Parkinson's Disease 2026

ICER SNAPSHOT

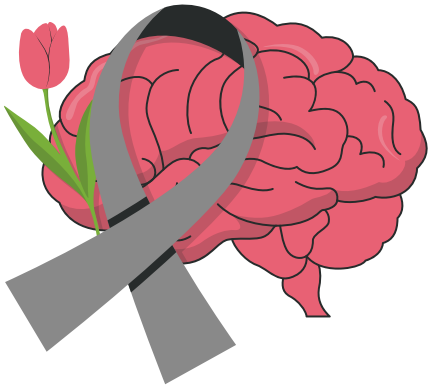
This document's language and design were revised with assistance from Claude (Opus 5.5), an AI assistant created by Anthropic.

The ICER Snapshot is a summary designed to help the Parkinson's disease patient community learn about the key results and recommendations from ICER's 2026 Final Evidence Report on tavapadon for Parkinson's disease.

The information included is up to date as of November 2, 2026. New information about these treatments may become available, but is not captured here.

Let's Take a Look

What is Parkinson's Disease?
Impact on Patients and Families
Treatment & Clinical Trial Results
How Did ICER Calculate a Fair Price?
Policy Recommendations
Impact of Patient Engagement



What is Parkinson's Disease?

Parkinson's disease (PD) is a **neurodegenerative disorder** (when the nerve cells in the brain slowly stop working and die over time). PD causes **stiffness, slow movement, shaking (tremor), and balance problems.** It can also cause **non-motor symptoms** (problems not related to movement) such as trouble thinking clearly, depression, anxiety, and poor sleep. About **1.2 million** people in the United States (US) live with PD or a similar condition called atypical Parkinsonism. PD is more common in men than in women, and more common in non-Hispanic White people.

PD is also costly. In 2024, it cost the US about **$82 billion a year:**

$24 billion	$26 billion	$32 billion
Medical Care	Lost work & unpaid family caregiving	Other costs, such as out-of-pocket expenses & disability payments

Costs rise as PD progresses — especially once patients develop movement complications, memory or thinking problems, or need nursing home care.

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Levodopa is currently the best treatment for controlling PD symptoms, but over time its effects can **wear off too soon between doses,** so most patients end up taking it several times a day. It can also cause jerky, uncontrolled movements (dyskinesias), which often lead patients to add other drugs to help control them.

Other treatment options, like **dopamine agonists** are also used for early PD or in addition to levodopa for patients with motor fluctuations, but can cause sleepiness, blood pressure drops, hallucinations, dyskenisas and other motor fluctuations. Additional add-on options include **monoamine oxidase-B (MAO-B) inhibitors** and **catechol-O-methyltransferase (COMT) inhibitors.**

Glossary of Key Clinical Terms

Adjunct A treatment that is added to a person's main treatment to help it work better. It isn't meant to be used on its own.	**Comparator** A comparator is the treatment or standard of care that a new drug is tested against to see if it works better.
COMT inhibitor A medication that blocks the enzyme that breaks down levodopa, helping it last longer in the body.	**Dopamine agonist** A medication that mimics dopamine, a brain chemical involved in movement control.
Dyskinesia Involuntary, uncontrolled muscle movements that can occur as a side effect of long-term levodopa use.	**Hallucinations** Seeing, hearing, or sensing something that isn't really there.
Impulse control disorder (ICD) A side effect of some PD medications causing urges like gambling, overeating, or compulsive shopping that are hard to control.	**Levodopa** The most effective medication for PD motor symptoms; the body converts it into dopamine.
MAO-B inhibitor A medication that blocks the enzyme that breaks down dopamine, helping more of it stay active in the brain.	**Monotherapies** Treating a condition with just one medicine or one type of treatment, rather than several at the same time.
Motor fluctuations When movement symptoms like stiffness, slowness or tremor get better and worse as each dose of levodopa kicks in and wears off.	**Non-motor symptom** A PD symptom that isn't related to movement, such as trouble sleeping, depression, anxiety, or changes in thinking.
ON time / OFF time "ON" = medication is working and symptoms are controlled. "OFF" = medication has worn off and symptoms return.	**UPDRS / MDS-UPDRS** A standard rating scale doctors use to measure how PD affects movement and daily activities; a lower score is better.

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Impact on Patients and Families

What ICER Learned from the Community

PATIENTS

Patients want treatments that control their symptoms more consistently. They also want **easier access to trustworthy information about new treatments**. Right now, many rely on peer support groups or word of mouth.

Not knowing when medicine will be working ("ON" time) or not working ("OFF" time) makes daily life hard to plan. **Even small changes in how well someone can move impact independent function**, like tying their shoes or walking safely.

Patients often call levodopa a "blessing and a curse". It's essential for controlling symptoms, but it requires constant dose changes, exact timing, and the "ON" time shortens while the disease progresses.





CARE PARTNERS

Care partners want **new treatments judged** not only by how much they help those living with PD, but also **by how much they ease the burden on care partners**.

Caregiving duties grow over the years including managing medicines, helping with movement, coordinating care, and planning finances. Care partners often say it **feels like "a second full-time job."**

As PD progresses, **non-motor symptoms** like memory and thinking problems, hallucinations, and depression or anxiety become **just as hard to manage as movement symptoms**.

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Treatment of Focus

TAVAPADON (JUVMO™)

ONCE DAILY PILL
Made by AbbVie

FDA Status: Approved

September 25, 2026

Indication: Treatment of motor symptoms in adults with Parkinson's disease (as a monotherapy or alongside levodopa)

Tavapadon works on the brain differently than current treatment options by targeting different dopamine receptors.

D1 **D5** vs. **D2** **D3** **D4**

Tavapadon targets

Older dopamine agonists target

Patient Populations & Comparators

For this review, ICER compared how well tavapadon worked in two different patient populations against several different comparators:

1 Early-stage PD

Tavapadon **on its own**

COMPARED TO

1. **Placebo***
2. **Levodopa**
3. **Dopamine agonists**
4. **MAO-B inhibitors**

2 PD with Motor Fluctuations

Tavapadon **added to levodopa**

COMPARED TO

1. **Levodopa alone**
2. **Dopamine agonists**
3. **MAO-B inhibitors**
4. **COMT inhibitors**

*Placebo: an inactive treatment intended to hide whether a patient received the studied drug.

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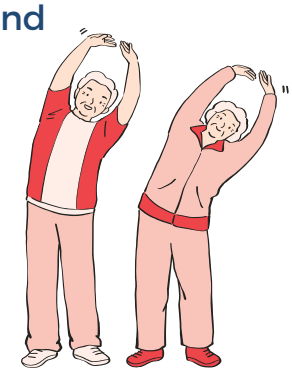
Clinical Trial Results & Overview

Population 1: Early Stage PD - tavapadon on its own

Key Clinical Trials: TEMPO-1 and TEMPO-2

Did tavapadon improve movement & daily activity scores (UPDRS)? Yes

Yes, tavapadon showed clear improvement vs. placebo in TEMPO-1 and TEMPO-2. It wasn't tested head-to-head against other PD medicines, and when we compared it with data from older PD medicines (indirect comparison), it showed no consistent benefits.



Did tavapadon improve quality of life? Only Slightly

Tavapadon showed a small improvement in quality of life vs. placebo. There was no data to answer this question for tavapadon vs. other PD medicines.

Population 2: PD with Motor Fluctuations - tavapadon added to levodopa

Key Clinical Trial: TEMPO-3

Did tavapadon improve ON and OFF time? Yes vs. levodopa alone

Yes, tavapadon resulted in less OFF time and more ON time than levodopa alone (TEMPO-3). It wasn't tested directly (head-to-head trials) against other add-on PD medicines, and when we compared it with data from those medicines (indirect comparison), it showed no clear difference.

Did tavapadon improve movement & daily activity scores (UPDRS)? Yes vs. levodopa alone

Yes, tavapadon showed improvement vs. levodopa alone in TEMPO-3. There was no data directly comparing tavapadon to other add-on medicines. When we compared it to data from add-on medicines (indirect comparison), tavapadon showed no difference vs. other add-on medicines.

Did tavapadon improve quality of life? No

Tavapadon showed no difference in quality of life vs. placebo in TEMPO-3. There was no data directly comparing tavapadon to other add-on medicines. When we compared it to data from add-on medicines (indirect comparison), tavapadon showed no difference vs. other add-on medicines.



*All TEMPO trials used MDS-UPDRS and data were converted to UPDRS scale for analyses purpose

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Safety

More people discontinued (stopped taking) tavapadon compared to placebo in all three TEMPO trials mainly due to side effects.

tavapadon
placebo

TEMPO-1
29% vs. **15%**
discontinuation

TEMPO-2
38% vs. **15%**
discontinuation

TEMPO-3
37% vs. **19%**
discontinuation

Side effects in all three TEMPO trials:

- **Hallucinations:** 31 people (4.1%) with tavapadon vs. 3 people (<1%) with placebo
- **ICDs:** 11 people (1.5%) with tavapadon vs. 3 people (<1%) with placebo but none were severe
- **Orthostatic hypotension** (a form of low blood pressure that happens when standing up from a sitting or lying position): 42 people (5.6%) with tavapadon vs. 6 people (1%) with placebo

What We Still Don't Know

- **Results of a direct comparison:** Tavapadon was only compared with other PD medicines indirectly, so we can't be sure the differences found would remain in a direct comparison.

- **Side effect profile:** More people stopped taking tavapadon compared to placebo because of side effects. We don't have long-term data past 27 weeks to know how side effects may change over time and how it impacts treatment adherence.

- **Risk of ICDs:** A lower risk of ICDs (hard-to-control urges, like gambling) was expected to be a key advantage over older dopamine agonists, but the data so far don't show a clear benefit. We also don't know how many more people may develop ICDs over time. Early results from the TEMPO-4 trial suggest new cases may level off, but more follow-up is needed.

- **Benefit big enough to matter?** Experts disagree on what level of improvement in function or reduction in OFF time is meaningful for patients, so it's unclear if some results make a real difference in daily life for patients.

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Clinical Conclusions

For both populations, the three TEMPO trials provide direct comparisons between tavapadon and placebo, so the level of certainty is moderate to high. The evidence comparing tavapadon with other drugs, either on its own or as an add-on, are indirect, so there is greater uncertainty.

For early-stage PD

C++

Given the mix of benefits and harms and the lack of follow-up beyond six months for the primary outcomes, we found **tavapadon** works **at least as well and possibly somewhat better (C+) than placebo**.

P/I

Compared to other monotherapies (i.e., levodopa, dopamine agonists, MAO-B inhibitors), **tavapadon** showed some promise but we don't have enough evidence to show it actually works better. Therefore, it is **"promising, but inconclusive" (P/I).**

For patients on levodopa experiencing motor fluctuations

C++

For similar reasons, **tavapadon added to levodopa** works **at least as well and possibly somewhat better (C+)** than levodopa alone.

P/I

Compared to other add-on therapies (i.e., dopamine agonists, MAO-B inhibitors, and COMT inhibitors), **tavapadon added to levodopa** showed some promise, but we don't have enough evidence to show it actually works better. Therefore, it is **"promising, but inconclusive" (P/I).**

ICER's report findings are not treatment advice. Patients and families should always talk with their doctors to make shared decisions about treatment for Parkinson's disease.

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How Did ICER Calculate Fair Prices?

Model 1: Early PD

Comparing tavapadon to levodopa

Population

Men and women ages 40 to 80 diagnosed with PD within the past 3 years and not yet started any PD medication.

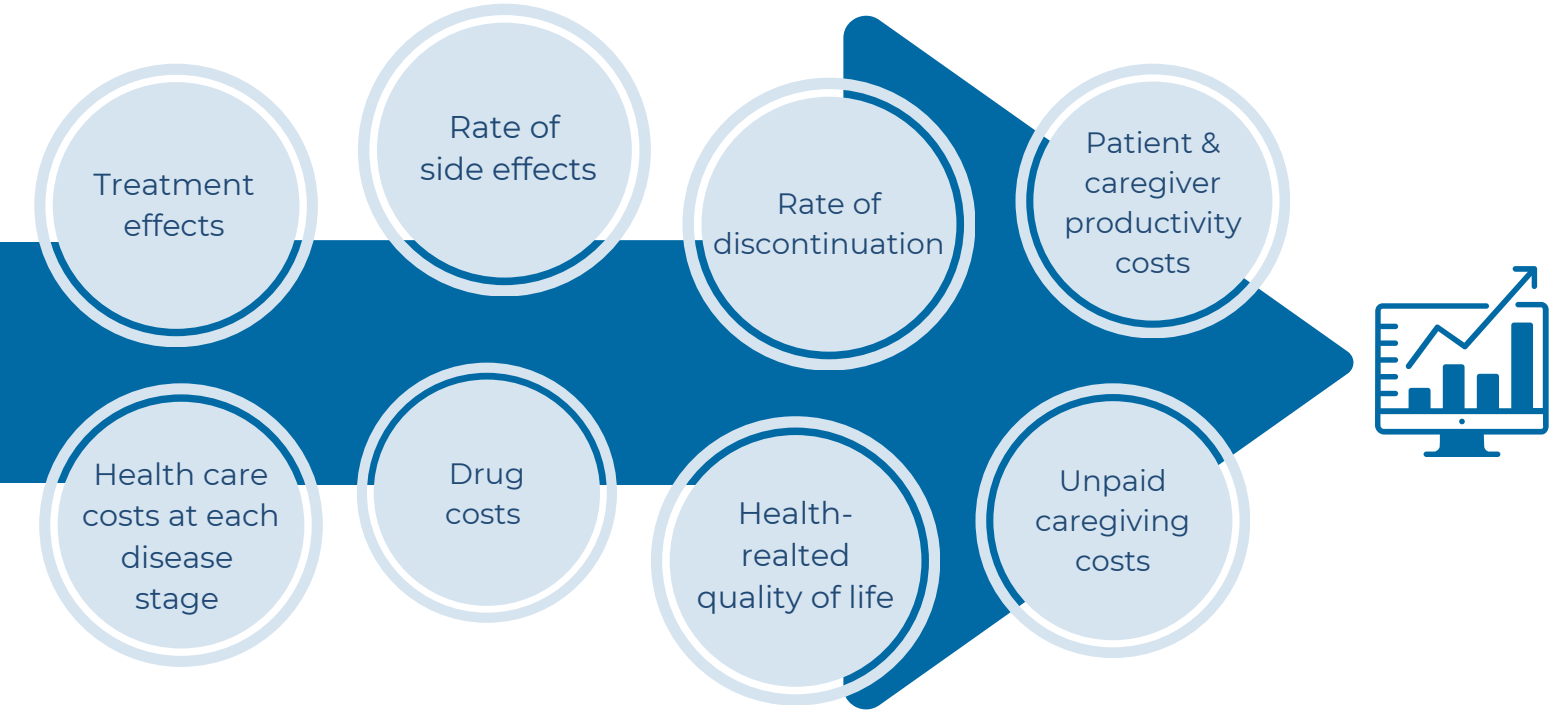
Model 2: PD with Motor Fluctuations

Comparing tavapadon plus levodopa to other dopamine agonists plus levodopa

Population

Men and women ages 40 to 80 with more established PD who were already taking levodopa but still experiencing at least 2.5 hours of "OFF" time each day.

Factors Included in ICER's Economic Analysis



Fair Price Range for Tavapadon

A fair price is how much a treatment should cost based on how well it works for patients.

For the **early PD population (Model 1),** we did not find that tavapadon helps patients more than other available treatments, and therefore was not cost effective at any price.

For the population of **PD with motor fluctuations (Model 2),** we found that tavapadon would be cost effective at an annual price between $4,764 - $6,861.

Model 1:
No price would make tavapadon cost effective

Model 2:
$4,764 - $6,861 per year

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Key Policy Recommendations

The Policy Roundtable at the ICER public meeting included a patient living with PD and a patient advocacy group representative whose contributions informed several policy recommendations for pricing, access, guidelines, and future research in PD. A few key recommendations are summarized below.

1

All stakeholders have a responsibility to ensure that patients with PD have equitable access to specialized clinicians.

HEALTH EQUITY



Fewer than 10% of patients with PD are treated by a Movement Disorder Specialist. Given the complexity of PD management, access to clinicians with expertise in PD is an important component of high-quality care. Strategies to increase access to specialized care include increasing the number of Movement Disorders fellowship positions, restructuring care delivery, expanding telemedicine, and offering group medical visits.

2

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

HEALTH EQUITY

There is evidence of substantial underdiagnosis of PD and access to specialists among these populations, which may contribute to delays in diagnosis, undertreatment, and poorer outcomes. Increasing awareness of the early signs and symptoms of PD among primary care clinicians should therefore be a priority.



3

Clinical trials of PD therapies should incorporate patient- and caregiver-centered outcomes and should engage patients in clinical trial design.

RESEARCH NEEDS

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



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4

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.

FAIR PRICING

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



Impact of Patient Engagement

A patient group shared a **recent report about the economic burdens of PD.** This report underscored the financial impact of PD on individuals, care partners, and the medical system. The data in this report **helped inform ICER's background section.**

The patient community pointed us to a helpful study called the Parkinson's **Precision Medicine Initiative (PPMI)**. This dataset **directly informed ICER's economic model** of how PD progresses over time, what patients typically experience at each disease stage, and more.

Through patient group discussions and public comments, we learned that the **greatest burdens of PD** are the loss of motor function and unpredictable symptom control, **both of which were highlighted in ICER's report.**

The Institute for Clinical and Economic Review (ICER) is an independent nonprofit organization that does research on how well new treatments work and what a fair price should be. Patients and families should always talk with their doctor to make shared decisions about the best treatment option for them.

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