
Tavapadon for Parkinson's Disease

Effectiveness and Value

Public Meeting — October 1, 2026

Meeting materials available at: <https://icer.org/assessment/parkinsons-disease-2026/#timeline>



Participating Members of the CTAF

Elizabeth J. Murphy, MD, DPhil, CTAF Chair,

Professor of Medicine, UCSF; Chief, Division of Endocrinology, San Francisco General Hospital

- **Felicia Cohn, PhD**, Bioethics Director, Kaiser Permanente Orange County
- **Bob Collyar**, Patient Advocate, Patient Advocates In Research
- **Sanket Dhruva, MD, MHS**, Associate Professor of Medicine, UCSF School of Medicine
- **Rena K. Fox, MD**, Professor of Medicine, UCSF
- **Jeffrey Klingman, MD**, Neurologist, Kaiser Permanente
- **Annette Langer-Gould, MD, PhD**, Regional Lead for Clinical and Translational Neuroscience, Southern California Permanente Medical Group, Kaiser Permanente; Professor, Kaiser Permanente School of Medicine
- **Sei Lee, MD**, Professor of Medicine, UCSF, Division of Geriatrics
- **Joy Melnikow, MD, MPH**, Professor Emeritus, University of California, Davis
- **Kavita V. Nair, PhD**, Professor of Neurology and Pharmacy, CU Skaggs School of Pharmacy & Pharmaceutical Sciences, Anschutz Medical Campus
- **Ann Raldow, MD, MPH**, Associate Professor, Department of Radiation Oncology, David Geffen School of Medicine, UCLA
- **Rita F. Redberg, MD, MSc, FACC**, Professor of Medicine, UCSF
- **Tony Sowry**, Patient Advocate and Lead Volunteer, National Patient Advocate Foundation

Patient Experts

William (Bill) F. Ryan, Volunteer Board Member, Wisconsin Chapter, American Parkinson Disease Association

- *Mr. Ryan has no conflicts to disclose.*

Catherine (Katie) Kopil, PhD, Senior Vice President, Head of Clinical Research, Michael J. Fox Foundation

- *Dr. Kopil is a full-time employee of the Michael J. Fox Foundation (MJFF). MJFF receives less than 1% of its annual funding from health care companies.*
- *MJFF has engaged Katharina Klapper of Katharina Klapper Consulting GmbH to support its preparation for the ICER public meeting. Ms. Klapper is a former MJFF staff member who now consults for the Foundation.*
- *Dr. Kopil's spouse is a salaried Managing Director at L.E.K. Consulting, a strategy consulting firm with significant business in the biopharmaceutical sector. Dr. Kopil does not have visibility into L.E.K's client relationships, and AbbVie or other manufacturers active in Parkinson's disease may be among the firm's clients.*

Clinical Experts

Katherine Wong, MD, Assistant Professor of Neurology, University of Southern California

- *Dr. Wong has no conflicts to disclose.*

Rebecca Gilbert, MD, PhD, Neurologist and Movement Disorders Specialist, Bellevue Hospital Center, NY; Chief Mission Officer, American Parkinson Disease Association

- *Dr. Gilbert is a full-time employee of the American Parkinson Disease Association (APDA). The APDA receives less than 5% of financial support from health care companies.*
- *The APDA public comment letter on the Draft Evidence Report was written after joint conversation with the Michael J Fox Foundation, Parkinson's Foundation, Davis Phinney Foundation, and PMD Alliance.*

ICER Speakers



Sarah K. Emond, MPP
President & CEO



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



Dan Ollendorf, PhD, MPH
*Chief Scientific Officer and Director
of HTA Methods and Engagement*



Surrey Walton, PhD, MA
*Lead Modeler,
Professor, College of Pharmacy,
Pharmacy Systems Outcomes and
Policy; Assistant Director, Center for
Pharmacoepidemiology and
Pharmacoeconomics, University of
Illinois Chicago*



Why are we here today?

The more I learn about it [Parkinson's Disease] from other people, the more I see that we're all different, and there isn't a magic formula for anyone.

Patient Living with Parkinson's Disease

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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Only 1 in 4 employers able to 'absorb' increasing health benefit costs without impacting business

S+ | OUT OF POCKET, OUT OF REACH

America's small businesses are giving up on health insurance

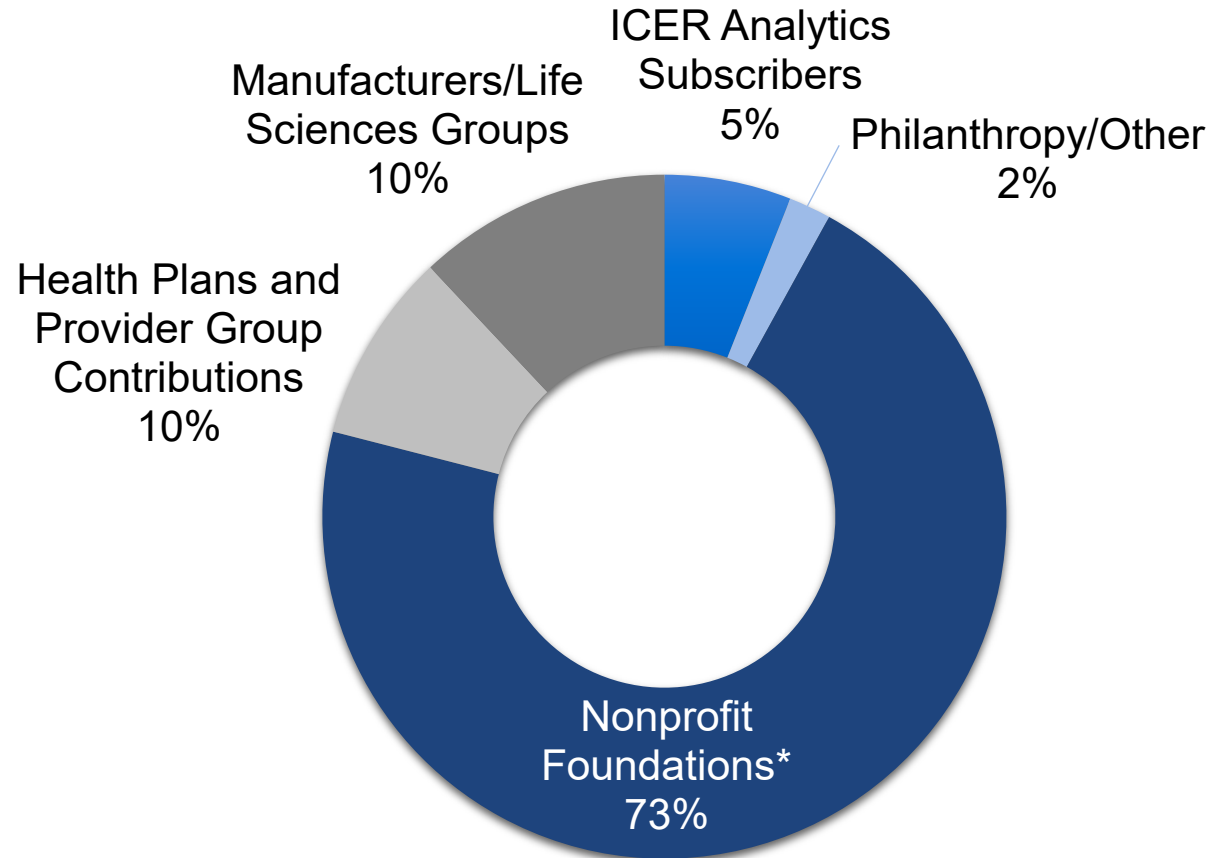
Employers and workers confront unaffordable premium hikes, with no relief in sight



Organizational Overview



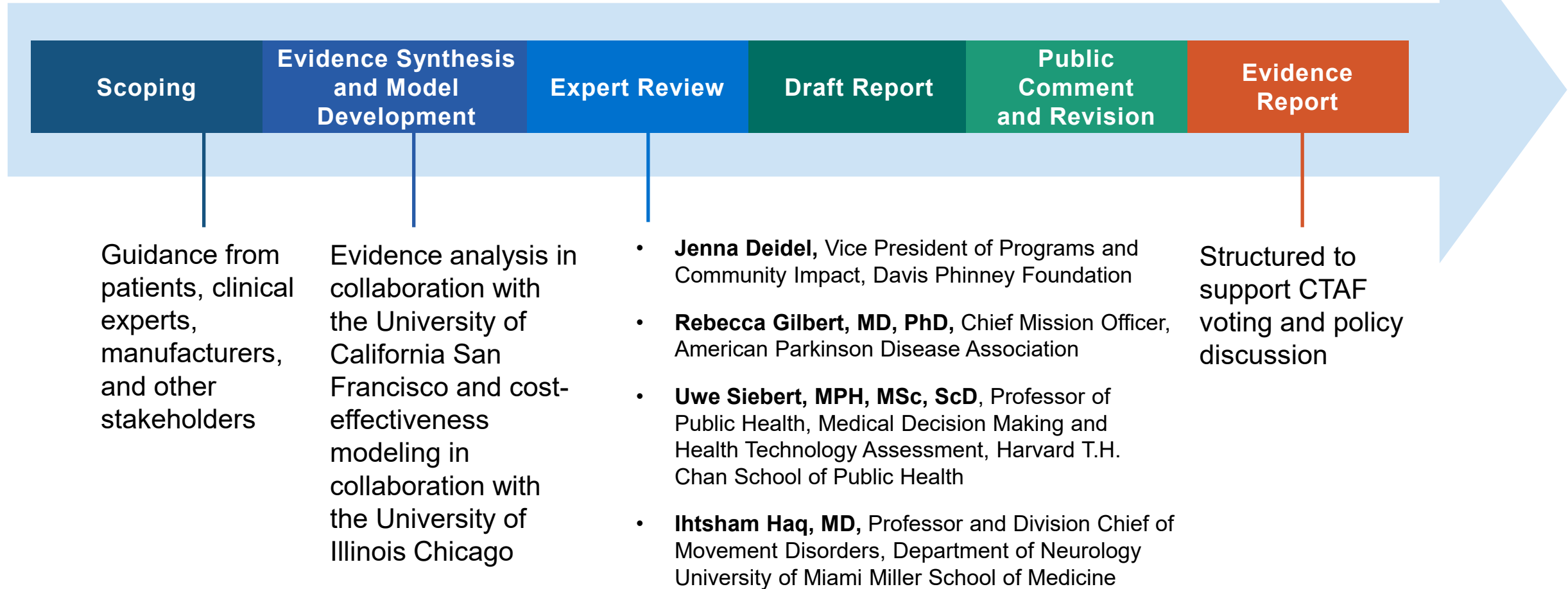
2026 Funding and Managing COIs



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How Was the ICER Report Developed?



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 (PT)

9:00 AM Meeting Convened and Opening Remarks

9:20 AM Presentation of the Clinical Evidence

10:00 AM Presentation of the Economic Model

10:40 AM Public Comments and Discussion

10:55 AM Lunch Break

11:45 AM CTAF Deliberation and Vote

12:50 PM Break

1:00 PM Policy Roundtable Discussion

2:30 PM Reflections from CTAF

3:00 PM Meeting Adjourned

Presentation of the Clinical Evidence

Jeffrey A. Tice, MD

Professor of Medicine

University of California San Francisco



Key Team Members

Name	Title
Jeffrey A. Tice, MD	Professor of Medicine, UCSF
Shahariar Mohammed Fahim, PhD, MSc	Senior Research Lead, ICER
Sol Sanchez, BA	Research Assistant, ICER

Disclosures

Financial support provided to Dr. Jeffrey A. Tice from the Institute for Clinical and Economic Review (ICER).

SMF and SS are employees of the Institute for Clinical and Economic Review (ICER) and have no conflicts to disclose.

Parkinson's Disease

Disease Background

- Chronic, progressive neurodegenerative disorder
- **Motor symptoms:** Stiffness, slowed movement, tremor, instability
- **Non-motor symptoms:** Insomnia, cognitive issues, fatigue, hallucinations, depression, anxiety

Input from Patients on Disease Impact

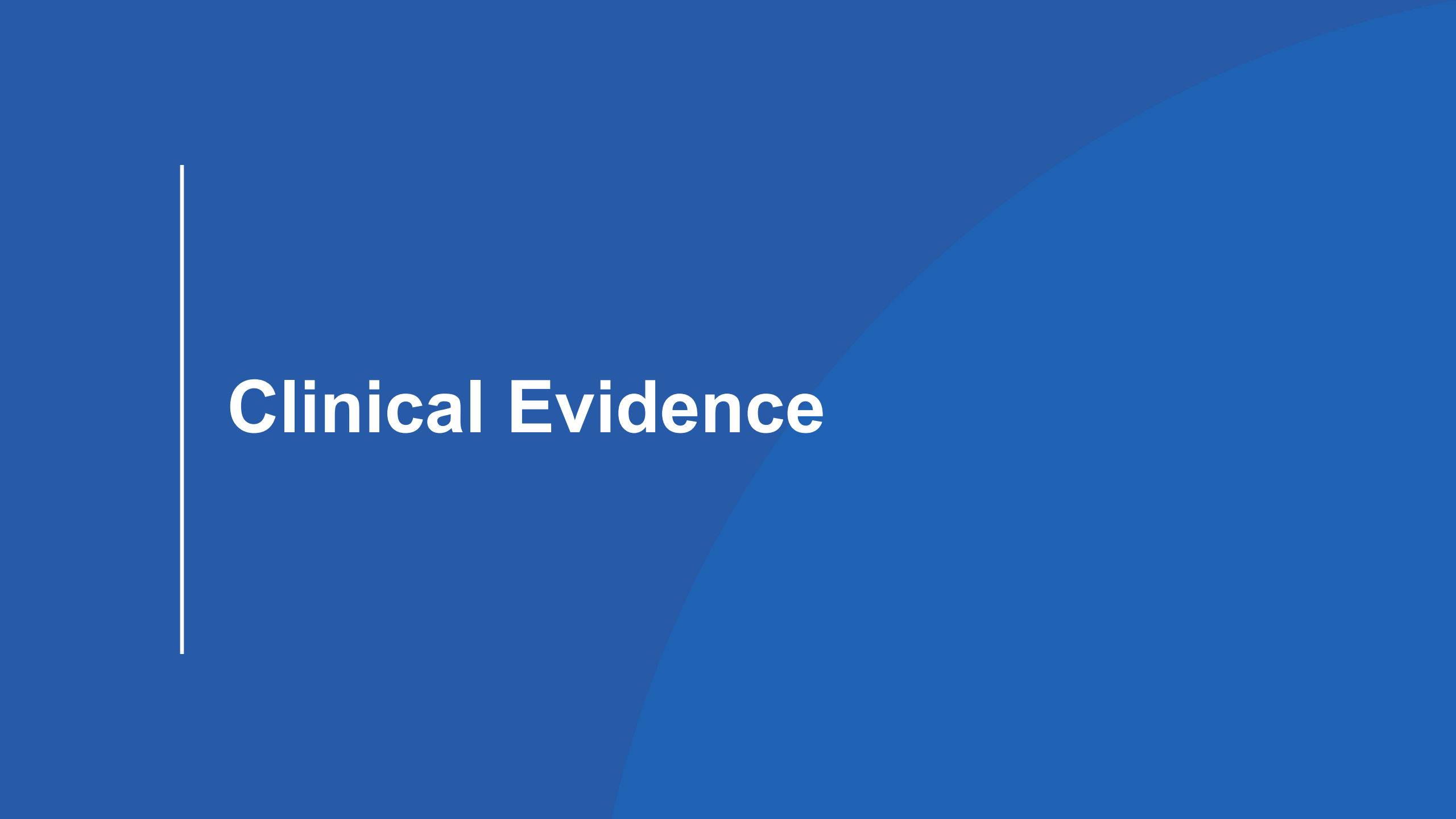
- Loss of independence – reliance on care partner
- Unpredictability of symptom control: ON and OFF times
- Difficulty walking / falls
- Pill burden, particularly with levodopa
- Financial toxicity: co-pays, non-reimbursed equipment, home health aides, loss of income

Standard Medical Management

- Early Parkinson's Disease
 - **Levodopa/Carbidopa**
- Patients on levodopa experiencing motor fluctuations
 - **Dopamine agonists**
 - MAO-B inhibitors
 - COMT inhibitors

Novel Therapy: Tavapadon (JUVMO™, AbbVie, Inc.)

- Dopamine D1/D5 selective partial agonist
 - Approved by FDA on September 28, 2026
- 5 to 15 mg once daily
- Prior dopamine agonists target D2 and D3 receptors. AEs:
 - Impulse control disorders (gambling, compulsive eating, compulsive shopping, and increased sex drive)
 - Hallucinations
 - Orthostatic hypotension
 - Dyskinesias (uncontrolled, sudden movements)



Clinical Evidence

Key Clinical Trials

Study	Group	N	F/U Weeks	Age, Years	Primary Outcome
TEMPO-1 (Pahwa, 2026)	Early PD	529	27	64	MDS-UPDRS Part II and III
TEMPO-2 (Fernandez, 2026)	Early PD	304	27	63	MDS-UPDRS Part II and III
TEMPO-3 (Fernandez, 2026)	Motor fluctuations	507	27	65	Good ON time
TEMPO-4 (Pahwa, 2025)	Open label extension	992	58	-	Safety

Key Outcomes

- Unified Parkinson's Disease Rating Scale (UPDRS)
 - Part II: Activities of daily living. Range 0-52, lower is better. MCID 1.8 to 3.1
 - Part III: Motor activities. Range 0-108, lower is better. MCID 4.8 to 6.2
- OFF time: when Parkinson's symptoms — motor and/or non-motor — return or worsen between medication doses (hours/day)
- Parkinson's Disease Questionnaire (PDQ-39)
 - Parkinson's Disease specific Quality of life measure
- EuroQol 5 Dimension (EQ-5D): Health related quality of life / utility

Early Parkinson's Disease

Early PD: Tavapadon Versus No Additional Therapy

Measure	Units	Results
UPDRS Part II	Mean difference	-1.9 (-2.6 to -1.2)
UPDRS Part III	Mean difference	-7.2 (-8.9 to -5.5)
Discontinuation due to AEs	Relative risk	5.1 (2.0 to 13.3)
Impulse Control Disorder	N	5 versus 0
Hallucinations	N	17 versus 0
PDQ-39; EQ-5D	Mean difference	Minimal differences in subdomains

Bold: Statistically significant (Results from NMA)
Others primarily from TEMPO-1 and TEMPO-2.

Early PD: Tavapadon Versus Levodopa

Measure	Units	Results
UPDRS Part II	Mean difference	0.8 (-3.5 to 5.1)
UPDRS Part III	Mean difference	-0.9 (-3.6 to 1.9)
Discontinuation due to AEs	Relative risk	3.5 (0.9 to 15.6)
Impulse Control Disorder	N	NA
Hallucinations	N	NA
PDQ-39; EQ-5D	Mean difference	NA

Results primarily from NMA.

Patients on Levodopa and Experiencing Motor Fluctuations

Motor Fluctuations on Levodopa: Tavapadon Versus No Additional Therapy

Measure	Units	Results
OFF Time	Mean difference, hours/day	-0.95 (-1.6 to -0.3)
Good ON Time	Mean difference, hours/day	1.1 (0.3 to 1.9)
Discontinuation due to AEs	Relative risk	1.8 (0.9 to 3.7)
All Discontinuations	Relative risk	1.9 (1.1 to 3.4)
Impulse Control Disorder	N	6 versus 3
PDQ-39; EQ-5D	Mean difference	No significant differences

Bold: Statistically significant (Results from NMA).
ICD and QoLs primarily from TEMPO-3.

Motor Fluctuations on Levodopa: Tavapadon Versus Other Dopamine Agonists

Measure	Units	Results
OFF Time	Mean difference, hours/day	0.46 (-0.2 to 1.2)
Good ON Time	Mean difference, hours/day	-0.5 (-1.5 to 0.4)
Discontinuation due to AEs	Relative risk	2.1 (0.96 to 4.4)
All Discontinuations	Relative risk	2.7 (1.5 to 5.1)
Impulse Control Disorder	N	No difference
PDQ-39; EQ-5D	Mean difference	NA

Bold: Statistically significant, results primarily from NMA.

Subgroup Analyses and Heterogeneity

- No effect modification by age, sex, HY stages, or disease duration in the TEMPO-1 and TEMPO-2 trials
- No subgroup analyses for TEMPO-3

Controversies and Uncertainties

Key Points

- Early PD: no head-to-head trials with levodopa
 - Dependent on indirect comparisons
- Levodopa with motor fluctuations: no head-to-head trials with DAs
 - Dependent on indirect comparisons
- Impulse control disorders increase linearly over at least three years with DAs: unclear if lower with tavapadon over time

Benefits Beyond Health and Special Ethical Priorities

Key Points

- Unmet needs: large evLY/QALY shortfalls in both populations. Significant.
- More common in White men, but likely significant underdiagnosis in Black and Hispanic populations.
- Once daily dosing may improve adherence compared with levodopa, but once daily dosing available for other dopamine agonists.

Public Comments Received

- **Insufficient methodological rigor:**
 - PRISMA guidelines specifically enumerated in supplement and highlighted in pre-specified protocol submitted to Center for Open Science.
- **There is significant unmet need in Parkinson's Disease:**
 - We agree as highlighted in the Benefits Beyond Health and Special Ethical Priorities Section of the Report (Section 5).
- **Unmet need related to pill burden is underrepresented.**

Summary

- Tavapadon: D1/D5-specific dopamine agonists
 - Mechanism should lead to fewer adverse effects including ICDs
- Indirect comparisons with older dopamine agonists
 - No better in terms of OFF and good ON time
 - More discontinuations: A surprise
 - Uncertainty in the long run about comparative incidence of ICDs
- Better than placebo for primary outcome in RCTs

Evidence Ratings of Interventions in Early Parkinson's Disease

Tavapadon

versus

No additional therapy

Modest improvements in UPDRS Parts II and III, but more ICDs, hallucinations, and no significant improvements in QoL. Much higher discontinuations due to AEs.

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

Evidence Ratings of Interventions in Early Parkinson's Disease

Tavapadon

versus

Levodopa, dopamine agonists, MAO-B inhibitors

Indirect evidence, mixed NS findings on UPDRS Parts II and III scores, but no significant improvements in QoL. Much higher discontinuations due to AEs.

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**

Evidence Ratings of Interventions in Patients Experiencing Motor Fluctuations

Tavapadon

versus

No additional therapy

Modest improvements in good ON time, but more ICDs, and no significant improvements in QoL. Higher discontinuation rate.

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

Evidence Ratings of Interventions in Patients Experiencing Motor Fluctuations

Tavapadon

versus

Dopamine agonists, MAO-B inhibitors, COMT-I

Indirect evidence, NS findings trending worse for ON and OFF time; no data on QoL. Higher overall discontinuation rates.

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?

Presentation of the Economic Model

Surrey Walton, PhD, MA

Professor, College of Pharmacy, Pharmacy Systems Outcomes and Policy;

Assistant Director, Center for Pharmacoepidemiology and Pharmacoeconomic Research,
University of Illinois Chicago



Tavapadon for Parkinson's Disease

Economic Modeling Team Introductions

Team Member	Title
Surrey Walton, PhD, MA	Professor, College of Pharmacy, Pharmacy Systems Outcomes and Policy; Assistant Director, Center for Pharmacoepidemiology and Pharmacoeconomic Research, University of Illinois Chicago
Aaron Winn, PhD, MPP	Associate Professor, University of Illinois Chicago
Jyotirmoy Sarker, PhD, MPharm, MBiotech	Research Assistant Professor, School of Pharmacy, University of Mississippi
Woojung Lee, PharmD, PhD	Director of Health Economics and Decision Modeling, ICER

Disclosures

Financial support provided to the University of Chicago Illinois (UIC) economic modeling team from the Institute for Clinical and Economic Review (ICER).

Dr. Winn has consulted for Takeda and Novo Nordisk. Dr Winn receives salary support from AbbVie as a fellowship director.

Dr. Walton has consulted for Hisamitsu.

Dr. Sarker received salary in the past 36 months from AbbVie not related to this work.

WL is an employee of the Institute for Clinical and Economic Review (ICER) and has no conflicts to disclose.

ICER's full policy for managing and disclosing potential conflicts of interest can be found here: <https://icer.org/wp-content/uploads/2025/03/ICER-COI-Policy-2025.pdf>

Objective

Parkinson's Disease

Population One: Among early-stage patients with Parkinson's disease, to evaluate the lifetime cost-effectiveness of tavapadon compared to levodopa.

Population Two: Among patients with Parkinson's disease on levodopa experiencing motor fluctuations, to evaluate the lifetime cost-effectiveness of adding tavapadon to levodopa compared to adding other dopamine agonists.

Unmet Need

Condition	Absolute evLY Shortfall	Proportional evLY Shortfall
<i>Parkinson's Disease</i>	9.8 for early-stage PD; 11.1 for PD with motor fluctuations	59% for early-stage PD; 67% for PD with motor fluctuations
Other Example Conditions		
Tardive Dyskinesia	11.6	32%
Spinal Muscular Atrophy	54.8	82%
Osteoporosis	2.6	19%



Methods in Brief

Methods Overview

Methods	Model One	Model Two
Model Structure	Markov Model	
Setting	United States	
Perspective	Health Care Sector Perspective and Modified Societal Perspective	
Time Horizon	Lifetime	
Discount Rate	3% per year (costs and outcomes)	
Cycle Length	6 months	
Primary Outcome	Cost per quality-adjusted life year (QALY) gained; equal value life years (evLY) gained	Cost per quality-adjusted life year (QALY) gained; equal value life years (evLY) gained

Treatment Regimens

Model One

Role	Generic Name	Dose	Approval Status
Intervention	Tavapadon	5–15 mg orally once daily (flexible dose)	Approved
Comparator	Carbidopa/Levodopa	25/100 mg tablet up to eight tablets daily or 100/250 mg tablet up to three times daily	Approved

Model Two

Role	Generic Name	Dose	Market Share For Cost Calcs (MarketScan 2024)
Intervention	Tavapadon + Levodopa	5–15 mg once daily + stable levodopa dose	—
Comparator (Dopamine Agonist Market Basket)	Ropinirole HCl (generic)	24 mg daily	51.9%
	Pramipexole DiHCl IR (generic)	4.5 mg daily	41.7%
	Rotigotine (Neupro patch)	8 mg daily	6.4%

Treatment Switching After Discontinuation

Model One

Role	Initial Treatment	Treatment After Discontinuation
Intervention	Tavapadon	Carbidopa/Levodopa
Comparator	Carbidopa/Levodopa	No switch; remains on Carbidopa/Levodopa

Model Two

Role	Initial Treatment	Treatment After Discontinuation
Intervention	Tavapadon + Levodopa	Monotherapy market basket*
Comparator	Dopamine agonist market basket + Levodopa	Monotherapy market basket*

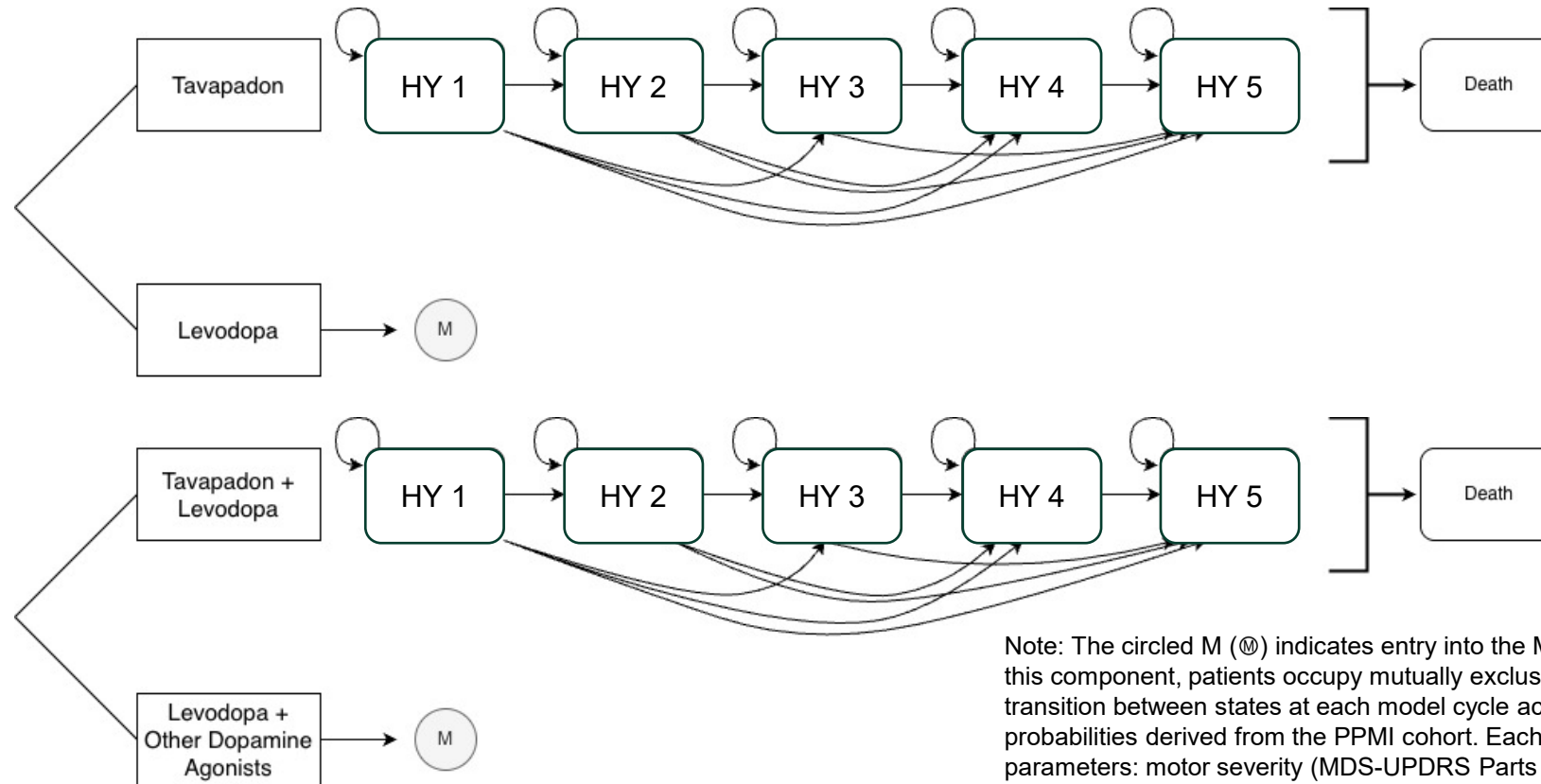
*Monotherapy market basket: 65% Carbidopa/Levodopa + 35% dopamine agonist market basket

Model Structure

- The models use Hoehn and Yahr stages to characterize progression and form baseline cost and utility values.
- Several key inputs including transition rates, baseline utility and costs, and mortality were derived directly from what is now called the Parkinson's Precision Medicine Initiative (PPMI).
- In determining transition rates for the model small percentages of patients going from higher to lower HY states annually were dropped.
- No treatments examined have any evidence of slowing progression or impacting mortality.

Model Schematic

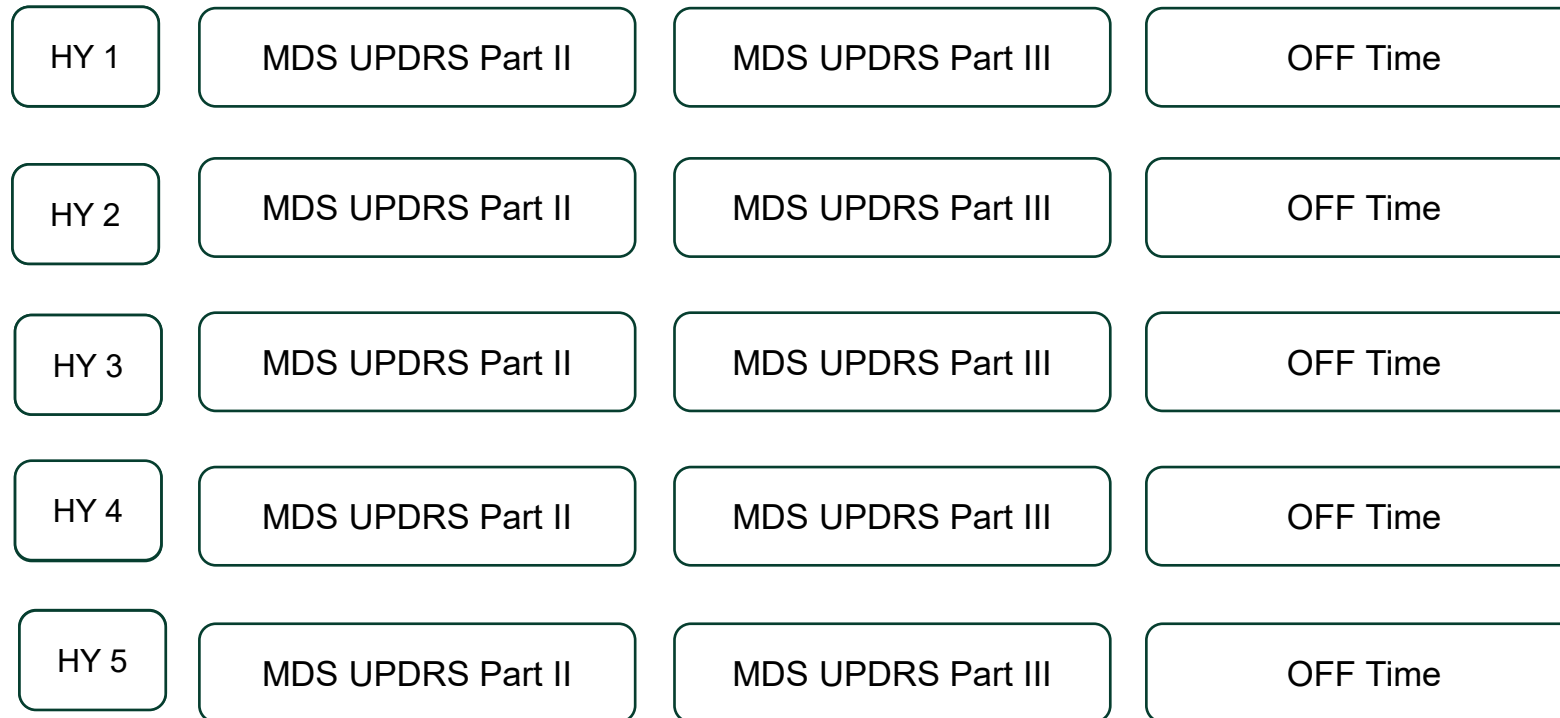
Model Structure Overview – Disease Progression



Note: The circled M (®) indicates entry into the Markovian component of the model. Within this component, patients occupy mutually exclusive health states defined by HY stage and transition between states at each model cycle according to estimated transition probabilities derived from the PPMI cohort. Each health state captures the following parameters: motor severity (MDS-UPDRS Parts II and III), OFF-time burden (proportion of waking day in OFF), health-related quality of life, direct medical costs, informal care partner costs, and adverse event rates and associated disutility and costs.

Model Schematic

Model Structure Overview – Disease Progression



Model Cohort Characteristics—Baseline Severity from the Trials

Baseline Characteristic	Model One (TEMPO-1)	Model Two (TEMPO-3)
Mean Age, Years (SD)	63.7 (9.6)	64.9 (8.4)
Male, %	64.7%	63.3%
Modified HY Stage 1, %	23.7%	0%
Modified HY Stage 2, %	76.3%	66.6%
Modified HY Stage 3, %	N/A	33.4%

Treatment Related Efficacy

Model One – MDS-UPDRS Parts II+III

Treatment	Change from Baseline Parts II	Change from Baseline Parts III	Source
Tavapadon	-1.86 (-2.59, -1.15)	-7.17 (-8.86, -5.46)	NMA
Levodopa (comparator)	-2.67 (-6.92, 1.56)	-6.31 (-8.49, -4.19)	NMA

Model Two – Daily OFF-Time (hours)

Treatment	Change in Total OFF Time Hours	Source
Tavapadon + Levodopa	-0.95 (-1.55, -0.34)	NMA
DA + Levodopa (comparator)	-1.41 (-1.75, -1.06)	NMA

Treatment Costs

Drug	Estimate	Annual Cost Used in Model
Tavapadon	Reported WAC	\$58,800
Carbidopa/Levodopa 25/100 mg (Generic, Model 1 Comparator)	Median generic WAC	~\$289/year
DA Market Basket (Model 2 Comparator)	See breakdown below	~\$3,588/year

Dopamine Agonist Market Basket (Model Two Comparator)

Drug	Market Share	Annual/Net Price	Weighted Annual Cost
Ropinirole HCl (Generic)	51.9%	\$5,945	\$3,085
Pramipexole DiHCl IR (Generic)	41.7%	\$161	\$67
Rotigotine / Neupro Patch	6.4%	\$10,785	\$436†
Weighted Average Annual DA Cost			\$3,588

Market share: Merative MarketScan Medicare Supplemental 2024. Wholesale acquisition cost from RED BOOK. All costs in 2026. Price for Neupro is the net price.

† after applying 36.9% discount

Non-Drug Medical Costs

HY Stage Costs – Model One & Two (Johnson 2013, inflated to 2026 USD)

HY Stage	Annual Health Care Cost
HY 1	\$7,604
HY 2	\$8,021
HY 3	\$35,054
HY 4	\$53,502
HY 5	\$96,063

Source: Johnson SJ, Diener MD, Kaltenboeck A, Birnbaum HG, Siderowf AD. An economic model of Parkinson's disease: Implications for slowing progression in the United States. *Movement Disorders*. 2013 Mar;28(3):319-26.

Inflated using PCE-H price index (BEA Table 2.3.4). ICD costs will be subject to one-way sensitivity analysis given uncertainty in DA-specific prevalence.

OFF Time Costs and Caregiver Burden

- No published evidence available to tie MDS-UPDRS scores to caregiver burden in Model 1.
- In Model 2, caregiver productivity related costs are tied to OFF hours in the societal perspective.
- OFF time is also tied to annual HCP consultation costs and hospitalization costs.

AE Costs

Treatment-Related Adverse Event Costs – Both Models (Song 2023, Francois 2017, inflated to 2026 USD)

Adverse Event	Incremental Cost per 6-Month Cycle (2026 USD)
Dyskinesia	\$5,164
Somnolence	\$7,548
Orthostatic Hypotension	\$6,606
Hallucination	\$13,463
Impulse Control Disorders (ICD)	\$14,505

Sources: Thach 2021 (OFF episode costs); Song 2023 (AE costs, except hypotension); Francois 2017 (hypotension). ICD costs will be subject to one-way sensitivity analysis given uncertainty in DA-specific prevalence.

Utilities

- Baseline utilities are set by HY stage and proportion of waking hour OFF-time (Lowin et al. 2017) ranges from 0.79 to 0.37.
- Model 1 has within-state MDS-UPDRS Part II and III adjustment 0.04 for each reduced Part II and 0.02 for each reduced Part III.
- Model 2 makes treatment related utility adjustments based on OFF-time reductions from the baseline values by HY stage.
- AEs also impact utilities.

Further Analyses

- Standard deterministic and probabilistic sensitivity analyses.
- 10 different scenario analyses were also conducted including assumptions about caregiver utility tied to patient utility, estimates of pill burden, and changing ICD rate projections for tavapadon.



Results

Base Case Results – Model 1

Treatment	Intervention Acquisition Costs	Total Costs	OFF Time (Total Hour)	QALYs	evLYs	Life Years	Cost per QALY Gained	Cost per evLY Gained
Model 1: Health System Perspective								
Levodopa	\$3,200	\$1,056,000	-	6.716	6.716	11.13		
Tavapadon	\$138,000	\$1,183,000	-	6.701	6.701	11.13	More Costly, Less Effective	More Costly, Less Effective
Model 1: Modified Societal Perspective								
Levodopa	\$3,200	\$1,671,000	-	6.716	6.716	11.13		
Tavapadon	\$138,000	\$1,798,000	-	6.701	6.701	11.13	More Costly, Less Effective	More Costly, Less Effective

Base Case Results – Model 2

Treatment	Intervention Acquisition Costs	Total Costs	OFF Time (Total Hour)	QALYs	evLYs	Life Years	Cost per QALY Gained	Cost per evLY Gained
Model 2: Health System Perspective								
Levodopa + DAs	\$17,200	\$1,165,000	7,015	5.467	5.467	9.63		
Levodopa + Tavapadon	\$123,000	\$1,265,000	7,100	5.477	5.477	9.63	\$10,000,000	\$10,000,000
Model 2: Modified Societal Perspective								
Levodopa + DAs	\$17,200	\$2,037,000	7,015	5.467	5.467	9.63		
Levodopa + Tavapadon	\$123,000	\$2,141,000	7,100	5.477	5.477	9.63	\$10,400,000	\$10,400,000

Scenario Analyses: Cost per QALY/evLY Gained

Scenario	Model 1: Tavapadon vs. Levodopa		Model 2: Tavapadon vs. Other DAs	
	Health Care Sector	Modified Societal	Health Care Sector	Modified Societal
Base Case	More Costly, Less Effective	More Costly, Less Effective	\$10,000,000	\$10,400,000
S1. Shorter Time Horizon (2 years)	More Costly, Less Effective	More Costly, Less Effective	More Costly, Less Effective	More Costly, Less Effective
S2. Shorter Time Horizon (10 years)	More Costly, Less Effective	More Costly, Less Effective	\$10,800,000	\$11,200,000
S3. Zero Discontinuation After Cycle 1 for Tavapadon	\$92,100,000	\$92,100,000	\$3,400,000	\$3,200,000
S4. Distribution of MDS-UPDRS Part II/III Scores and OFF-time	More Costly, Less Effective	More Costly, Less Effective	\$10,000,000	\$10,400,000
S5. Excluding Future Unrelated Health Care Costs	More Costly, Less Effective	More Costly, Less Effective	\$10,000,000	\$10,400,000

Cost per QALY gained and cost per evLY gained are identical in both models because no treatment affected survival.

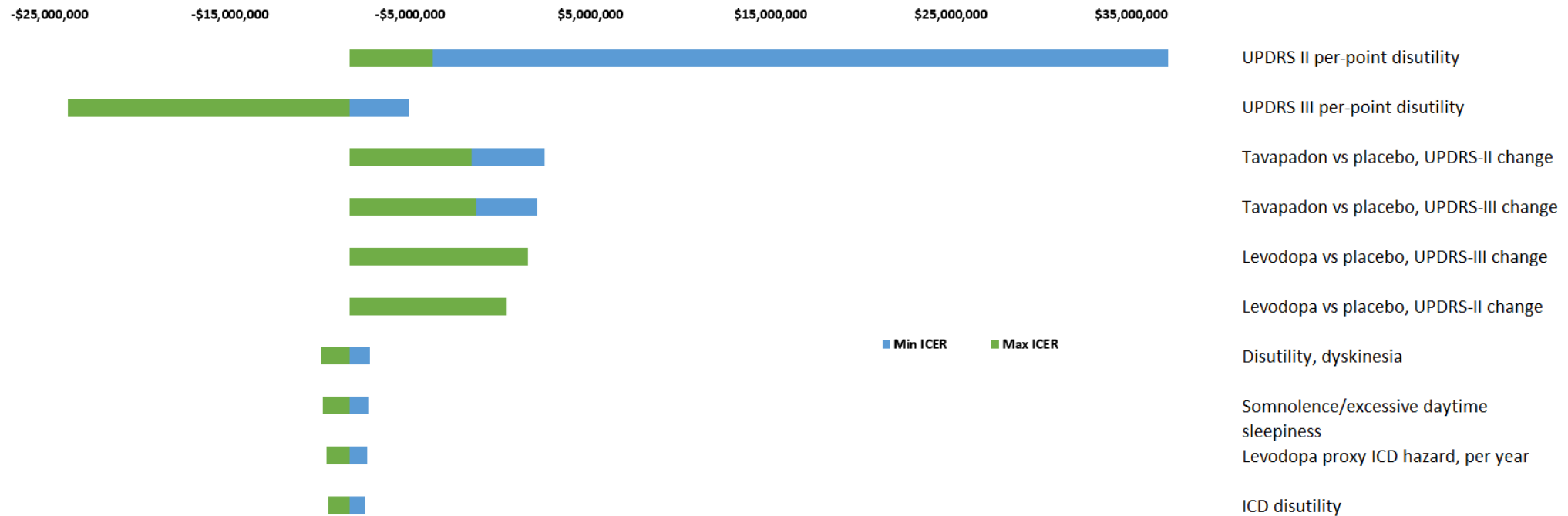
Scenario Analyses: Cost per QALY/evLY Gained (cont.)

Scenario	Model 1: Tavapadon vs. Levodopa		Model 2: Tavapadon vs. Other DAs	
	Health Care Sector	Modified Societal	Health Care Sector	Modified Societal
Base Case	More Costly, Less Effective	More Costly, Less Effective	\$10,000,000	\$10,400,000
S6. No Adverse Events in Tavapadon Group After Cycle 1	More Costly, Less Effective	More Costly, Less Effective	\$4,000,000	\$4,200,000
S7. OFF-time Related Disutility Halved	NA	NA	\$6,300,000	\$6,600,000
S8. 1 Hour per Week Productivity Gain for Patient and Care Partner	NA	More Costly, Less Effective	NA	\$9,400,000
S9. 0.5 QALY Gain for Care Partner per 1 QALY Gained by Patient	NA	NA	NA	\$6,000,000
S10. Tavapadon ICD Rates Increase Over Time as Seen with Other DAs	NA	NA	\$35,100,000	\$36,200,000

Cost per QALY gained and cost per evLY gained are identical in both models because no treatment affected survival.

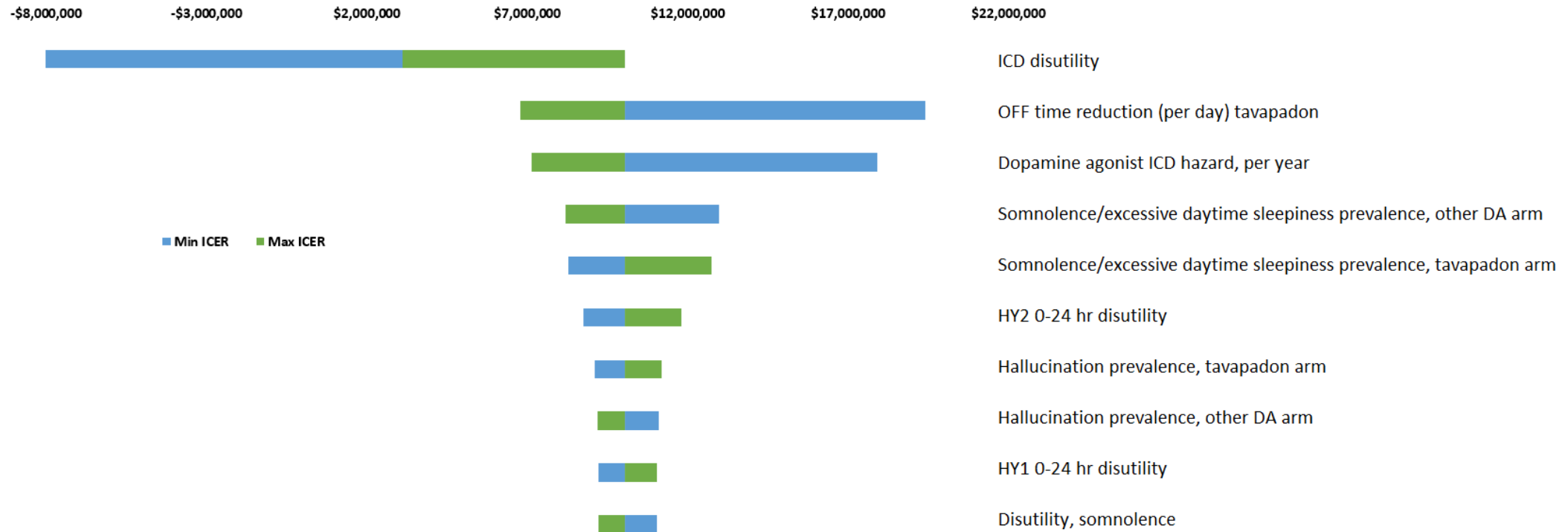
One Way Sensitivity Analyses

Model 1, Health System Perspective



One Way Sensitivity Analyses

Model 2, Health System Perspective



Probabilistic Sensitivity Analysis Results

Percentage of simulations cost-effective at each threshold, cost per evLY gained

	\$50,000 per evLY	\$100,000 per evLY	\$150,000 per evLY	\$200,000 per evLY
Model 1, Health System Perspective	0.0%	0.0%	0.0%	0.4%
Model 1, Modified Societal Perspective	0.0%	0.0%	0.0%	0.4%
Model 2, Health System Perspective	0.0%	0.0%	0.0%	0.0%
Model 2, Modified Societal Perspective	0.0%	0.0%	0.0%	0.0%

Health Benefit Price Benchmarks (HBPBs) for Tavapadon

Intervention	Annual WAC	Annual Price at \$100,000 Threshold	Annual Price at \$150,000 Threshold
Model 1: Tavapadon vs. Levodopa (Early PD)			
Tavapadon, Health Care Sector Perspective	\$58,800	No positive price*	No positive price*
Tavapadon, Modified Societal Perspective	\$58,800	No positive price*	No positive price*
Model 2: Tavapadon vs. Other DAs (PD with Motor Fluctuations)			
Tavapadon, Health Care Sector Perspective	\$58,800	\$6,598	\$6,861
Tavapadon, Modified Societal Perspective	\$58,800	\$4,764	\$5,026

*Tavapadon was more costly and less effective than levodopa, so no positive price reached any threshold.
Threshold prices per evLY gained are identical to those per QALY gained because no treatment affected survival.

Changes Since the Draft Report

Corrections

- Identified a Model 2 switching cost error: higher threshold prices and HBPB; conclusions unchanged
- Societal cost formula: slightly higher Model 2 incremental cost; conclusions unchanged
- Orthostatic hypotension NMA update: small changes in results

Added in Response to Public Comments

- S8: one hour per week productivity gain for patient and care partner
- S9: care partner utility gain set at one-half of patient utility gain
- S10: tavapadon ICD rates increase over time, as seen with other DAs
- Clarifying edits to methods in the report and Supplement, including OFF-time related utility and costs

Limitations

Top Limitations

- Wide, overlapping NMA treatment effect intervals
- No evidence-based mechanism to tie treatment effects to caregiver impacts in Model 1
- Model treatment effects based on short-term trials, no long-term data
- Limited evidence on ICD rates over time

Key Findings

- Model 1: tavapadon more costly and slightly less effective than levodopa
- Model 1: no positive price reaches common cost-effectiveness thresholds
- Model 2: tavapadon more costly and slightly more effective than other DAs
- Model 2: ratios far above common thresholds; threshold prices well below WAC price
- Both models sensitive to changes in effectiveness estimates, but the conclusions were stable across scenarios

Questions?

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Public Comment and Discussion

Steven Bishop, PhD

Individual Living with Parkinson's Disease

Conflicts of Interest:

- *Affiliated with the Michael J. Fox Foundation.*

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Emily Su

Individual Living with Parkinson's Disease

Conflicts of Interest:

- *No conflicts to disclose.*

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Jillian Zivanovic

Care Partner

Conflicts of Interest:

- *Affiliated with the Michael J. Fox Foundation.*

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Lunch

Meeting will resume at 11:45 AM PT





Voting Questions

***Patient Population for all Special
Ethical Priorities Questions:
Patients with Parkinson's disease.***

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Special Ethical Priorities

To help inform judgments of overall long-term value for money, please answer the following questions:



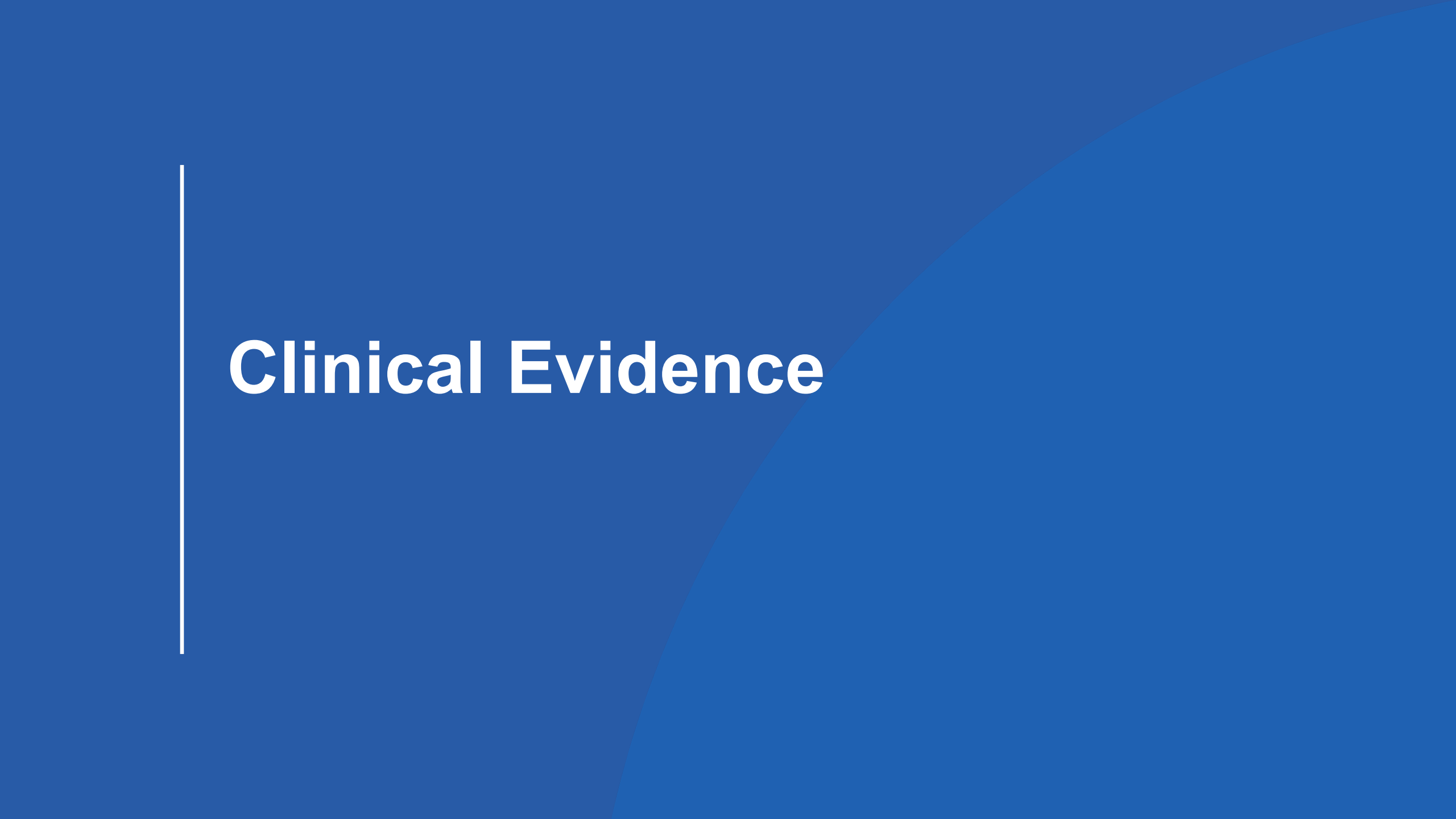
1. Are there particular obligations to people with this condition because of disease severity and/or unmet need with currently available therapies?



2. Are there particular obligations to people with this condition because it disproportionately affects those from a racial/ethnic group that have not been equitably served by the health care system?



3. Apart from issues around disease severity/unmet need and race/ethnicity, are there other particular obligations to people with this condition?



Clinical Evidence

***Patient Population for all
questions: Patients with Early
Parkinson's disease.***



4. Is the current evidence adequate to demonstrate that the net health benefit of tavapadon is greater than that of no additional pharmacological treatment?



5. Is the current evidence adequate to demonstrate that the net health benefit of tavapadon is greater than that of levodopa, dopamine agonists (DAs), or monoamine oxidase-B (MAO-B) inhibitors?

Patient Population for all questions 9-13: Patients on levodopa (and possibly on stable doses of other therapies) experiencing motor fluctuations.



9. Is the current evidence adequate to demonstrate that the net health benefit of tavapadon plus levodopa is greater than that of levodopa alone?



10. Is the current evidence adequate to demonstrate that the net health benefit of tavapadon plus levodopa is greater than that of DAs plus levodopa, MAO-B inhibitors plus levodopa, or catechol-O-methyltransferase (COMT) inhibitors plus levodopa?

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Benefits Beyond Health

***Patient Population for all
benefits beyond health
questions: Patients with
Parkinson's disease.***

To help inform judgments of overall long-term value for money, please answer the following questions about tavapadon when compared to levodopa, DAs, or MAO-B inhibitors



14. Is tavapadon likely to improve caregivers' quality of life and/or ability to pursue their own education, work, and family life?



15. If payment/cost were not an issue, would tavapadon be likely to improve access to treatment because of its method of delivery and/or treatment setting?

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Long-Term Value for Money

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



16. What is the long-term value for money of tavapadon compared to levodopa for patients with early Parkinson's disease?

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



17. What is the long-term value for money of tavapadon plus levodopa compared to DAs plus levodopa for patients experiencing motor fluctuations?

Break

Meeting will resume at 1:00 PM PT





Policy Roundtable

Policy Roundtable

Participant	Conflict of Interest
Victoria (Vicky) Brown, PharmD, BCOP Associate Vice President of Clinical Drug Strategies, Humana Pharmacy Solutions	Vicky Brown is a full-time employee of Humana Pharmacy Solutions.
Rebecca Gilbert, MD Neurologist and Movement Disorders Specialist, Bellevue Hospital Center, NY Chief Mission Officer, American Parkinson Disease Association	Rebecca Gilbert is a full-time employee of the American Parkinson Disease Association (APDA). The APDA receives less than 5% of financial support from health care companies. The APDA public comment letter on the Draft Evidence Report was written after joint conversation with the Michael J. Fox Foundation, Parkinson's Foundation, Davis Phinney Foundation, and PMD Alliance.
Catherine (Katie) Kopil, PhD SVP, Head of Clinical Research, Michael J. Fox Foundation	Katie Kopil is a full-time employee of the Michael J. Fox Foundation (MJFF). MJFF receives less than 1% of its annual funding from health care companies. MJFF has engaged Katharina Klapper of Katharina Klapper Consulting GmbH to support its preparation for the ICER public meeting. Katharina is a former MJFF staff member who now consults for the Foundation. Dr. Kopil's spouse is a salaried Managing Director at L.E.K. Consulting, a strategy consulting firm with significant business in the biopharmaceutical sector. Dr. Kopil does not have visibility into L.E.K.'s client relationships, and AbbVie or other manufacturers active in Parkinson's Disease may be among the firm's clients.
William (Bill) Ryan Volunteer Board Member, Wisconsin Chapter, American Parkinson Disease Association	No conflicts to disclose.
Marina Sehman, PharmD, CSP Director, Clinical Pharmacy, IPD Analytics	Marina Sehman is a full-time employee of IPD Analytics.
Katherine Wong, MD Assistant Professor of Neurology, University of Southern California	No conflicts to disclose.

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CTAF Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around November 2nd, 2026
 - Includes description of CTAF votes, deliberation, policy roundtable discussion
- Materials available at: <https://icer.org/assessment/parkinsons-disease-2026/#overview>

Adjourn

