INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Tavapadon for Parkinson's Disease: Final Policy Recommendations

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Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the October 1, 2026, California Technology Assessment Forum (CTAF) public meeting on the use of tavapadon for the treatment of Parkinson's Disease. At the meeting, ICER presented the findings of its revised report on these treatments and the CTAF voting council deliberated on key questions related to their comparative clinical effectiveness, benefits beyond health and special ethical priorities, and long-term value for money at current prices. Following the votes, ICER convened a Policy Roundtable of two patient representatives, two clinical experts, and two individuals from the payer perspective to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Sarah K. Emond, President and Chief Executive Officer at ICER.

Current Context for Parkinson's Disease Treatment

Patients with Parkinson's disease find themselves in a challenging treatment environment in need of innovation: significant unmet patient need as well as care partner burden, no disease-modifying treatments available, and no notable improvements in symptomatic treatment over many years. There was understandable interest in tavapadon as an effective and possibly safer symptomatic therapy, but current evidence raises more questions than answers, and announced pricing far exceeds not only ICER's benchmarks but previous analyst estimates. This puts further pressure on already overstretched health care system for coverage of a drug that has not clearly demonstrated how it benefits patients.

These concerns and others were raised during the roundtable discussion and are organized by audience below.

Health Equity

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that patients with Parkinson's disease have equitable access to clinicians with expertise in Parkinson's disease and movement disorders.

Fewer than 10% of patients with Parkinson's disease are treated by a Movement Disorder Specialist. Given the complexity of Parkinson's disease management, including optimization of medication dose and timing to maximize ON time, minimize OFF time, and address non-motor symptoms and treatment-related adverse effects, access to clinicians with expertise in Parkinson's disease is an important component of high-quality care.

Several strategies could increase access to specialized care while recognizing the limited supply of Movement Disorder Specialists, many of which are also noted in a recent Duke-Margolis white paper on the topic.[1]

- **Increase the number of Movement Disorders fellowship positions.** Patient organizations, including the Michael J. Fox Foundation,[2] already support some fellowship positions, but additional national funding and grants are necessary to grow the specialist workforce for Parkinson's management.
- **Restructure care delivery to make greater use of advanced practice providers (APPs).** APPs can provide routine follow-up, medication assessment, and monitoring, with Movement Disorder Specialists engaged when more complex management questions or treatment conundrums arise.
- **Expand telemedicine for Parkinson's disease care.** Telemedicine should be used to support clinicians and patients in rural or otherwise underserved communities where Movement Disorder Specialists are not readily available.
- **Expand opportunities for shared medical visits, either in person or through telemedicine.** Group visits can provide peer support while also allowing individualized treatment-plan updates to be developed during one-on-one meetings with a specialist.

Recommendation 2

All stakeholders should work to reduce disparities in the recognition and diagnosis of Parkinson's disease among Black, Hispanic, and female patients.

There is evidence of substantial underdiagnosis of Parkinson's disease and access to specialists among Black, Hispanic, and female patients, which may contribute to delays in diagnosis,

undertreatment, and poorer outcomes. Increasing awareness of the early signs and symptoms of Parkinson's disease among primary care clinicians should therefore be a priority.

- Clinical specialty societies and public health organizations should develop and disseminate educational materials for primary care physicians on the early symptoms and presentation of Parkinson's disease.
- These efforts should complement the goals of the federally funded **National Plan to End Parkinson's**, which includes increasing awareness and improving earlier recognition of Parkinson's disease.[3]

Payers

Given the significant uncertainty that remains about the longer-term safety and effectiveness of tavapadon for Parkinson's disease and its high cost relative to its limited clinical value, it is reasonable for payers to use prior authorization as a component of coverage. Prior authorization criteria should be based on clinical evidence and input from clinical experts and patient groups. The process for authorization should also be clear, accessible, efficient, and timely for providers. Perspectives on specific elements of cost sharing and coverage criteria within insurance coverage policy are discussed below. Relevant Fair Access Design Criteria set out in ICER's previous work are included.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy in the report: Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals

Recommendation 1

Payers could reasonably limit coverage to patients whose clinical characteristics are consistent with those studied in the pivotal clinical trials.

Using the populations represented in the pivotal TEMPO trials as a guide for clinical eligibility is a reasonable approach (although we note that this approach may not be feasible for Medicare Part D plans, which are required to align coverage with FDA labeling and/or CMS-approved compendia). Specifically:

Early Parkinson's disease: Patients should meet the following characteristics:

- Age 40-80 years.
- No prior deep-brain stimulation surgery.

- Low risk of suicide.

Patients with Parkinson's disease receiving levodopa and experiencing motor fluctuations: Patients should meet the following characteristics:

- Age 40-80 years.
- At least 2.5 hours of OFF time per day.

Recommendation 2

Step therapy is reasonable, but the requirements should reflect the treatment pathways evaluated in the pivotal trials and should not impose unnecessary treatment burden.

For **early Parkinson's disease**, payers could require two steps:

1. A trial of levodopa.
2. A trial of at least one first-generation dopamine agonist.*

For **patients receiving levodopa who are experiencing motor fluctuations**, payers could require:

1. A trial of at least one first-generation dopamine agonist; and
2. A trial of at least one additional agent, such as sustained-release levodopa (e.g., Crexont), a catechol-O-methyltransferase (COMT) inhibitor, or a monoamine oxidase B (MAO-B) inhibitor.*

*Some payers may allow bypassing of this step if prescribers can provide sufficient clinical evidence that a patient is at high risk for adverse reactions with D2/D3 dopamine agonist therapy (e.g., neuropsychiatric vulnerability, age/frailty, autonomic/sleep risk).

Recommendation 3

It is reasonable for payers to limit prescribing to neurologists, although a Movement Disorder Specialist should not be required, given the limited availability of these subspecialists.

Restricting initial prescribing to neurologists may help ensure appropriate diagnosis, treatment selection, and monitoring while avoiding an access barrier that would result from requiring all patients to be evaluated by a Movement Disorder Specialist. We do note, however, that this approach may not be feasible for Medicare Part D plans, who are required to align coverage with FDA labeling and/or CMS-approved compendia.

Recommendation 4

Payers should require annual attestation of continued clinical benefit for renewal of coverage.

Annual reassessment should focus on whether the patient is experiencing meaningful clinical benefit from continued treatment and should avoid administrative requirements that do not contribute to an assessment of treatment effectiveness.

Manufacturers

Recommendation 1

Manufacturers should set prices that will foster affordability and good access for all patients by aligning prices with the patient-centered therapeutic value of their treatments.

Drug prices that are set well beyond the cost-effective range cause not only financial toxicity for patients and families using the treatments but also contribute to general health care cost growth that pushes families out of the insurance pool, and that causes others to ration their own care in ways that can be harmful.

Manufacturers should therefore price novel treatments in accordance with the demonstrated benefits to patients. In settings of substantial uncertainty, initial pricing should err on the side of being more affordable. This would allow more patients access, generating additional data on the real-world effectiveness of novel treatments that could be used in future assessment updates.

In this case, the launch price for tavapadon is far out of line with the available evidence on its clinical value, exceeding even industry analyst estimates by a factor of four. The manufacturer should substantially lower its price until additional data clearly demonstrate a significant benefit over currently available alternative therapies.

Recommendation 2

Clinical trials of Parkinson's disease therapies should incorporate patient- and caregiver-centered outcomes and should engage patients in the design of trials from the outset.

Trials should include outcomes that capture dimensions of disease and treatment burden that may not be fully represented by conventional clinical measures. Potential outcomes include patient independence, gait instability, falls, fractures, predictability of OFF time, and hours per week of caregiver time.

Recommendation 3

Researchers should conduct subgroup analyses and biomarker and pharmacogenetic studies to identify patients most likely to respond to tavapadon, with particular attention to identifying patients who may achieve benefit with fewer adverse events.

Better identification of patients who are most likely to benefit from tavapadon could improve treatment selection and reduce exposure to ineffective or poorly tolerated therapy.

Research Needs

Recommendation 1

For patients with early Parkinson's disease, manufacturers and research funders should support head-to-head trials of tavapadon compared with levodopa. Similarly, for patients with Parkinson's disease receiving levodopa who experience motor fluctuations, manufacturers and research funders should support head-to-head trials of tavapadon compared with other once-daily dopamine agonists.

The absence of direct comparative evidence of tavapadon with the standard medications used in a population leaves important uncertainty regarding the relative benefits, harms, and value of tavapadon for Parkinson's disease. Head-to-head evidence would better inform decisions by patients, clinicians, and payers. For example, direct comparative evidence would clarify whether tavapadon provides clinically meaningful advantages over established once-daily dopamine agonists with respect to motor symptoms, OFF time, and important adverse effects such as impulse control disorders and orthostatic hypotension.

Recommendation 2

Researchers should develop and validate earlier diagnostic tools for Parkinson's disease based on wearable technologies, including smart watches and related devices, and should evaluate the potential role of artificial intelligence in identifying patients with early Parkinson's disease.

More accessible and objective methods for identifying early Parkinson's disease could improve the timeliness of diagnosis and facilitate earlier treatment and enrollment in clinical trials. Validation should include evaluation of accuracy across diverse patient populations to avoid exacerbating existing disparities in diagnosis.

Recommendation 3

Researchers and clinical trial sponsors should work toward greater agreement on minimally clinically important differences (MCIDs) for commonly used Parkinson's disease outcomes, including MDS-UPDRS subscales, and clinical trials should report the proportion of patients achieving an MCID in addition to mean changes from baseline.

Mean changes in clinical trial outcomes do not necessarily demonstrate how many individual patients experience a meaningful benefit. Reporting the proportion of patients achieving a clinically meaningful improvement would provide information that is more directly interpretable for patients

and clinicians. Where appropriate, MCIDs should be defined separately according to the severity of Parkinson's disease.

References

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2. Michael JFFfPsR. The Edmond J. Safra Fellowship in Movement Disorders. *The Michael J Fox Foundation for Parkinson's Research*.
3. National Institute of Neurological D, Stroke. National Plan to End Parkinson's. *National Institute of Neurological Disorders and Stroke*. 2026/08/25 2026;

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the October 1, 2026 Public meeting of CTAF.

Appendix Table 1. ICER Staff and External Collaborators Conflict of Interest Disclosures

ICER Authors and External Collaborators	Conflict of Interest
Shahariar Mohammed Fahim, PhD, Senior Research Lead, Institute for Clinical and Economic Review	Dr. Fahim has no conflicts to disclose.
Woojung Lee, PharmD, PhD, Associate Director of Health Economics and Decision Modeling, Institute for Clinical and Economic Review	Dr. Lee has no conflicts to disclose.
Daniel A. Ollendorf, PhD, MPH, Chief Scientific Officer and Director of HTA Methods and Engagement, Institute for Clinical and Economic Review	Dr. Ollendorf has no conflicts to disclose.
Marie Phillips, BA, Health Economics Research Assistant, Institute for Clinical and Economic Review	Marie Phillips has no conflicts to disclose.
Jyotirmoy Sarker, PhD, MPharm, MBiotech, Research Assistant Professor, School of Pharmacy, University of Mississippi	Dr. Sarker received salary in the past 36 months from AbbVie not related to this work.
Jeffrey A. Tice, MD, Professor of Medicine, University of California, San Francisco	Dr. Tice has no conflicts to disclose.
Surrey Walton, PhD, MA, Professor, College of Pharmacy-Pharmacy Systems Outcomes and Policy; Assistant Director, Center for Pharmacoepidemiology and Pharmacoeconomics, University of Illinois Chicago	Dr. Walton has no conflicts to disclose**.**
Aaron Winn, PhD, MPP, Associate Professor, University of Illinois Chicago	Dr. Winn is the director of a fellowship in partnership with AbbVie.

Appendix Table 2. CTAF Panel Member Participants Conflict of Interest Disclosures

CTAF Member	Conflict of Interest
Felicia Cohn, PhD Bioethics Director, Kaiser Permanente Orange County	No conflicts to disclose.
Bob Collyar Patient Advocate, Patient Advocates In Research Co-Founder, Clinical Trials Information Project	No conflicts to disclose.
Sanket Dhruva, MD, MHS Associate Professor of Medicine, UCSF School of Medicine	No conflicts to disclose.
Rena Fox, MD Professor of Medicine, UCSF	No conflicts to disclose.
Jeff Klingman, MD Neurologist, Kaiser Permanente, Walnut Creek	No conflicts to disclose.
Annette Langer-Gould, MD, PhD	No conflicts to disclose.

Regional Lead for Clinical and Translational Neuroscience, Southern California Permanente Medical Group, Kaiser Permanente Professor, Kaiser Permanente School of Medicine Practicing Multiple Sclerosis (MS) Specialist, Los Angeles Medical Center	
Sei Lee, MD Professor of Medicine, UCSF, Division of Geriatrics	No conflicts to disclose.
Joy Melnikow, MD, MPH Professor of Family and Community Medicine, UC Davis	No conflicts to disclose.
Elizabeth (Lisa) Murphy, MD, DPhil Professor of Medicine, UCSF Chief, Division of Endocrinology, San Francisco General Hospital	No conflicts to disclose.
Kavita V. Nair, PhD Professor of Neurology and Pharmacy, CU Skaggs School of Pharmacy & Pharmaceutical Sciences, Anschutz Medical Campus	No conflicts to disclose.
Ann Raldow, MD, MPH Associate Professor, Department of Radiation Oncology, David Geffen School of Medicine, UCLA	No conflicts to disclose.
Rita Redberg, MD, MSc, FACC Professor of Medicine, UCSF	No conflicts to disclose.
Tony Sowry Patient Advocate and Lead Volunteer, California, National Patient Advocate Foundation	No conflicts to disclose.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

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.
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. Katie's spouse is a salaried Managing Director at L.E.K. Consulting, a strategy consulting firm with significant business in the biopharmaceutical sector. Katie 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	No conflicts to disclose.

Volunteer Board Member, Wisconsin Chapter, American Parkinson Disease Association	
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.