



Oveporexton for Narcolepsy: 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 May 14, 2026 Midwest Comparative Effectiveness Public Advisory Council (CEPAC) public meeting on the use of ovesporexton for the treatment of narcolepsy type 1 (NT1). At the meeting, ICER presented the findings of its revised report on ovesporexton, and the Midwest CEPAC voting council deliberated on key questions related to their comparative clinical effectiveness, benefits beyond health, and special ethical priorities. Following the votes, ICER convened a Policy Roundtable of two patient representatives, two clinical experts, two payers, and one representative from a pharmaceutical manufacturer 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 ovesporexton, which includes the same policy recommendations, can be found [here](#).

The roundtable discussion was facilitated by Sarah Emond, President and Chief Executive Officer at ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

Health Equity

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that effective new treatment options for patients with narcolepsy type 1 (NT1) are introduced in a way that will help reduce health inequities.

Although current therapies for NT1 treat symptoms such as excessive daytime sleepiness (EDS) and cataplexy, the majority of persons living with NT1 are not satisfied with their current treatment.¹ Clinical experts and patient representatives highlighted that the approval of ovesporexton would shift the paradigm of treatment for NT1, as it would be the first therapy aimed directly at the underlying orexin deficiency characteristic of the disorder. However, efforts are needed to ensure that new therapies for NT1 such as ovesporexton improve the health of patients and families and do not aggravate existing health inequities. For example, the high cost of new therapies may worsen

disparities in accessing care. This may be due to a lack of health insurance that limits access to specialists and the new therapies that they may prescribe, or high-deductible health insurance plans that can result in steep out of pocket costs, rendering treatments unaffordable. This is particularly relevant for persons living with NT1, as they may not be able to hold full-time employment due to the severity of their symptoms. Furthermore, the cost of care is not the only factor that may contribute to health inequities. Our clinical and patient experts noted that diagnosis can be severely delayed due to under-recognition of symptoms related to NT1, and that those with poor access to care may be particularly vulnerable to missed or delayed diagnosis.

To address these concerns:

Manufacturer actions:

- Set the price for new treatments for NT1 in fair alignment with added benefits for patients. This is particularly important for first-in-class medications that may shift the treatment paradigm – setting prices in line with value can broaden and expedite access.
- Take steps necessary to expeditiously test ovesporexton in areas of high clinical need. In the case of NT1, conducting trials of ovesporexton in children and collecting data on safety in pregnancy and lactation is of high priority in order for these populations to have equitable access. In addition, head-to-head trials of ovesporexton compared with other treatments, as well as in combination with other treatments, are needed to develop a robust evidence base.

Payer actions:

- Allow for telemedicine consultation with sleep medicine specialists, including across state lines if necessary, given the shortage of sleep medicine providers, particularly in rural areas.
- Ensure that benefit designs developed in conjunction with employers and other plan sponsors do not create requirements for out-of-pocket spending that create major barriers to appropriate access for vulnerable patients.

Educational institution and employer action:

- Provide appropriate accommodations (e.g., designated rooms for short naps, flexible work schedules, secure locations to keep controlled medications) for people living with NT1. Successful accommodation of persons with NT1 could increase work productivity and school achievement.

Clinical specialty society actions:

- Develop and disseminate educational materials to primary care physicians, including pediatricians, about the symptoms and diagnosis of NT1, to heighten awareness and decrease delays in diagnosis.
- Seek ways to increase access to sleep specialists, including advocating for expansion of telemedicine and expanding the sleep medicine workforce.

Policymaker action:

- Ensure affordable access to non-employer-based health insurance programs, such as Medicaid and health insurance exchange plans, given that full-time employment can be challenging for persons living with NT1.

Payers

Recommendation 1

In conjunction with other stakeholders (e.g., manufacturers and clinicians), work to find innovative ways to ensure access for all appropriate patients to therapy given the apparent advantage in efficacy of ovesporexton over current treatments.

NT1 is a chronic disorder and persons diagnosed with NT1 generally require lifelong therapy. A survey of patients with NT1 suggested that treatment satisfaction with current therapies is low, likely because, in part, current therapies treat symptoms but do not address the underlying etiology of NT1. Ovesporexton is the first drug to correct the underlying orexin deficiency characteristic of NT1. Data from pivotal trials of ovesporexton show large improvements in measures of excessive daytime sleepiness, cataplexy, and other patient-important measures, including health-related quality of life, and participants who had taken part in the clinical trials confirmed the substantial difference in efficacy between ovesporexton and current standard of care therapies. Given ovesporexton's efficacy and relatively benign safety profile, if approved, clinical experts predicted that ovesporexton would be considered first-line therapy. Thus, it is critical that payers, manufacturers, and other stakeholders work together to find innovative solutions to ensure access to all NT1 patients who may benefit from treatment with ovesporexton. Payers have a role to play in encouraging pricing aligned to value – for example, payers could reduce or eliminate utilization management and cost-sharing for new drugs for manufacturers who pick value-based launch prices. Conversely, if ovesporexton is priced beyond its expected value, payers will likely seek to restrict its use, limiting access for patients. Payers could consider outcomes-based agreements in case there are patients who do not respond to or do not tolerate the drug, or a financial-risk based contracts that reimburse the payer if financial outcomes, such as treatment at a lower cost than current standard of care drugs, are not met. Finally, given that NT1 is a chronic disorder requiring lifelong

treatment, payers and manufacturers could consider implementing a subscription model, where payers could negotiate a set price for unlimited access to opeporexton for a set period of time.

Recommendation 2

For new therapies that have demonstrated safety and efficacy, particularly where there is substantial unmet need, develop coverage policies in advance of Food and Drug Administration (FDA) approval and avoid new-to-market blocks so that patients can access new treatments as soon as possible after launch.

Many payers now employ new-to-market blocks for nearly all newly approved drugs, lasting up to 180 days, in order to have time to assess the evidence and develop coverage policies. However, these new-to-market blocks pose a significant barrier to access, as clinicians and patients then need to appeal to the health plan for exceptions to have access to the drug during this period of time. For the majority of newly approved drugs, data from pivotal trials are available prior to drug approval and launch. Payers should develop mechanisms to more rapidly craft coverage policies, ideally having coverage policies available at or shortly following the launch of a new drug; the delay in coverage policy development should not exceed the standard set by the Centers for Medicare and Medicaid (review of a new treatment within 90 days, coverage decision within 180 days).

Prior Authorization

Given that some uncertainty remains about the efficacy of opeporexton over current combination treatments and longer-term safety and effectiveness, 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.

Cost Sharing

Patient cost sharing should be based on the net price to the plan sponsor, not the unnegotiated list price.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies as cornerstones of any drug coverage policy in the report: [Cornerstones of “Fair” Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals](#).

Drug-Specific Coverage Criteria: Oveporexton

If the price for oveporexton is out of line with value, and given the uncertainty of durability of effect and potential need for combination therapy, payers may develop prior authorization criteria and consider other limits on utilization.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right.² To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for oveporexton.

Coverage Criteria

- **Age:** Age criteria are likely to follow the FDA label for oveporexton. However, given that NT1 can have a severe detrimental effect on children’s lives and the relatively benign safety profile of oveporexton, payers should have efficient mechanisms for clinicians to seek coverage exceptions for younger patients with serious unmet need.
- **Clinical eligibility:** Payers are likely to require a diagnosis of NT1 to be eligible for treatment. Diagnostic criteria include ≥ 3 months of excessive daytime sleepiness and at least one of the following: (1) presence of cataplexy and either a mean sleep latency of ≤ 8 minutes and ≥ 2 sleep-onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test or a SOREMP on nocturnal polysomnogram, or (2) cerebrospinal fluid orexin or hypocretin level of ≤ 110 pg/mL.
 - We heard from clinical experts that given the potential logistical challenges of obtaining a lumbar puncture in the United States (US), it is not reasonable for payers to require lumbar puncture prior to approving therapy.
- **Exclusion criteria:** Oveporexton is not currently indicated for treatment of narcolepsy type 2.
- **Dose:** Consistent with dosages tested in clinical trials, 1 mg or 2 mg twice daily.

- **Duration of coverage and renewal criteria:** Initial coverage will likely be for a period of six to 12 months, which is long enough for dose titration, assessment of side effects, or disorder progression. Clinician attestation of efficacy is reasonable to require prior to renewal.
- **Provider restrictions:** Given the complexity of diagnosing NT1, it is reasonable to restrict initial prescriptions of oveporexton to sleep medicine specialists (e.g., neurologist or pulmonologist), or by generalist clinicians in consultation with sleep medicine specialists. Once a patient is stable on treatment, given the safety profile of oveporexton and the potential difficulty in accessing specialty care, it is reasonable for prescription renewals to be done by non-specialist prescribers such as primary care physicians.

Step Therapy

If oveporexton is priced in line with its value, because it has a novel mechanism of action that directly addresses the underlying cause of NT1, it would not be appropriate for payers to restrict access to oveporexton using step therapy.

- Clinical experts highlighted that the approval of oveporexton would potentially represent a paradigm shift in the treatment of NT1, in that there would finally be a treatment that addresses the underlying etiology of NT1. Available data from pivotal clinical trials demonstrated large improvements in outcomes compared with placebo, and indirect evidence also suggests improvement over current therapies. Additionally, oveporexton has a favorable safety profile. Given the evidence, clinical experts suggested that oveporexton should become a first-line therapy, and if that were the case, step therapy would inappropriately delay access to an effective drug and cause harm to patients.

If oveporexton is priced beyond its expected value, the principles of fair access require that step therapy be used only if the policies are implemented in a patient-centered manner, providing adequate flexibility to meet the needs of diverse patients transparently and efficiently, for example by allowing patients and clinicians to choose from multiple options rather than requiring patients to try multiple options. Utilization management is also reasonable for combination therapy with oveporexton (if required), given the high cost of most of the treatments for NT1.

- Clinical and patient experts stated that medication failures and polypharmacy are common for NT1 patients, which raises the concern that inappropriate step therapy requirements could delay and restrict access to treatment. While it is possible to tailor step therapy in a clinically responsible fashion, it is often administered with documentation burdens and inadequate procedures for exceptions that make step therapy a source of great frustration and the cause of poor outcomes for some patients.

- Currently available specialty society guidelines recommend multiple options for treatment for NT1, depending on patient symptoms. Clinical experts and patients stated since symptoms of NT1 differ from patient to patient, individualized treatment is necessary. Additionally, some medications can lose efficacy over time, as patients develop medication tolerance, or side effects become intolerable. Finally, because no current treatment addresses all NT1 symptoms, patients often require multiple medications for adequate symptom relief. Thus, there is no justification to require patients to attempt trials with all options prior to obtaining coverage for a newer, more expensive agent. This kind of policy does not meet ICER's Fair Access Criteria. Additionally, some patients may require combination therapy with an additional agent and given the high cost of most of the drugs for NT1, utilization management is reasonable for combination therapy.

Manufacturers

Recommendation 1

Manufacturers have a responsibility to set prices at levels 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.

Pricing novel treatments in accordance with the demonstrated benefits to patients as determined through independent analyses would contribute to fair, affordable access for patients with NT1.

Recommendation 2

Conduct research that directly compares real-world treatment options and effectiveness of combination therapy.

Multiple stakeholders expressed concerns about the lack of information directly comparing treatments and the need for active comparator trials. With combination therapy the norm for treatment of NT1, there is an urgent need to understand both the efficacy of opeporexton compared with combination treatment with existing therapies, and whether some NT1 patients treated with opeporexton may require combination therapy for optimal treatment of NT1 symptoms. Appropriate head-to-head trials would inform decision making by patients and clinicians.

Recommendation 3

Support the development of improved diagnostic tests to support timely diagnosis of NT1.

Clinical experts and patients highlighted that there are multiple barriers to getting a diagnosis of NT1, ranging from low awareness of the disorder to the high burden of diagnostic tests such as the Multiple Sleep Latency Test or a lumbar puncture to test orexin levels. This has led to lengthy diagnostic delays, with surveys showing that the mean time to diagnosis is almost 9 years.³ Clinical experts mentioned that the development of more accessible diagnostic tests such as blood-based biomarkers tests could potentially help increase the accuracy of diagnosis and decrease diagnostic delay.

Clinicians and Clinical Societies

Recommendation 1

Develop a process to rapidly update treatment guidelines for patients with NT1 when new treatment options are approved in a form that is easy to interpret and use by clinicians, patients, and payers.

Although the American Academy of Sleep Medicine issued an updated clinical practice guidelines in 2025, the approval of new drugs can cause guidelines to be out-of-date quickly. Since payers often base their coverage decisions on clinical guidelines, it is imperative for clinical specialty societies to have processes to rapidly update treatment guidelines when new treatment options emerge, particularly if they substantially change clinical practice. The approach of the National Comprehensive Cancer Network (NCCN), which updates their clinical practice guidelines at least annually and when needed with the approval of a new treatment, is a helpful model.

Patient Organizations

Recommendation 1

Patient organizations have a vital role to play to raise awareness of NT1 and its impact on patients. In particular, patient organizations are well-positioned to advocate to policymakers, educators, and employers to ensure that the needs of the community are being met.

Patient-led efforts can raise awareness of NT1 in order to decrease diagnostic delays, decrease stigma related to having a diagnosis of NT1, ensure reasonable accommodations from educators as well as employers, and educate patients about the potential risks and benefits of new therapies, including the development and dissemination of evidence-based, balanced materials that are accessible to all patients, including those with limited health literacy.

Recommendation 2

Patient organizations have a powerful voice to create significant pressure for fair pricing and appropriate insurance coverage across all sectors of the health system.

Patient groups have a large role to play in publicly promoting access and fair pricing of new therapies, particularly when a therapy like ovesporexton represents a substantial improvement over current standard of care treatments. This can be done both through advocacy (e.g., releasing public statements calling for manufacturers to price new treatments according to expected value, and encouraging patients and families to write to Congress, state legislatures, and state regulators to advocate for fair pricing and broader access of new treatments), and through direct engagement with stakeholders (e.g., payers, pharmacy benefit managers, employers) to craft patient-centered coverage policies promoting fair access.

Researchers/Regulators

Recommendation 1

There are multiple high priority research areas for NT1 on which researchers and funders can focus attention to close gaps as quickly as possible.

As previously discussed, there can be lengthy delays in receiving a diagnosis of NT1, in part due to the fact that diagnosis generally requires a clinician trained in sleep disorders and either a sleep study and/or a lumbar puncture. Given the potential consequences of untreated NT1, more streamlined diagnostic tests are needed. This could be in the form of blood-based biomarkers, or testing the use of an orexin agonist as a diagnostic tool.

Current outcome measures for NT1 may be subject to bias and may not fully capture all aspects of NT1. For example, the Epworth Sleepiness Scale (ESS) score has been criticized for its inconsistent association with physiologic sleepiness.⁴ Persons living with NT1 have described suffering from “brain fog” and other cognitive symptoms that may not be well-captured by the ESS, MWT, or other commonly used measures in NT1 trials. Thus, researchers have an opportunity to develop more comprehensive patient-centered scales to measure the impact of NT1.

Finally, combination therapy is the norm for treatment of NT1; however, ovesporexton was studied as a monotherapy. We heard from clinical and patient experts that it is likely that some patients will require combination therapy to satisfactorily address all their symptoms. This is a key area of future research on which researchers and funders can focus.

Recommendation 2

Regulators have a role in promoting trials comparing new agents with current standard of care prior to approval, rather than placebo-controlled trials for conditions that have existing therapies.

There are currently no head-to-head trials of ovelorexton compared with the current standard of care therapies and thus clinicians and patients do not have all the information needed to make informed and shared decisions about treatment. The FDA has an opportunity to encourage manufacturers to design and conduct trials that reflect real-world treatment of NT1.

References

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Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the May 14, 2026 public meeting of the Midwest CEPAC.

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

ICER Staff and External Collaborators	Conflict of Interest
Foluso Agboola, MBBS, MPH Senior Vice President of Research Institute for Clinical and Economic Review	No conflicts to disclose.
Josh J. Carlson, PhD Professor & Graduate Program Director CHOICE Institute, University of Washington	Josh Carlson has received consulting fees from Takeda that are not related to Narcolepsy.
Hui-Hsuan Chan, MHS Research Assistant University of Washington	No conflicts to disclose.
Sarah Emond, MPP CEO and President Institute for Clinical and Economic Review	No conflicts to disclose.
Chloe Fandetti, BA Operations and Program Coordinator Institute for Clinical and Economic Review	No conflicts to disclose.
Woojung Lee, PharmD, PhD Associate Director of Health Economics and Decision Modeling Institute for Clinical and Economic Review	No conflicts to disclose.
Grace A. Lin, MD Medical Director for Health Technology Assessment Institute for Clinical and Economic Review	Grace Lin receives research grant funding from the National Institutes of Health, Mt. Zion Health Fund, GRAIL, Inc., and the California Health Benefits Research Program.
Linda Luu, MS Research Scientist University of Washington	No conflicts to disclose.
Dmitriy Nikitin, MSPH Senior Research Lead Institute for Clinical and Economic Review	No conflicts to disclose.
Marie Phillips, BA Health Economics Research Assistant Institute for Clinical and Economic Review	No conflicts to disclose.
Sol Sanchez, BA Research Assistant Institute for Clinical and Economic Review	No conflicts to disclose.
Temiwunmi Shobanke, MS Program Manager Institute for Clinical and Economic Review	No conflicts to disclose.

Appendix Table 2. Midwest CEPAC Panel Member Participants Conflict of Interest Disclosures

Midwest CEPAC Member	Conflict of Interest
<p>Eric Armbrrecht, PhD Professor and Associate Provost, Saint Louis University Center for Health Outcomes Research, School of Medicine and College for Public Health & Social Justice</p>	<p>No conflicts to disclose.</p>
<p>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</p>	<p>No conflicts to disclose.</p>
<p>Donald E. Casey Jr., MD, MPH, MBA, MACP, FAHA, DFACMQ, DFAAPL, CPE 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)</p>	<p>No conflicts to disclose.</p>
<p>Yngve Falck-Ytter, MD, AGAF Professor of Medicine, Case Western Reserve University; Chief, Gastroenterology and Hepatology VA Northeast Ohio Healthcare System, Cleveland</p>	<p>No conflicts to disclose.</p>
<p>Jayani Jayawardhana, PhD Associate Professor, Department of Health Management and Policy, University of Kentucky College of Public Health Associate Professor, Department of Pharmacy Practice and Science, University of Kentucky College of Public Health</p>	<p>No conflicts to disclose.</p>
<p>Jill Johnson, PharmD Professor, Department of Pharmacy Practice, University of Arkansas for Medical Sciences College of Pharmacy</p>	<p>No conflicts to disclose.</p>
<p>Bradley Martin, PharmD, PhD Professor, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy</p>	<p>No conflicts to disclose.</p>
<p>Timothy McBride, PhD School of Public Health, Washington University in St. Louis Co-Director, Center for Advancing Health Services, Policy & Economics Research (CAHSPER)</p>	<p>No conflicts to disclose.</p>

Midwest CEPAC Member	Conflict of Interest
Reem Mustafa, MD, MPH, PhD Professor of Medicine, Division of Nephrology and Hypertension Director, Evidence Based Practice Center (EPC), University of Kansas	No conflicts to disclose.
Jimi Olaghere Sickle Cell Disease Advocate Entrepreneur, Sugarloaf Capital	No conflicts to disclose.
Rachel Sachs, JD, MPH Professor of Law, Washington University in St. Louis	No conflicts to disclose.
Kurt Vanden Bosch, PharmD Pharmacist, St. Luke’s Health System, Idaho	No conflicts to disclose.
Stuart A. Winston, DO Cardiologist in the Sub-Specialty of Cardiac Electrophysiology, Trinity Health IHA Medical Group, Ann Arbor, MI Physician Lead, Professional Enhancement Program, Trinity Health IHA Medical Group, Ann Arbor, MI	No conflicts to disclose.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Tammy Anderson Executive Director, Wake Up Narcolepsy	Tammy Anderson is a full-time employee of Wake Up Narcolepsy. Wake Up Narcolepsy receives grants/sponsorships from Jazz Pharmaceuticals, Harmony Biosciences, Avadel, and Takeda Pharmaceuticals to support patient programming. These grants represent approximately 80% of the funding received through pharmaceutical grants/sponsorships for the most recent year.
Emily Clegg Barker, PhD Freelance Medical Communicator; Person with Narcolepsy; Patient Advocate	Emily Clegg Barker has received honoraria from Jazz Pharmaceuticals and compensation for supporting advisory boards by Jazz Pharmaceuticals and Centessa Pharmaceuticals. She volunteers with Wake Up Narcolepsy as a peer support facilitator.
Becky Faustgen, PharmD Manager, Clinical Pharmacy, UnitedHealthcare	Becky Faustgen is a full-time employee of UnitedHealthcare.
Phil Naughten, PharmD Head of US Value and Evidence Generation, Takeda Pharmaceuticals	Phil Naughten is a full-time employee of Takeda Pharmaceuticals.
Luis Ortiz, MD Sleep Medicine Physician, John Hopkins All Children’s Hospital Assistant Professor of Pediatrics, John Hopkins University School of Medicine	Luis Ortiz has received fees from serving on advisory boards for Harmony Biosciences, Jazz Pharmaceuticals, and Avadel regarding pitolisant and Oxybate products.
Thomas Scammell, MD Professor of Neurology, Harvard Medical School	Over the last three years, Thomas Scammell has received consulting fees from Takeda, Jazz Pharmaceutical, Harmony Biosciences, Avadel Pharmaceuticals, and Merck.

Policy Roundtable Participant	Conflict of Interest
Emily Tsiao, PharmD, BCPS Senior Clinical Pharmacist, Trend Management Strategies and Programs, Premera Blue Cross	Emily Tsiao is a full-time employee of Premera Blue Cross.