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# Cytisinicline for Smoking Cessation: Effectiveness and Value

Public Meeting — January 15, 2026

Meeting materials available at: <https://icer.org/assessment/smoking-cessation-2025/>



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# Participating Members of the Midwest CEPAC

**Jill Johnson, PharmD, BCPS, Midwest CEPAC Chair,**  
*Professor, College of Pharmacy, University of Arkansas for Medical Sciences*

- **Eric Ambrecht, PhD,** Professor and Associate Provost, Saint Louis University Center for Health Outcomes Research, School of Medicine and College for Public Health & Social Justice
- **Alan Balch, PhD,** Chief Executive Officer, Patient Advocate Foundation and the National Patient Advocate Foundation
- **Bijan Borah, PhD,** Professor of Health Services Research, Mayo Clinic College of Medicine and Science, Consultant, Division of Health Care Policy and Research, Department of Health Sciences Research, Mayo Clinic, Joint Appointment as a Consultant, Department of Obstetrics and Gynecology, Mayo Clinic
- **Kurt Vanden Bosch, PharmD,** System Formulary Manager, St. Luke's Health System, Idaho
- **Donald Casey, MD, MPH, MBA, MACP, FAHA,** Associate Professor of Internal Medicine, Rush Medical College, Adjunct Professor of Healthcare Quality & Safety and Population Health, Thomas Jefferson University College of Population Health, Affiliate Faculty, Institute for Healthcare Informatics, University of Minnesota, Faculty, Artificial Intelligence in Cardiology Program (ATRIA)
- **Gregory Curfman, MD,** Executive Editor, JAMA
- **Yngve Falck-Ytter, MD, AGAF,** Professor of Medicine, Case Western Reserve University; Chief, Gastroenterology and Hepatology VA Northeast Ohio Healthcare System, Cleveland
- **Heather Guidone, BCPA,** Program Director, Center for Endometriosis Care (CEC)
- **Jayani Jayawardhana, PhD,** Associate Professor, University of Kentucky
- **David Kim, PhD,** Assistant Professor, University of Chicago
- **Timothy McBride, PhD,** Co-Director, Center for Health Economics and Policy, Professor, Brown School, Washington University in St. Louis
- **Reem Mustafa, MD, MPH, PhD, FACP,** Professor of Medicine, Division of Nephrology & Hypertension, The University of Kansas Medical Center
- **Rachel Sachs, JD, MPH,** Associate Professor of Law, Washington University in St. Louis, Faculty Scholar, Washington University in St. Louis Institute for Public Health
- **Timothy Wilt, MD, MPH,** Professor of Medicine, Core Investigator, and Staff Physician at the Minneapolis VA Center for Chronic Disease Outcomes Research, University of Minnesota School of Medicine

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# Clinical Experts

**Hayden McRobbie, MB, ChB, PhD**, Professor of Population Health, Queen Mary University of London

- *No conflicts to disclose.*

**Nancy Rigotti, MD**, Professor of Medicine, Harvard Medical School; Director, Tobacco Research & Treatment Center, Massachusetts General Hospital

- *Dr. Nancy Rigotti has received research funding through Massachusetts General Hospital from Achieve Life Sciences, Inc. for conducting clinical trials of cytisinicline. She received consulting fees from Achieve Life Sciences through the end of 2022, but not since that time.*

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# Patient Experts

**Mike Hess**, Senior Director of Advocacy & Regulatory Affairs, COPD Foundation

- *80% of COPD Foundation's annual funding is from health care companies.*

**Judy Nagy**, Patient Advocate

- *Judy Nagy volunteers with the Global Healthy Living Foundation, AiArthritis, and the Arthritis Foundation and does not receive any income from these organizations.*

# ICER Speakers



**Sarah K. Emond, MPP**  
*President & CEO*



**Jeffrey A. Tice, MD**  
*Evidence Author,  
Professor of Medicine, University of  
California, San Francisco*



**David Rind, MD, MSc**  
*Chief Medical Officer*



**Kangho Suh, PharmD, MS, PhD**  
*Lead Modeler and Assistant Professor,  
University of Pittsburgh School of  
Pharmacy; University of Washington  
Modeling Group*



# Why are we here today?

“Trying to quit smoking was one of the hardest things I had ever done in my life. I saw my parents struggle with smoking. My mother died of COPD and my father died of heart issues because of smoking. I think we all know better, but it is an addictive habit that is extremely difficult to break.”

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ICER patient interview  
with former smoker

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# 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?

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# The Impact on Rising Health Care Costs for Everyone

# GALLUP®

APRIL 1, 2025

## In U.S., Inability to Pay for Care, Medicine Hits New High

Rates among Hispanic, Black adults and those with lower incomes worsen markedly since 2021

## Business Group on Health Survey: 9% Health Care Cost Increase for 2026

Peterson-KFF  
**Health System Tracker**

Health Spending

## How much and why ACA Marketplace premiums are going up in 2026



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# Organizational Overview



20  
YEARS

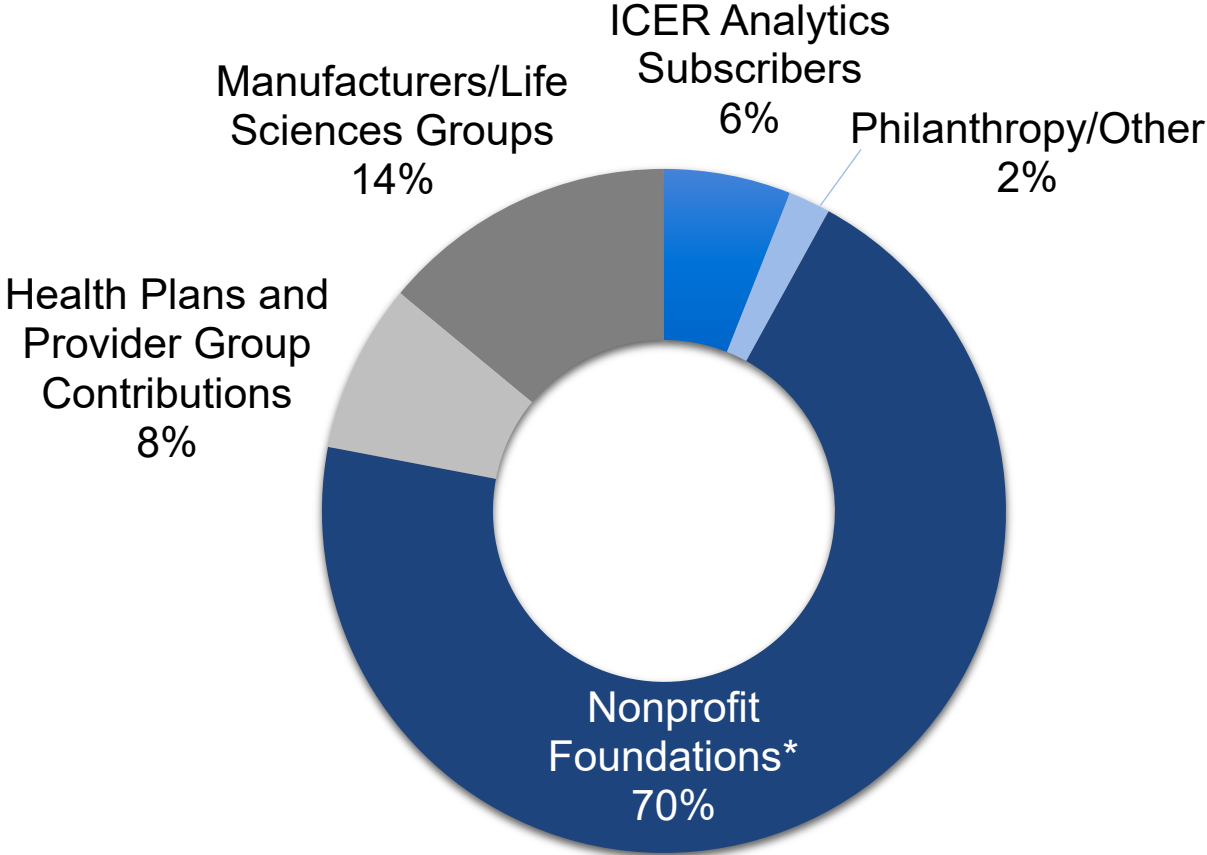


MIDWEST

CEPAC

COMPARATIVE EFFECTIVENESS  
PUBLIC ADVISORY COUNCIL

# Funding Overview and Managing COIs



Read our policies to manage potential conflicts of interest: <https://icer.org/our-approach/policies/policies-to-manage-conflicts-of-interest/>

■ ICER Policy Summit and non-report activities only

# How Was the ICER Report Developed?



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# 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

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# 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** Midwest 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

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# Presentation of the Clinical Evidence

**Jeffrey A. Tice, MD**

Professor of Medicine

University of California, San Francisco



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# Key Team Members

Name	Title
Jeffrey A. Tice, MD	Evidence Author and Professor of Medicine, UCSF
Dmitriy Nikitin, MSPH	Senior Research Lead, ICER
Sol Sanchez, BA	Research Assistant, ICER

## Disclosures

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

Jeffrey Tice has no conflicts to disclose.

Dmitriy Nikitin and Sol Sanchez are employees of ICER and have no conflicts to disclose.

# Smoking

## Disease Background in the United States

- #1 preventable cause of death
- 500,000 smoking related deaths annually
- \$600 billion annually in medical costs and lost productivity
- \$76 billion spent on tobacco products annually

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# Impact on Patients

- Why I smoke
  - Positive feedback with short term stress relief
  - Association with pleasurable activities
- Why I want to quit
  - Stigma as a smoker
  - Challenges of addiction
  - Health: cancer, cardiovascular disease, lung disease, death

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# Standard of Care and Management

- Behavioral support: empathy, motivation, triggers, strategies, quit date
  - Core for all smoking cessation efforts
- Pharmacologic
  - Nicotine replacement, especially combination
  - Varenicline
  - Bupropion
  - Nicotine-containing e-cigarettes

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# Scope of Review: Two Populations

- Adult cigarette smokers interested in quitting
  - Most have tried to quit before
- E-cigarette users interested in quitting

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# Intervention: Cytisinicline

- Cytisine
  - Smoking cessation in Eastern Europe for 50 years
  - Plant alkaloid from the seeds of an acacia bush
  - 25-day taper
  - Varenicline: rationally designed analog of cytisine; FDA approved 2006
- Partial agonist of the nicotinic acetylcholine receptor
- New formulation: 3 mg TID for 12 weeks

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# Comparators

- Behavioral support alone
- Varenicline 1 mg twice daily for 12+ weeks
- Electronic cigarettes with nicotine

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# Outcomes

- Confirmed continuous abstinence weeks 9-24
- Long-term continuous abstinence
- Reductions in cancer, CVD, and lung disease



# Clinical Evidence

# Key Clinical Trials

Study	Population	N	F/U Weeks	Age, Years	Primary Outcome
<b>ORCA-2</b>	Smokers	541	24	~53	Continuous abstinence weeks 9-12
<b>ORCA-3</b>	Smokers	529	24	~52	Continuous abstinence weeks 9-12
<b>ORCA-V1</b>	Vapers	160	16	~33	Continuous abstinence weeks 9-12
<b>ORCA-V2</b>	Vapers	~800	24	-	Continuous abstinence weeks 9-12

Note: Cochrane Review 2023 for some comparisons: <https://doi.org/10.1002/14651858.CD015226.pub2>

# Results: Cytisinicline versus behavioral support Cigarette Smokers

	ORCA-2		ORCA-3		Meta-Analysis CYT vs. PCB
	Cytisinicline (12 Week)	Placebo	Cytisinicline (12 Week)	Placebo	
<b>N</b>	<b>270</b>	<b>271</b>	<b>264</b>	<b>265</b>	
<b>Abstinence* 9-12 Weeks</b>	32.6%	7.0%	30.3%	9.4%	23% (19,28)
<b>Abstinence* 9-24 Weeks</b>	21.1%	4.8%	20.5%	4.2%	16% (12,20)

\*Biochemically confirmed continuous abstinence

# Results: Cytisinicline versus Varenicline NMA Risk Ratio (95% Credible Interval)

<b>Cytisinicline</b>		
1.1 (0.76 to 1.7)	<b>Varenicline</b>	
<b>2.7 (1.9 to 4.0)</b>	2.45 (2.2 to 2.7)	<b>Behavioral Support</b>

**Outcome:** Continuous abstinence weeks 9-24

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# Results: Cytisinicline versus E-cigarettes

- No head-to-head data
- Cochrane 2023 NMA
  - No difference in abstinence at 6+ months
  - OR 0.94; 95% CrI: 0.62 to 1.43

# Harms

## Key Points

- Cytisinicline versus placebo
  - More insomnia (11% versus 6%)
  - More abnormal dreams (8% versus 5%)
- Cytisinicline versus varenicline
  - Less nausea
  - Black box for varenicline removed
- Cytisinicline versus e-cigarettes
  - No significant differences
- Discontinuations due AEs and SAEs
  - No significant differences for all three comparisons

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# Subgroup Analyses and Heterogeneity

- ORCA-2: No effect modification by age, gender, or prior quit attempts
  - Light smokers ( $\leq 20$  cigarettes/day): OR 10.2
  - Heavy smokers ( $> 20$  cigarettes): OR 5.40, p for interaction 0.321
- Patients with COPD analysis (ORCA-2 & 3)
  - No difference in treatment effect
  - Lower quit rates in both groups (cytisinicline and placebo)

# Controversies and Uncertainties

## Key Points

- Optimal treatment duration unclear
  - 12 weeks better than 6 weeks
  - Longer therapy may be better
- Patients with serious mental illness excluded despite higher smoking rates
- Limited evidence for cytisinicline in vaping cessation
  - Phase III ORCA V-2 was planned
- Cytisinicline and varenicline
  - Indirect evidence only. Direct evidence needed.

# Benefits Beyond Health and Special Ethical Priorities

## Key Points

- **Substantial unmet need**
- **Health Equity**
  - Serious psychiatric illness
  - Low socioeconomic status
  - Native American/Alaska Native
- **Additional Factors**
  - “Natural” (acacia plant seeds)

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# Public Comments Received from Achieve Life Sciences

- Cytisinicline is a new chemical entity
  - FDA web page for cytisinicline
    - Cytisine is **synonym** for cytisinicline
  - Achieve Life Sciences Website
    - “Achieve Announces Presentation of Investigator-Led RAUORA Trial Data Demonstrating Significantly Fewer Side Effects with Higher Quit Rates for **Cytisinicline (cytisine)**...”

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# Summary of Cytisinicline TID for 12 Weeks in Cigarette Smokers

- Compared with behavioral support alone
  - Substantially higher abstinence weeks 9-24
  - Minimally more adverse events (insomnia, dreams)
- Compared with varenicline
  - Similar abstinence weeks 9-24
  - Less nausea, though no difference in discontinuation rates due to AEs
- Compared with e-cigarettes
  - Similar outcomes, but limited evidence and concerns about long term harms of e-cigarette use

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# Summary of Cytisinicline TID for 12 Weeks in Users of e-Cigarettes

- Compared with behavioral support
  - Small study suggesting net benefit
  - Phase III study was planned, but given a National Priority Voucher
- Compared with varenicline
  - No data, but likely similar based on comparison in cigarette smokers

# ICER Evidence Ratings for Cytisinicline

**Population: Adult Smokers interested in quitting**

Intervention	Comparator
Cytisinicline	Behavioral Support

<b>D</b>	<b>C</b>	<b>B</b>	<b>A</b>
Negative Net Benefit	Comparable Net Benefit	Small Net Benefit	Substantial Net Benefit

# ICER Evidence Ratings for Cytisinicline

Population: Adult Smokers interested in quitting

Intervention	Comparator
Cytisinicline	Varenicline

D	C	B	A
	← C+ →		
Negative Net Benefit	Comparable Net Benefit	Small Net Benefit	Substantial Net Benefit

At least as good, and possibly somewhat better

# ICER Evidence Ratings for Cytisinicline

Population: Adult Smokers interested in quitting

Intervention	Comparator
Cytisinicline	Electronic Cigarettes with Nicotine

D	C	B	A
←————— —————→			
Negative Net Benefit	Comparable Net Benefit	Small Net Benefit	Substantial Net Benefit

Insufficient evidence

# ICER Evidence Ratings for Cytisinicline

Population: Adult Users of e-cigarettes who want to quit

Intervention	Comparator
Cytisinicline	Behavioral Therapy

D	C	B	A
	← C++ →		
Negative Net Benefit	Comparable Net Benefit	Small Net Benefit	Substantial Net Benefit

At least as good, and possibly somewhat to substantially better

# ICER Evidence Ratings for Cytisinicline

Population: Adult Users of e-cigarettes who want to quit

Intervention	Comparator
Cytisinicline	Varenicline

D	C	B	A
	← P/I →		
Negative Net Benefit	Comparable Net Benefit	Small Net Benefit	Substantial Net Benefit

May be somewhat better, but possibly slightly worse

**Questions?**

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# Presentation of the Economic Model

**Kangho Suh, PharmD, PhD**

Assistant Professor, School of Pharmacy

University of Pittsburgh, Pennsylvania; University of Washington Modeling Group



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# Key Team Members

Name	Title
Kangho Suh, PharmD, PhD	<b>Assistant Professor, School of Pharmacy, University of Pittsburgh; University of Washington Modeling Group</b>
Josh Carlson, PhD, MPH	<b>Professor &amp; Graduate Program Director, CHOICE Institute, University of Washington</b>
Hui-Hsuan Chan, MHS	<b>PhD Student, University of Washington</b>
Marina Richardson, PhD, MSc	<b>Associate Director, Health Technology Assessment Methods and Health Economics, ICER</b>
Marie Phillips, BA	<b>Health Economics Research Assistant, ICER</b>

## Disclosures

Financial support provided to the Universities of Washington Modeling Group from the Institute for Clinical and Economic Review (ICER)

Marina Richardson and Marie Phillips are employees of ICER and have no conflicts to disclose.

Kangho Suh and Hui-Hsuan Chan have no conflicts to disclose.

Josh Carlson has received consulting fees from Pfizer, not related to smoking cessation.

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## Objective

To evaluate the lifetime cost-effectiveness of cytisinicline with behavioral support compared to varenicline with behavioral support or behavioral support alone in individuals interested in quitting cigarettes.

# Unmet Need

Condition	Absolute evLY Shortfall	Proportional evLY Shortfall
Smoking Cigarettes	11.0	44%
<b>Other Example Conditions</b>		
Depression	9.7	32%
Multiple Sclerosis	18.9	52%
Osteoporosis	2.6	19%



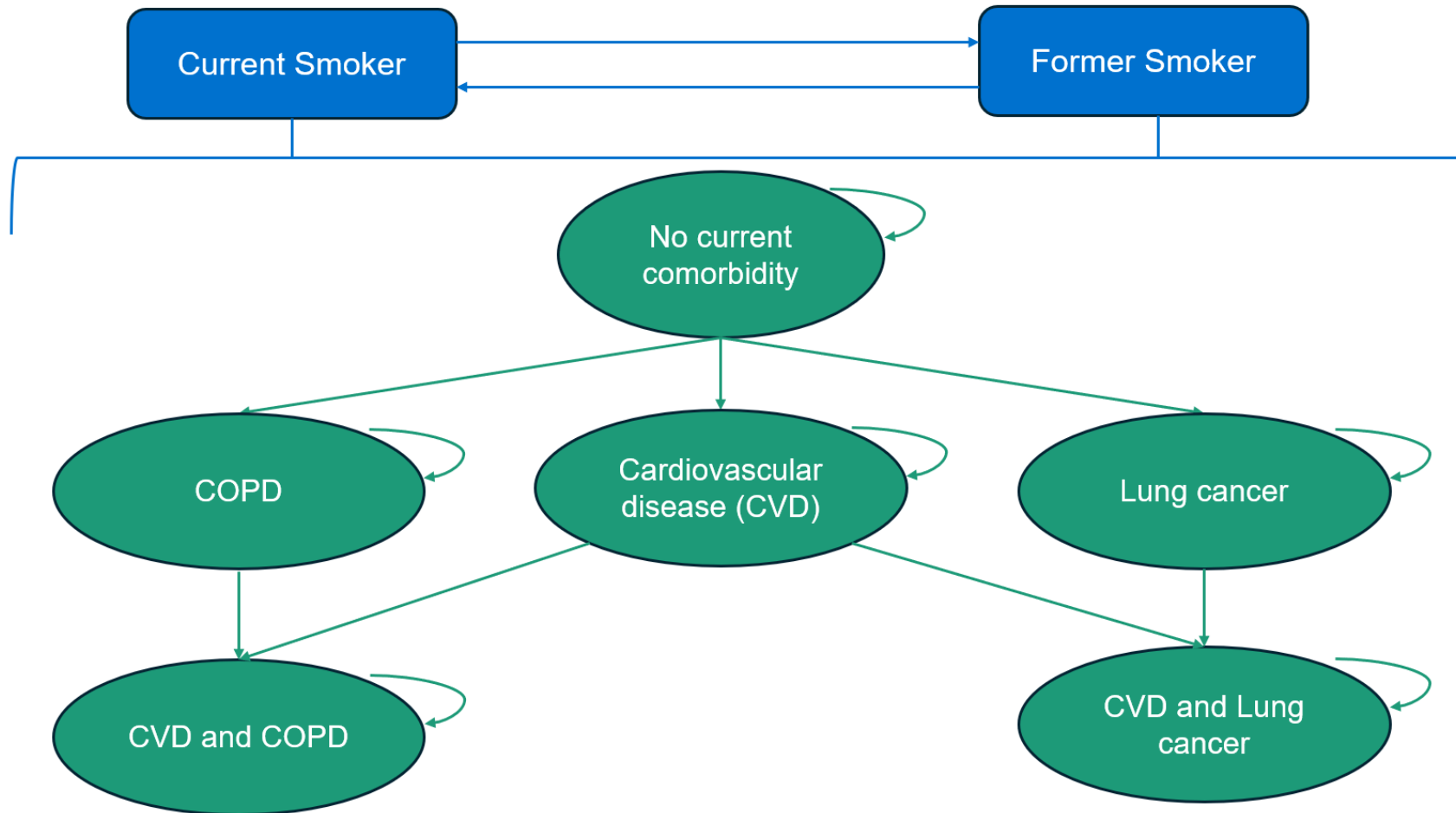
# Methods in Brief

# Methods Overview

Domain	Approach
<b>Model</b>	Markov
<b>Setting</b>	United States
<b>Perspective</b>	Health Care Sector Perspective*
<b>Time Horizon</b>	Lifetime
<b>Discount Rate</b>	3% per year (costs and outcomes)
<b>Cycle Length</b>	3 months
<b>Primary Outcome</b>	Cost per life year gained; cost per quality-adjusted life year (QALY) gained; cost per evLY gained; COPD cases averted

\*The modified societal perspective was conducted as a scenario analysis. The criteria for considering the modified societal perspective analysis as a co-base case are described in ICER's Reference Case

# Model Schematic



# Model Cohort Characteristics

Baseline Characteristic	Value	Source
Age, Mean (SD)	52.0 (11.8)	ORCA-2 and ORCA-3 trials
Male, %	44.8	
Daily Cigarettes Smoked, Mean (SD)	19.7 (7.4)	

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# Key Assumptions

- Former smokers have the same transition probabilities of clinical outcomes (CVD, COPD, lung cancer) regardless of how long ago they quit.
- Former smokers have the same relapse probability, regardless of time since quitting or cessation strategy.
- Patient cannot have COPD and lung cancer simultaneously.

# Key Model Inputs: Treatment-Related Efficacy

Intervention	Relative Risk Of Quitting (Compared to Behavioral Therapy* Alone)	Source
<b>Cytisinicline</b>	2.71 (95% CrI: 1.91, 4.02)	ICER internal network-meta analysis
<b>Varenicline</b>	2.45 (95% CrI: 2.19, 2.71)	

\*Quit probability for behavioral therapy alone calculated to be 10.06% for 3-month cycle

# Key Model Inputs: Transition Probabilities Per Cycle (3 Months)

Parameter	Current Smoker	Former Smoker	Source
<b>COPD</b>	0.31%-0.62% (age-specific)	0.10%-0.31% (age-specific)	Terzikhan et al. 2016
<b>Lung Cancer</b>	0.05%	0.04%	Tindle et al. 2018
<b>CVD Event</b>	0.31%	0.29%	McEvoy et al. 2015

# Key Model Inputs: Mortality Risk

Parameter	Relative Risk (Current vs. Never Smoked)	Relative Risk (Former vs. Never Smoked)	Source
All-Cause	2.8	1.5	Thun et al. 2013
COPD	22.4	8.1	
Lung Cancer	25.7	6.7	
CVD Event	2.6	1.3	

# Key Model Inputs: Utilities

Health State	Utility	Source
<b>Baseline Utility</b>	Age-adjusted	Jiang et al. 2021
<b>COPD</b>	0.79*	Rutten-van et al. 2006
<b>Lung Cancer</b>	0.78†	Tramontano et al. 2015
<b>Utility Multiplier: CVD</b>	0.94‡	Sullivan et al. 2006
<b>Disutility: Acute CVD Event (One 3-Month Cycle)</b>	-0.17‡	Matza et al. 2015
<b>Disutility: Smoking</b>	-0.035	Vogl et al. 2012

\*Calculated average across GOLD stage 2 through 4

†Calculated average across stage 1 through 4

‡Calculated average of myocardial infarction and stroke

# Key Model Inputs: Treatment Costs

Intervention	WAC per mg	Net Cost per Treatment Course	Source
<b>Cytisinicline</b>	\$6.61*	\$5,000*	IPD Analytics
<b>Varenicline</b>	\$4.88†	\$664†	Redbook
<b>Behavioral Support Therapy</b>	\$27 for initial session, \$14 for subsequent sessions	\$180	CMS Physician Fee Schedule

\*Placeholder price

†Represents the median price of all available generic options



# Results

# Base-Case Results

Drug	Treatment Costs*	Total Costs*	COPD Cases†	LYs	QALYs	evLYs
<b>Cytisinicline</b>	\$5,200	\$195,000	168	13.97	10.72	10.72
<b>Varenicline</b>	\$880	\$190,000	168	13.96	10.71	10.71
<b>Behavioral Support Alone</b>	\$200	\$189,000	172	13.89	10.63	10.63

\*Based on placeholder price

†Per 1,000 individuals

# Base-Case Incremental Results

Treatment	Comparator	Incremental LYs	Incremental QALYs	Incremental evLYs
<b>Cytisinicline</b>	Varenicline	0.01	0.01	0.01
<b>Cytisinicline</b>	Behavioral Support Alone	0.08	0.08	0.09

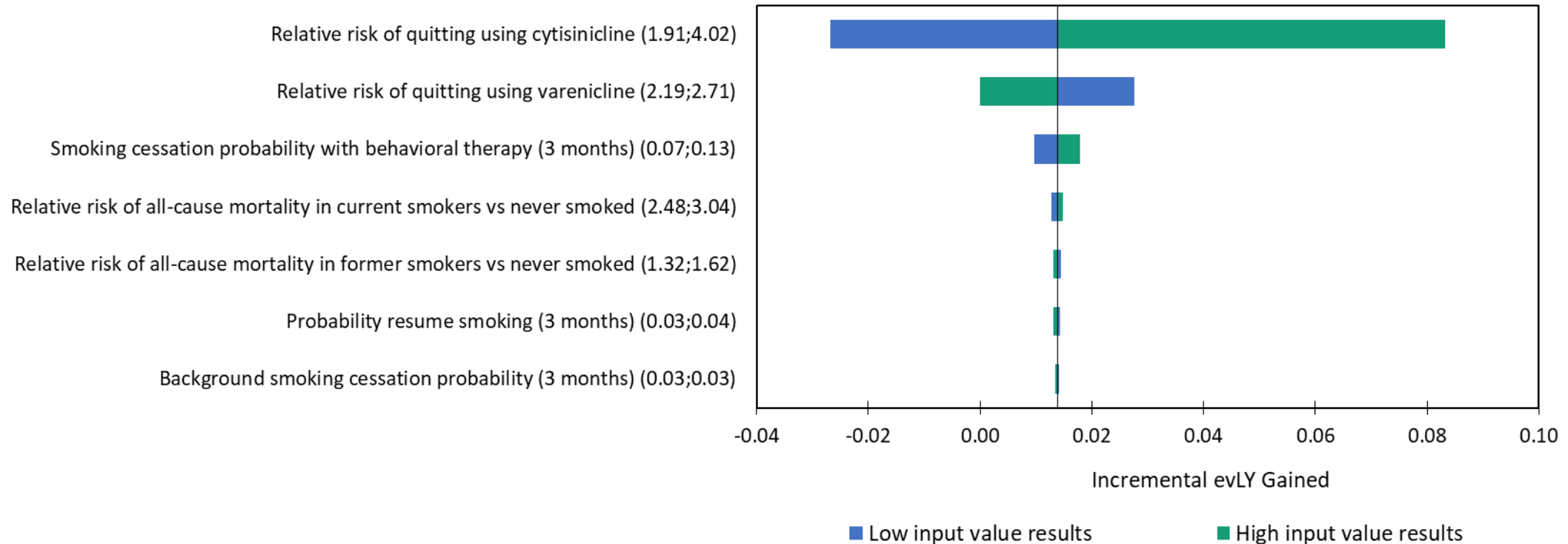
# Base-Case Incremental Cost-effectiveness Ratios

Treatment	Comparator	Cost per QALY Gained*	Cost per evLY Gained*
<b>Cytisinicline</b>	Varenicline	\$339,000	\$317,000
<b>Cytisinicline</b>	Behavioral Support Alone	\$64,400	\$60,200

\*Based on placeholder price

# One Way Sensitivity Analyses

## Cytisinicline vs. Varenicline (Incremental evLY Gained)



# Probabilistic Sensitivity Analysis

Drug	Cost-Effective at \$50,000 per QALY	Cost-Effective at \$100,000 per QALY	Cost-Effective at \$150,000 per QALY
<b>Cytisinicline vs. Varenicline</b>	0.4%	12.0%	25.1%
<b>Cytisinicline vs. Behavioral Support Alone</b>	17.1%	89.3%	98.6%

# Scenario Analyses

	Cytisinicline vs. Varenicline	Cytisinicline vs. Behavioral Support Alone
	Cost per evLY gained	
<b>Modified Societal Perspective</b>	\$294,000	\$44,000
<b>Minimum Price for Varenicline*</b>	\$363,000	--
<b>Lower Relapse Probability Starting in Year 5</b>	\$274,000	\$54,000

\*Treatment course cost of \$25

# Health Benefit Price Benchmark (HBPB)

Intervention	Treatment Course WAC	Treatment Course Cost at \$100,000/QALY Threshold	Treatment Course Cost at \$150,000/evLY Threshold	Discount from WAC to Reach Threshold Prices
<b>Cytisinicline + Behavioral Support†</b>	\$5,000*	\$1,900	\$2,700	46% - 62%

\*Placeholder price for a 12-week treatment course

†Compared to Varenicline with Behavioral Support

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# Limitations

## Top Limitations

- Health consequences of smoking limited to COPD, lung cancer, and CVD
- Risks of disease do not vary over time
- Assumed single quit attempt at treatment initiation
- Placeholder price for cytisinicline

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# Comments Received

- No comments on the model received between draft and evidence report
- Comments from external expert reviewers included:
  - Using a lower price for varenicline
  - Incorporating relapse rates that vary by time since quitting

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# Conclusions

- Cytisinicline provides gains in QALYs, evLYs, and LYs over varenicline from the healthcare sector perspective
- At the currently assumed placeholder price, cytisinicline would not meet commonly cited cost-effectiveness thresholds vs. varenicline
- At the currently assumed placeholder price, cytisinicline would meet commonly cited cost-effectiveness thresholds vs. behavioral support alone

**Questions?**



# Public Comment and Discussion

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# Judy Nagy

## Patient Advocate

*Judy Nagy volunteers with the Global Healthy Living Foundation, AiArthritis, and the Arthritis Foundation and does not receive any income from these organizations.*

00 : 05 : 00

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(Optional): -- --  
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# Lunch

Meeting will resume at 12:50 PM CT





# Voting Questions



# Clinical Evidence

***Patient Population for  
Questions 1-3: Adults who  
are interested in quitting  
cigarettes***



**1. For people who smoke cigarettes, is the current evidence adequate to demonstrate that the net health benefit of cytisinicline is greater than that of behavioral support alone?**



**2. For people who smoke cigarettes, is the current evidence adequate to demonstrate that the net health benefit of cytisinicline with behavioral support is greater than that of varenicline with behavioral support?**



**3. For people who smoke cigarettes, is the current evidence adequate to demonstrate that the net health benefit of cytisinicline with behavioral support is greater than that of electronic cigarettes containing nicotine with behavioral support?**

***Patient Population for  
Questions 4-5: Adults who  
are interested in quitting  
smoking electronic cigarettes  
(vapes) that contain nicotine***



**4. For people who vape nicotine, is the current evidence adequate to demonstrate that the net health benefit of cytisinicline with behavioral support is greater than that of behavioral support alone?**



**5. For people who vape nicotine, is the current evidence adequate to demonstrate that the net health benefit of cytisinicline with behavioral support is greater than that of varenicline with behavioral support?**

***Patient Population for  
Questions 6-11: Adults who  
are interested in quitting  
cigarettes***



# **Benefits Beyond Health and Special Ethical Priorities**

***To help inform judgments of overall long-term value for money, please indicate your level of agreement with the following statements:***



**6. There is substantial unmet need despite currently available treatments.**



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

***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 cytisinicline versus varenicline:***



**8. 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.**



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



**10. Other: The treatment may increase acceptability and thus uptake among a subset of people who smoke because cytisinicline is derived from the seeds of an acacia plant, and can be marketed as a ‘natural medicine’.**

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# Break

Meeting will resume at 2:00 PM CT





# Policy Roundtable

# Policy Roundtable

Participant	Conflict of Interest
<p><b>Benjamin Broder, MD, PhD</b></p> <p>Regional Assistant Medical Director of Quality and Clinical Analysis, Kaiser Permanente</p>	<p>Dr. Benjamin Broder is a full time employee of Kaiser Permanente.</p>
<p><b>Peter A. Glassman, MBBS, MSc, FACP</b></p> <p>Chair, Medical Advisory Panel, Veterans Affairs Pharmacy Benefits Management Services</p>	<p>Dr. Peter Glassman is a full time employee of the Department of Veterans Affairs.</p>
<p><b>Mike Hess</b></p> <p>Senior Director of Advocacy &amp; Regulatory Affairs, COPD Foundation</p>	<p>80% of COPD Foundation’s annual funding is from health care companies.</p>
<p><b>Julia Logan, MD, MPH</b></p> <p>Chief Medical Officer, CalPERS</p>	<p>Dr. Julia Logan is a full time employee of CalPERS.</p>
<p><b>Hayden McRobbie, MB, ChB, PhD</b></p> <p>Professor of Population Health, Queen Mary University of London</p>	<p>No conflicts to disclose.</p>
<p><b>Judy Nagy</b></p> <p>Patient Advocate</p>	<p>Judy Nagy volunteers with AiArthritis, Arthritis Foundation, and the Global Healthy Living Foundation and does not receive income from these organizations.</p>
<p><b>Nancy Rigotti, MD</b></p> <p>Professor of Medicine, Harvard Medical School; Director, Tobacco Research &amp; Treatment Center, Massachusetts General Hospital</p>	<p>Dr. Nancy Rigotti has received research funding through Massachusetts General Hospital from Achieve Life Sciences, Inc. for conducting clinical trials of cytisinicline. She received consulting fees from Achieve Life Sciences through the end of 2022, but not since that time.</p>



# **Midwest CEPAC Council Reflections**

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# Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around February 12<sup>th</sup>, 2026
  - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: <https://icer.org/assessment/smoking-cessation-2025/>

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# Adjourn

