No conflicts to disclose.*

ICER Speakers



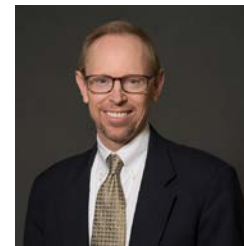
Sarah K. Emond, MPP
President & CEO



Grace Lin, MD
Evidence Author



David Rind, MD, MSc
Chief Medical Officer



Steven D. Pearson, MD, MSc
Special Advisor



Melanie Whittington, PhD
Lead Modeler



Why are we here today?

“I tire out a lot easier than I used to. I find that when I plan my day, I try to plan it for the mornings because I know by afternoon I’m done. I used to have a very active lifestyle, I used to walk everywhere. I can’t do that anymore. I’ve made many modifications around my home—I have chairs everywhere for support, so I can move around without a walker. I want to get a ramp to the front door, mainly for carrying oxygen tanks in and out of the house. Speaking of oxygen—that is another thing I need to factor in when planning for my day. COPD rules my life.”

Person with COPD
(<https://www.lung.org/blog/living-with-copd>)

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
 - What are the risks and benefits?
 - How do new treatments fit into the evolving landscape?
 - What are reasonable prices and costs to patients, the health system, and the government?
 - What lessons are being learned to guide our actions in the future?

The Impact on Rising Health Care Costs for Everyone

DIAGNOSIS: DEBT

100 Million People in America Are Saddled With Health Care Debt

By Noam N. Levey

JUNE 16, 2022



Why Delaware is eying a 27% premium hike on state employees' health insurance



Amanda Fries

Delaware News Journal

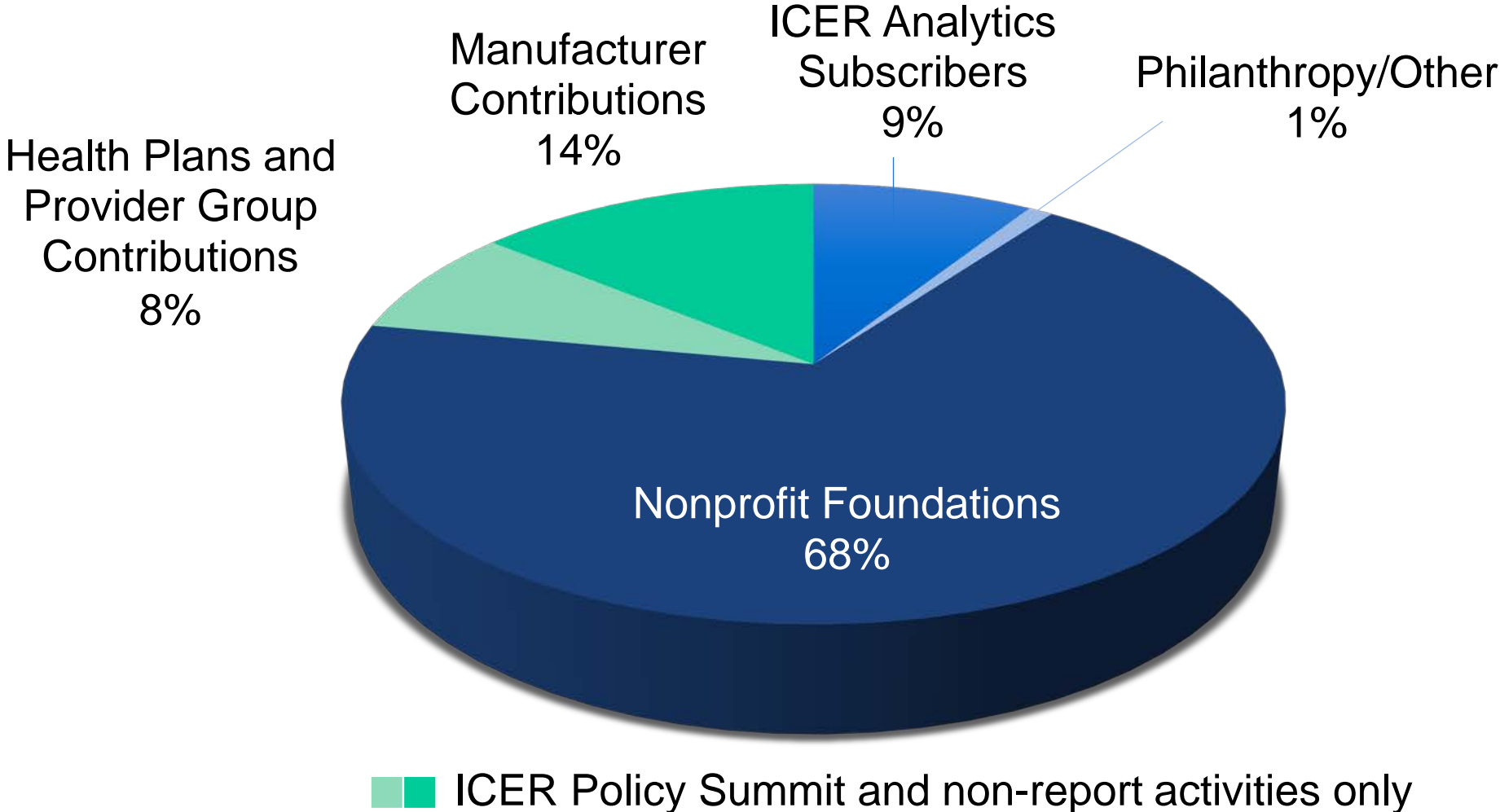
Published 4:35 a.m. ET Feb. 1, 2024 | Updated 9:29 p.m. ET Feb. 6, 2024



Organizational Overview

- Midwest CEPAC
- Institute for Clinical and Economic Review (ICER)

Funding 2024



How Was the ICER Report Developed?

- Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
- ICER evidence analysis in collaboration with University of California San Francisco, and cost-effectiveness modeling in collaboration with Tufts Medical Center
- Public comment and revision
- Expert reviewers:
 - Igor Barjaktarevic, MD, PhD, David Geffen School of Medicine at UCLA
 - David Mannino, MD, COPD Foundation
 - Martine Hoogendoorn-Lips, PhD, Erasmus University Rotterdam
- How is the evidence report structured to support Midwest CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Special Social/Ethical Priorities

Benefits Beyond “Health”

**Total Cost Overall
Including Cost Offsets**

**Health Benefits:
Return of Function, Fewer Side Effects**

**Health Benefits:
Longer Life**

Agenda (CT)

10:00 AM Meeting Convened and Opening Remarks

10:20 AM Presentation of the Clinical Evidence

11:00 AM Presentation of the Economic Model

11:40 AM Public Comments and Discussion

12:00 PM Lunch Break

12:50 PM MW CEPAC Deliberation and Vote

1:50 PM Break

2:00 PM Policy Roundtable Discussion

3:30 PM Reflections from Midwest CEPAC

4:00 PM Meeting Adjourned

Presentation of the Clinical Evidence

Grace Lin, MD, MAS

Medical Director for Health Technology Assessment, ICER

Associate Professor of Medicine and Health Policy, UCSF



Key Collaborators

- **Abigail Wright, PhD, MSc**, Research Scientist, ICER
- **Avery McKenna, BS**, Associate Research Lead, ICER
- **Finn Raymond, BS**, Research Assistant, ICER

Disclosures: Financial support provided to the Grace Lin from the Institute for Clinical and Economic Review (ICER)

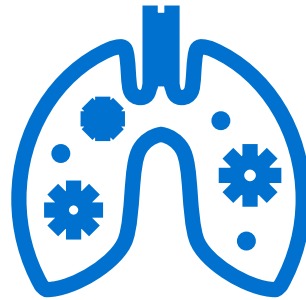
Grace Lin, Abigail Wright, Avery McKenna, and Finn Raymond have no conflicts to disclose defined as more than \$10,000 in healthcare company stock or more than \$5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.

Background: COPD

COPD is a group of lung diseases that is characterized by progressive and persistent airflow obstruction in the lungs.



COPD affects **16 million** people in the U.S. and is the **6th leading** cause of death.



Smoking is the leading cause of COPD in the US. Other factors such as **secondhand smoke exposure**, **occupational exposure**, and **chronic asthma** can play a role.



COPD leads to **1 million ED visits** and **50,000 hospitalizations**, resulting in a cost of **\$50 million** per year.

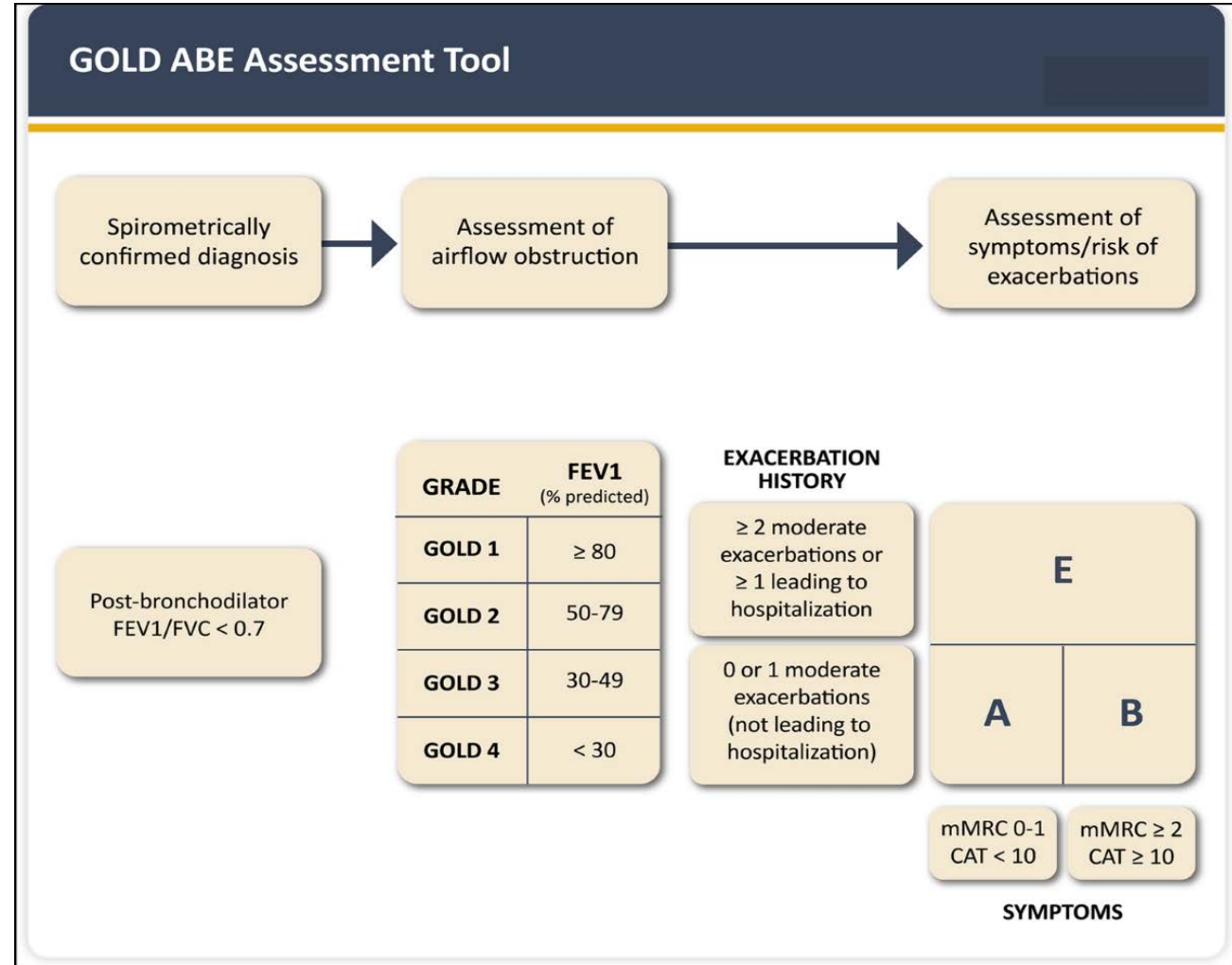
COPD Symptoms

- Diagnosis of COPD is based on **lung function** (e.g., $FEV_1/FVC < 0.7$).
- **Symptoms** include persistent shortness of breath, fatigue, wheezing, chest tightness, sputum production, and cough.
- **Exacerbations** are also an important marker of disease.

COPD Diagnosis and Classification

COPD classification is based on:

- **Severity of airflow obstruction**
- **Annual exacerbation history**
- **Symptoms**



Discussions with People with COPD

Impact on Daily Life

- Daily tasks are challenging, e.g., making the bed
- Needing to plan around symptoms - "pacing yourself"
- Travel can be difficult if oxygen tanks or wheelchairs are required

Treatment is Complex

- Needing to manage multiple inhalers/nebulizers, difficulty with proper inhaler technique
- Side effects (dry mouth, nausea, thrush, cough, diarrhea)
- Nebulized treatment can be time-consuming and less portable

Burden on Unpaid Caregivers

- Monitoring adherence
- Burden of physical and emotional support as disease progresses

Considerations for Future Treatments

- Disease-modifying treatments needed
- Decrease mucus production and need for supplemental oxygen

COPD Treatment

Non-
Pharmacologic



Smoking
cessation

Pulmonary
rehabilitation

Pharmacologic



Long-acting
beta-2-
agonists
(LABAs)

Long-acting
antimuscarinic
antagonists
(LAMAs)

Dual or triple
therapy

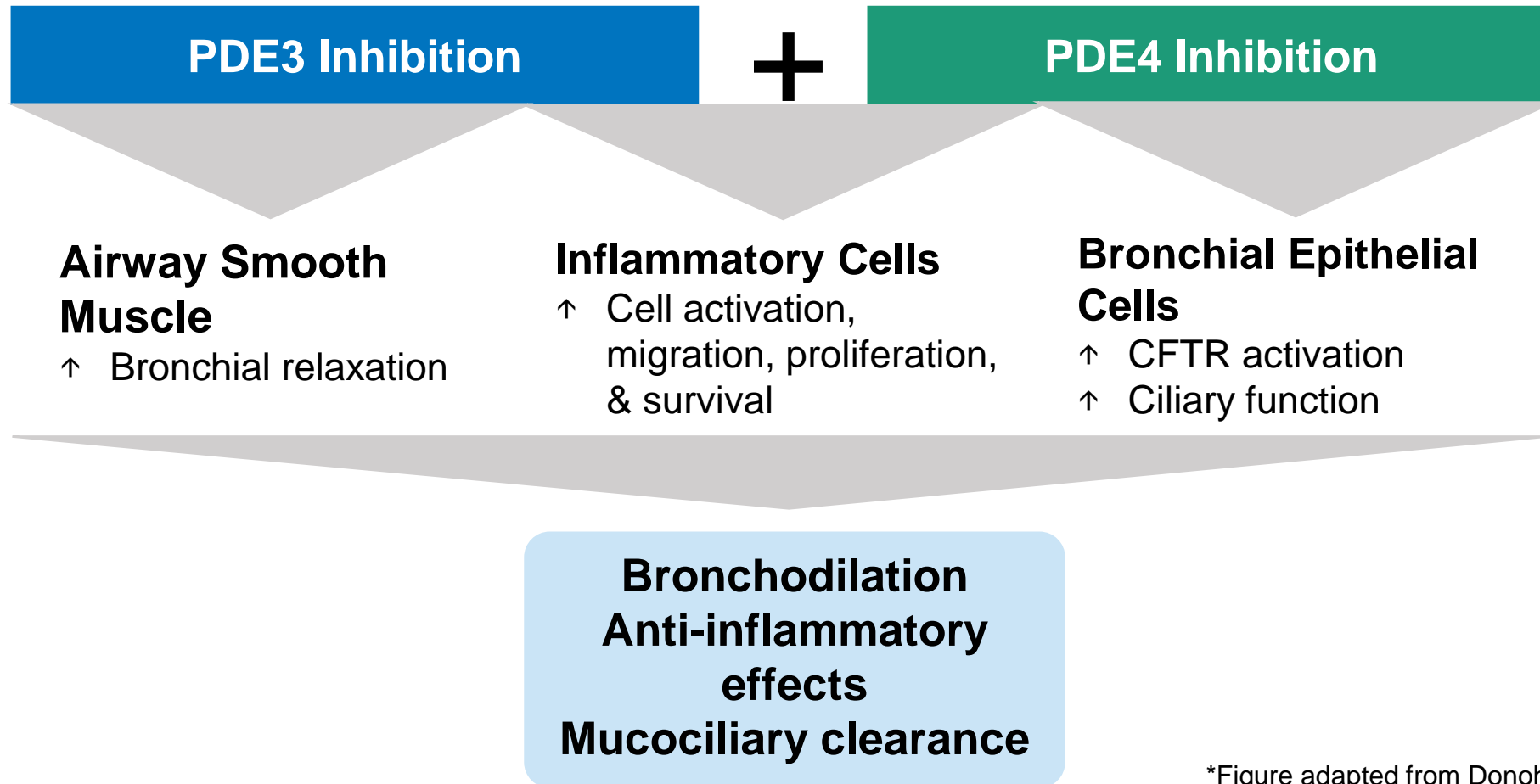
PDE4
inhibitor

Azithromycin

With or without
inhaled
corticosteroids
(ICS)

About **half of COPD patients reporting near daily symptoms**, and the majority reporting that symptoms have a moderate-to-great impact on everyday life.

Ensifentrine



*Figure adapted from Donohue et al. 2023

Scope of Review

- Adults with moderate to severe COPD
- Comparative clinical effectiveness of **ensifentrine** as an add-on therapy to current maintenance therapy, including:
 - LABAs
 - LAMAs
 - ICS
 - *Combination of the above*
- Comparator: Current maintenance therapy

Outcomes

Annualized Moderate or Severe Exacerbation Rate

- **Moderate**
 - Worsening of symptoms (e.g., dyspnea, sputum volume, cough, wheezing) for > 2 days and requiring systemic corticosteroids and/or antibiotics
- **Severe**
 - Required worsening of symptoms and inpatient hospitalization

Quality of Life Measures

- Transition Dyspnea Index (TDI), Evaluating-Respiratory Symptoms (E-RS), St. George's Respiratory Questionnaire (SGRQ), EuroQol-5-Domain Questionnaire (EQ-5D-5L)

Lung Function Measures

- Change in FEV₁ from baseline

Other Outcomes

- Time to first exacerbation and daily average rescue medication

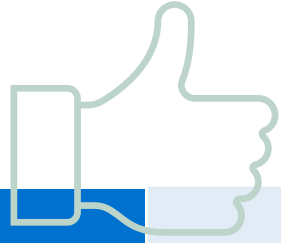
Clinical Evidence

Key Clinical Trials

Two Phase III RCTs (ENHANCE-1 and ENHANCE-2)

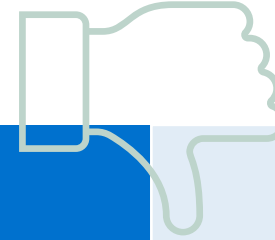
Trial	Design	N	Population	Follow-Up
ENHANCE-1	Phase III randomized, double-blind, placebo-controlled trial	763	Adults with moderate (56%) to severe (44%) COPD	24 weeks (with a 48-week safety subset)
ENHANCE-2		790		24 weeks

Background Therapy



Permitted

- **Rescue medication:**
 - Albuterol/salbutamol
- **Maintenance use:**
 - LAMA or LABA therapy
 - ICS taken with LAMA or LABA



Prohibited

- LAMA/LABA combinations
- Oral, systemic or parenteral steroid therapies
- High dose of ICS
- Antibiotics for respiratory tract infection
- Beta-2 agonists (<4 hours)
- Theophylline, leukotriene, and PDE4 inhibitors (48 hrs prior)

ENHANCE Trials

Baseline Characteristics

- Mean age of 65 years
- 92% White
- 53% male
- 62% on background therapy
 - 31% on LAMA, 1% on LAMA+ICS, 12% on LABA, 18% on LABA+ICS
- 24% of participants had an exacerbation ≤ 15 months prior to screening

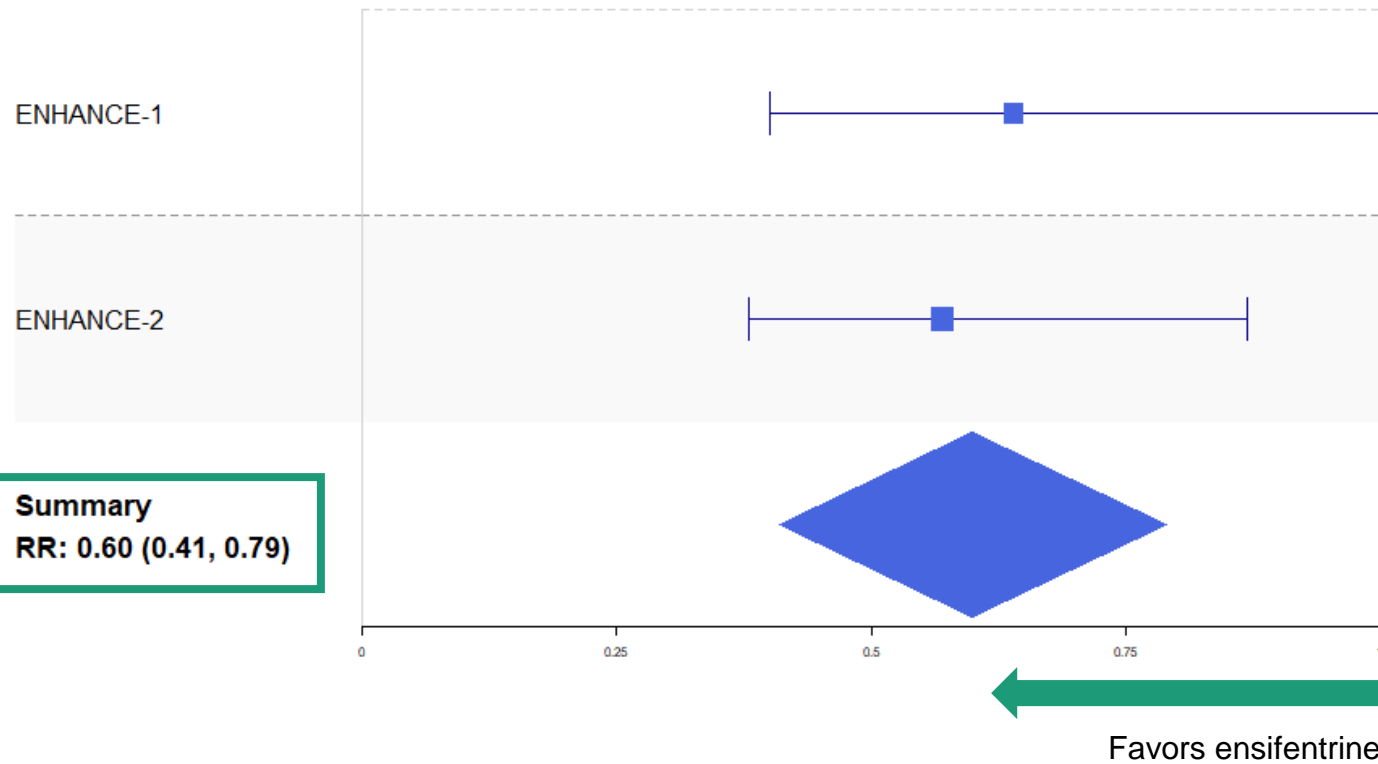
Pooled baseline characteristics from the ENHANCE-1 and -2 trials.

Trial Withdrawal

- Trial withdrawal was high
 - ENHANCE-1 at week 48: 14.8%
 - ENHANCE-2 at week 24: 23.1%
- Of those who withdrew:
 - 37-45% withdrew consent
 - 13-15% had COVID-19

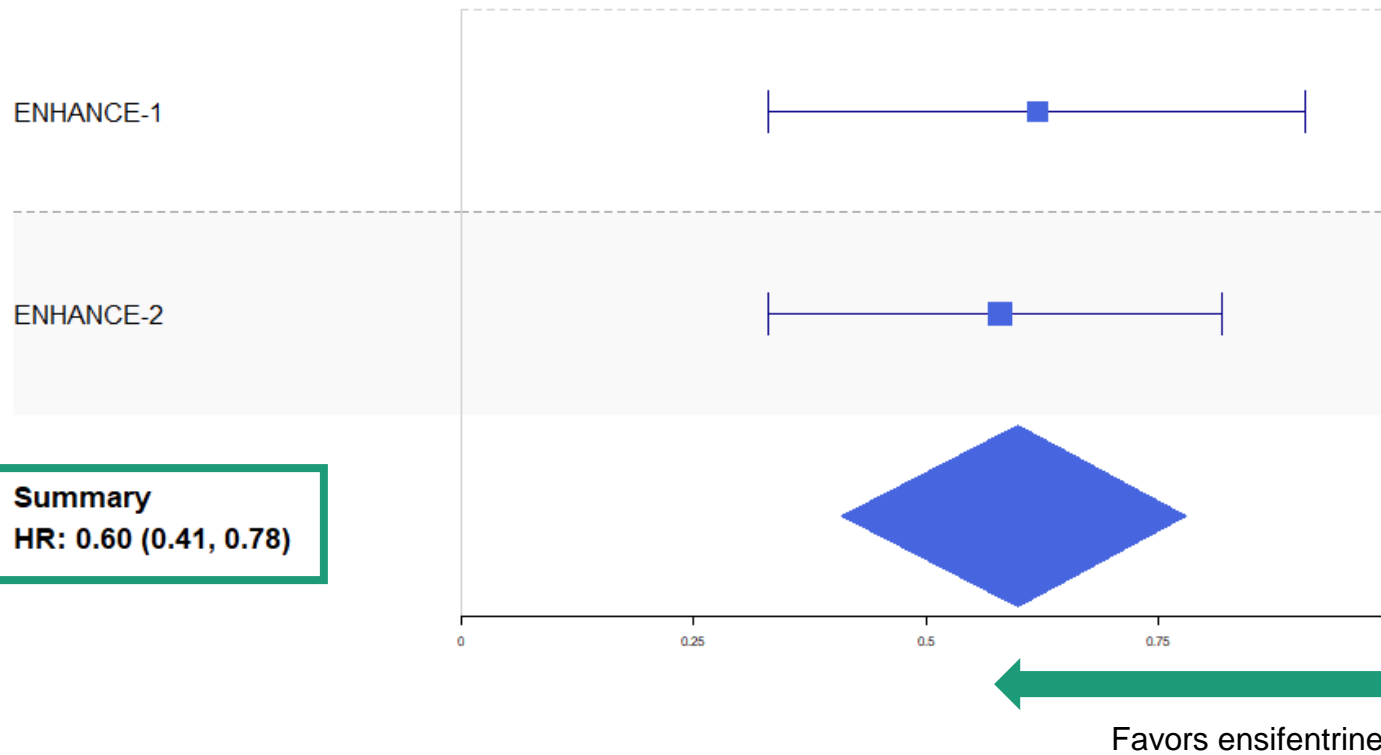
Ensifentrine Decreases Moderate or Severe COPD Exacerbations

**Exacerbation Rate
Versus Placebo**



Ensifentrine Increases Time to First Exacerbation

Time to First Exacerbation Versus Placebo



Effect on Quality of Life was Inconsistent

- Mean changes vs placebo did not exceed MCID for two of three quality of life measures (E-RS, SGRQ).
- However, a greater proportion of patients in ensifentrine group reached or exceeded MCID for E-RS, SGRQ.
- Mean change in TDI exceeded MCID in ENHANCE-1.
- Statistically significant improvement in EQ-5D in ENHANCE-2.

Other Outcomes

- Ensifentrine groups had a significant improvement in FEV₁ at 12 weeks in ENHANCE-1 and 2.
- Ensifentrine decreases use of rescue medication at 24 weeks (pooled data from ENHANCE-1 and 2).

Harms

Serious Adverse Events

Similar reporting between ensifentrine and placebo arms (~6-7%).

Discontinuation

Comparable reporting of TEAEs leading to discontinuation between arms (~6-10%). Similar trend was seen when COVID-19 cases were removed.

Gastrointestinal Harms

Reported by 5.2% in both arms, 0.4% were causally related to ensifentrine.

Other Harms

Low percentage of pneumonia, UTIs, hypertension, and cardiac disorder.

Controversies and Uncertainties

Demographic Differences to Real-world Patients

- Younger and had fewer exacerbations
- Background therapy did not reflect current standard of practice
 - 35-40% on no background therapy at baseline
 - No dual or triple therapy

Impact on Quality of Life

- Smaller changes in ENHANCE-2 since placebo group had relatively larger changes from baseline
- Two of the three QOL measures did not exceed MCID

Short trial follow-up and high withdrawal rate

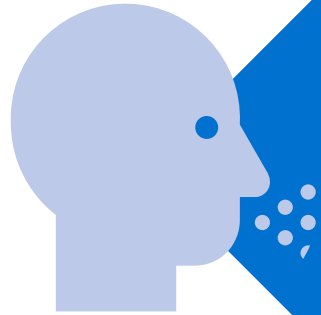
- Primary outcomes at 12 and 24 weeks
- Around 40% withdrawal rate, likely affected by pandemic

Benefits Beyond Health and Special Ethical Priorities

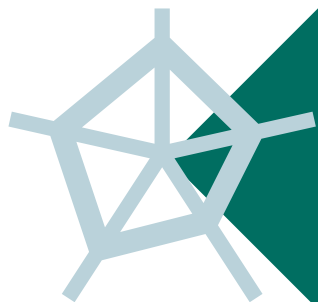
Key Points

- Has potential to fill gaps in COPD care
 - May be particularly valuable in patients with suboptimal disease control, continue to experience symptoms, or have side effects on therapy
- Impact on ability to achieve long-term goals
 - Ensifentrine not thought to be disease-modifying nor have a large effect patient/caregiver ability to achieve long-term goals
- Impact on access limited
 - Delivered via nebulizer, likely will not have an impact on access

Public Comments Received



The symptom burden associated with COPD is significant.



Quality of life measures do not capture the full spectrum of impact of COPD.

Summary

- Ensifentrine improved measures of lung function, including average FEV₁, at 12 weeks.
- Ensifentrine also decreased annualized rate of moderate to severe exacerbations by 40% at 24 weeks, maintained until 48 weeks.
- Evidence of the impact on quality of life was mixed.
- Adverse events and discontinuation rates were similar among those who received ensifentrine and placebo.

ICER Evidence Ratings

Treatment	Comparator	Evidence Rating
Ensifentrine added on to maintenance therapy	Maintenance therapy alone	B+

Questions?

Presentation of the Economic Evidence

Melanie D. Whittington, PhD, MS

Center for the Evaluation of Value and Risk in Health

Tufts Medical Center



Key Review Team Members

- **Melanie Whittington, PhD**, Senior Fellow, CEVR, Tufts Medical Center
- **Marina Richardson, PhD**, Associate Director, HTA Methods and Health Economics, ICER

Disclosures:

Financial support was provided from the Institute for Clinical and Economic Review.

No conflicts to disclose defined as more than \$10,000 in health care company stock or more than \$5,000 in honoraria or consultancies relevant to this report during the previous year from health care technology manufacturers or insurers.

Objective

COPD

To evaluate the lifetime cost-effectiveness of ensifentrine added on to current maintenance therapy compared to current maintenance therapy alone for the treatment of COPD in patients with moderate to severe COPD at baseline.

Unmet Need

Condition	Absolute evLY Shortfall	Proportional evLY Shortfall
COPD	8.1	54%
Other Example Conditions		
Multiple Sclerosis	18.9	52%
PTSD	7.4	21%
Osteoporosis	2.6	19%

COPD: chronic obstructive pulmonary disease; evLY: equal value of life years gained; PTSD: post-traumatic stress disorder

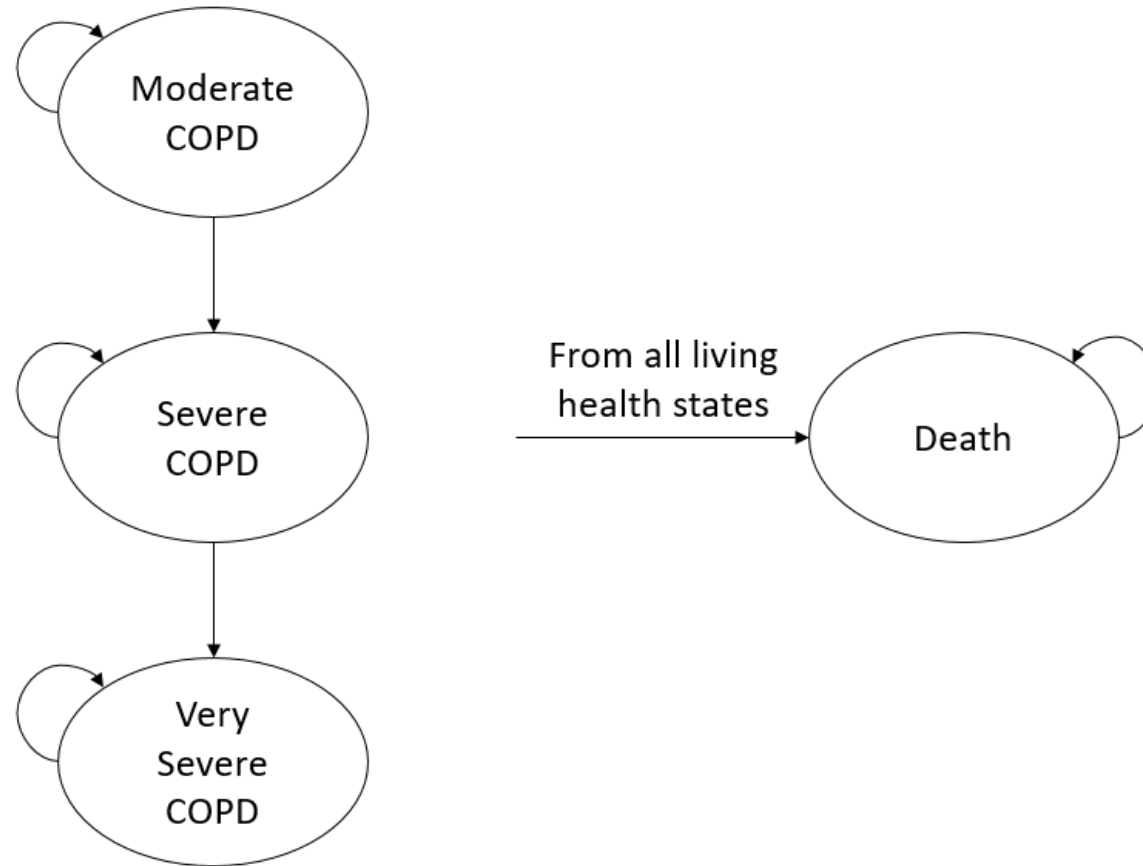


Methods in Brief

Methods Overview

Model	Markov
Setting	United States
Perspective	Health Care Sector and Modified Societal
Time Horizon	Lifetime
Discount Rate	3% per year (costs and outcomes)
Cycle Length	One year
Outcomes	Costs, Quality-adjusted life years (QALYs); Equal value life years (evLYs); Life years; Exacerbations

Model Schematic



Exacerbations as Events

- **Moderate Exacerbation**

- An exacerbation that results in a prescription of a corticosteroid and/or an antibiotic but did not result in a hospitalization.

- **Severe Exacerbation**

- An exacerbation that results in a hospitalization for COPD.

Cohort Characteristics

Baseline Characteristic	Value
Age, years	67
Female, %	56.4%
Current Smokers, %	41.2%
Moderate COPD* at Baseline, %	78.1%
Severe COPD† at Baseline, %	21.9%

COPD: chronic obstructive pulmonary disease

*Defined as an FEV₁ of 50%-79%

†Defined as an FEV₁ of 30% to 49%

Key Assumptions

Ensifentrine's effect on lung function did not translate to health state changes.

Ensifentrine's effect on improved quality of life was downstream of its effect on exacerbations.

Adverse event-related discontinuation occurred at week 12 and only impacted the percent receiving the treatment cost.

Exacerbations, Current Maintenance Therapy Alone

Health State	Exacerbations [§] per Year	Severe Exacerbations per Year [#]	Moderate Exacerbations per Year ^α
Moderate COPD*	1.17 (0.93, 1.44)	0.16	1.01
Severe COPD[†]	1.61 (1.49, 1.74)	0.22	1.39
Very Severe COPD[‡]	2.10 (1.46, 2.86)	0.29	1.81

* Defined as an FEV₁ of 50%-79%, GOLD 2

† Defined as an FEV₁ of 30% to 49%, GOLD 3

‡ Defined as an FEV₁ of less than 30%, GOLD 4

§ Either a moderate or severe exacerbation.

A severe exacerbation is defined as an exacerbation leading to a hospitalization for COPD.

α A moderate exacerbation is defined as an exacerbation leading to a prescription of systemic corticosteroids and/or antibiotics.

Exacerbations, Ensifentrine

Treatment	Exacerbation Rate Ratio (95% Confidence Interval)	Notes
Ensifentrine	0.60 (0.41, 0.79)	From ICER's meta-analysis of ENHANCE-1 and ENHANCE-2 at week 24

Mortality

Non-Exacerbation Mortality	Standardized Mortality Ratio	Notes
Moderate COPD*	1.6	For COPD not due to exacerbations; Applied to age- and sex-adjusted all-cause mortality
Severe COPD†	1.9	
Very Severe COPD‡	1.9	
Exacerbation Mortality	Case-Fatality Rate	Notes
Severe Exacerbation§	15.6%	Applied per severe exacerbation

* Defined as an FEV₁ of 50%-79%, GOLD 2

† Defined as an FEV₁ of 30% to 49%, GOLD 3

‡ Defined as an FEV₁ of less than 30%, GOLD 4

§ A severe exacerbation is defined as an exacerbation leading to a hospitalization for COPD.

Treatment Costs

Drug	Annual Estimate	Notes
Ensifentrine	\$18,000	Placeholder price based on IPD Analytics
Current Maintenance Therapy	\$3,453	Basket of drugs within LAMA only, LABA+ICS, and LABA+LAMA+ICS regimens

Results

Lifetime Model Outcomes – Cost Outcomes

Drug	Intervention Cost*	Non-Intervention Cost	Total Cost*
Ensifentrine + Current Maintenance Therapy	\$144,300	\$280,600	\$424,900
Current Maintenance Therapy Alone	\$0	\$283,600	\$283,600

*Based on placeholder price of \$18,000 per year

Lifetime Model Outcomes – Health Outcomes

Drug	Total Exacerbations	Life Years	QALYs	evLYs
Ensifentrine + Current Maintenance Therapy	8.03	8.43	6.25	6.34
Current Maintenance Therapy Alone	12.26	7.71	5.68	5.68

evLYs: equal value of life years, QALYs: quality-adjusted life years

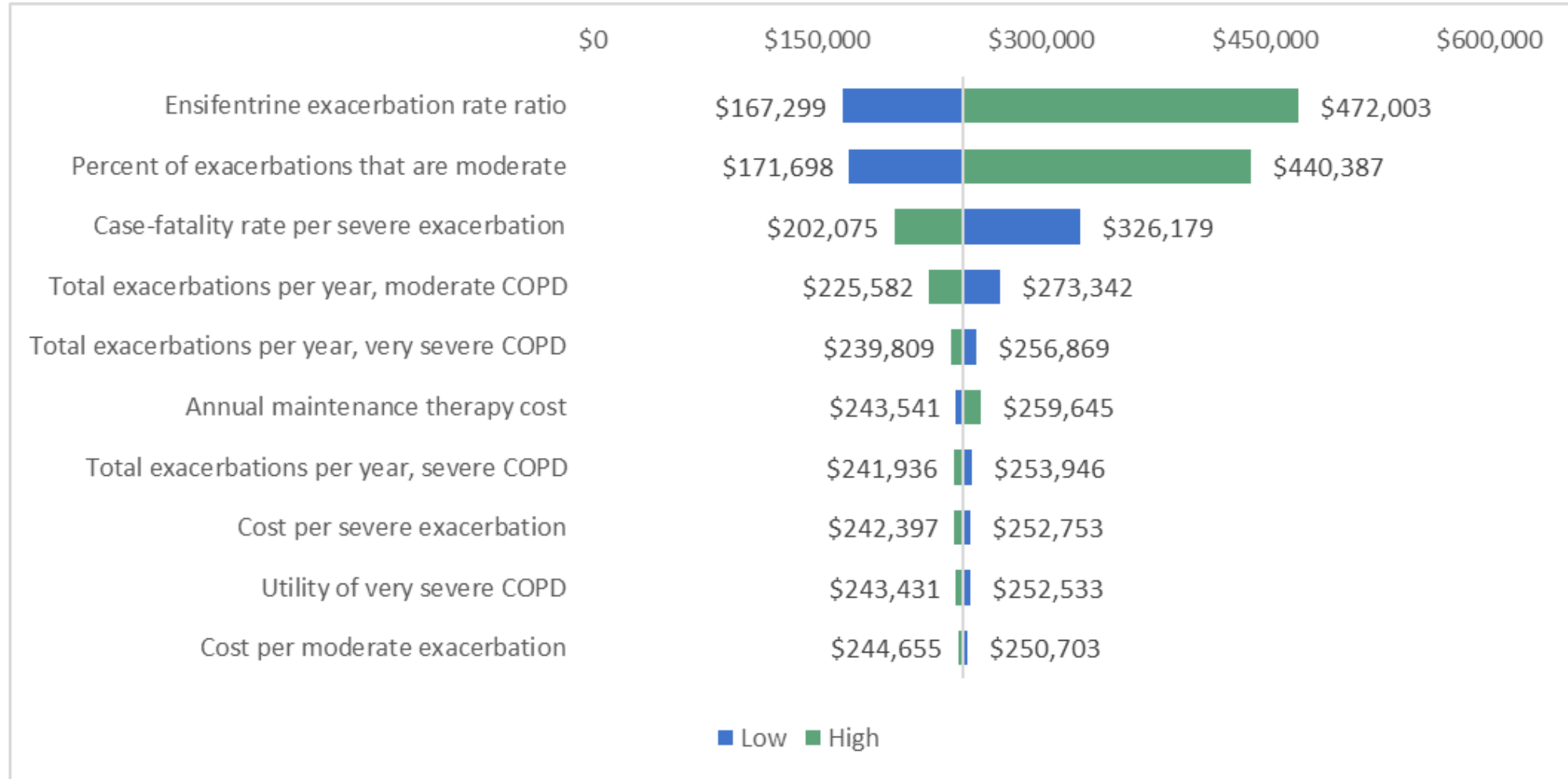
Base-Case Incremental Results

Treatment	Comparator	Cost per QALY Gained*	Cost per evLY Gained*
Ensifentrine + Current Maintenance Therapy	Current Maintenance Therapy Alone	\$248,000	\$214,000

evLY: equal value life year, QALY: quality-adjusted life year

*Based on placeholder price of \$18,000 per year

One Way Sensitivity Analysis



Probabilistic Sensitivity Analysis

Drug	Cost-Effective at \$50,000 per evLY	Cost-Effective at \$100,000 per evLY	Cost-Effective at \$150,000 per evLY
Ensifentrine*	0%	0%	12%

evLY: equal value life year

*Based on placeholder price of \$18,000 per year

Scenario Analyses

Treatment	Modified Societal Perspective* (\$/evLY)	Exclusion of Unrelated Costs* (\$/evLY)	Ensifentrine Effect on Quality of Life* (\$/evLY)
Ensifentrine	\$230,000	\$190,000	\$175,000

evLY: equal value life year

*Based on placeholder price of \$18,000 per year

Health Benefit Price Benchmarks (HBPBs)

Annual Prices Using...	Annual Price at \$100,000 Threshold	Annual Price at \$150,000 Threshold
QALYs Gained	\$7,500	\$11,000
evLYs Gained	\$8,600	\$12,700

Limitations

Top Limitations

- The evidence to inform the treatment basket for current maintenance therapy predated LABA/LAMA combination products.
- The modified societal perspective may not fully represent the impact of COPD on patients and caregivers.

Comments Received

- Use the GOLD ABE classification to define the health states.
- Allow for exacerbations to impact disease progression.
- Incorporate an effect of ensifentrine on day-to-day quality of life in the base case.

Conclusions

- Treatment with ensifentrine results in fewer exacerbations and in greater QALYs, evLYs, and life years.
- At a placeholder price of \$18,000 per year, ensifentrine exceeds commonly used thresholds.
- If ensifentrine is shown to improve the quality of life of patients not experiencing an exacerbation, cost-effectiveness improves.

Questions?



Manufacturer Public Comment and Discussion

Kavita Aggarwal, PharmD

SVP Medical Affairs, Verona Pharma

Conflicts of Interest:

- Dr. Aggarwal is a full-time employee at Verona Pharma.*

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Public Comment and Discussion

Tonya Winders, MBA

President and CEO, Global Allergy and Airways Patient Platform

Conflicts of Interest:

- Tonya has acted as a paid advisor for unbranded disease awareness, education and advocacy for AZ, Chiesi, GSK, Roche, MSD, and Sanofi Regeneron and has received <25% of overall funds from these health care companies.*

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Lunch

Meeting will resume at 12:50PM CT





Voting Questions

Patient Population for all questions: Adults with Moderate to Severe COPD on maintenance therapy. Maintenance therapy can be: LAMA, LABA, combination therapy or combination therapy with ICS.

Clinical Evidence

slido



1. Is the current evidence adequate to demonstrate that the net health benefit of ensifentrine added to maintenance therapy is superior to that of maintenance therapy alone?

① Start presenting to display the poll results on this slide.



Benefits Beyond Health and Special Ethical Priorities

slido



2. There is substantial unmet need despite currently available treatments.

① Start presenting to display the poll results on this slide.

slido



3. This condition is of substantial relevance for people from a racial/ethnic group that have not been equitably served by the healthcare system.

① Start presenting to display the poll results on this slide.

To help inform judgments of overall long-term value for money, please indicate your level of agreement with the following statements based on the relative effects of ensifentrine added to maintenance therapy versus maintenance therapy alone:

slido



4. The treatment is likely to produce substantial improvement in caregivers' quality of life and/or ability to pursue their own education, work, and family life.

① Start presenting to display the poll results on this slide.

slido



5. The treatment offers a substantial opportunity to improve access to effective treatment by means of its mechanism of action or method of delivery.

① Start presenting to display the poll results on this slide.



Long-Term Value for Money

7. Given the available evidence on comparative clinical effectiveness and incremental cost effectiveness, and considering benefits beyond health and special ethical priorities:

slido



What is the long-term value for money of ensifentrine added to maintenance therapy compared to maintenance therapy alone at assumed pricing?

① Start presenting to display the poll results on this slide.

Break

Meeting will resume at 2:00PM CT



Policy Roundtable

Policy Roundtable

Participant	Conflict of Interest
Mindy Bauer, PharmD , Pharmacist, IPD Analytics	Mindy Bauer is a full-time employee at IPD Analytics.
Valerie Chang, BA, JD , Executive Director, Hawaii COPD Coalition, Vice Chair of Board, COPD Foundation	Hawaii COPD Coalition receives annual sponsorships from a BCBS insurer and exhibit fees from pharmaceutical companies for the annual COPD Education Day. The COPD Foundation also receives greater than 25% of funding from health care companies.
Stephanie Christenson, MD, MAS , Associate Professor, Division of Pulmonary, Critical Care, Allergy, and Sleep Medicine, UCSF	Dr. Christenson reports grant support from the NIH, American Lung Association, COPD Foundation, and Department of Defense; consulting and advisory board fees from AstraZeneca, Sanofi, Regeneron, GSK, Verona Pharma, Glenmark Pharmaceuticals, Axon Advisors, Apogee Therapeutics, Amgen, Devpro Pharma, Kymera Therapeutics, and Genentech; Non-branded speaking fees from AstraZeneca, GSK, Sanofi, Regeneron, Amgen, Medscape, Horizon CME; writing fees from UpToDate.
Phylliss DiLorenzo , Patient Expert, COPD Foundation Board Member	No personal conflicts to disclose. The COPD Foundation receives greater than 25% of funding from health care companies.
David Dohan, MD, MHCM , Medical Director for Pharmacy and Appeals, Point34Health	Dr. Dohan is a full-time employee at Point34Health.
Juan Rojas, MD, MS , Director of Clinical Informatics & Data Science, Division of Translational & Precision Medicine, and Assistant Professor, Department of Internal Medicine, Division of Pulmonary, Critical Care, & Sleep Medicine, Rush University	No conflicts to disclose.

Midwest CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around July 16th, 2024
 - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: <https://icer.org/assessment/copd-2024/>

Adjourn

