[F4] Advancing Patient-Centered Care in Narcolepsy Type 1: Integrating the Latest Evidence, Guidelines, and Treatment Innovations

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Learning Objectives

At the completion of this program, participants should be able to:

1. Explain the latest diagnostic criteria and evidence-based guidelines for narcolepsy type 1, incorporating both objective findings and patient-reported experiences into managed care strategies.
2. Review current and emerging therapeutic options for narcolepsy type 1, including orexin-targeted treatments, in terms of efficacy, safety, mechanism of action, and ability to meet unmet patient needs.
3. Examine the patient's journey and perspective of the lived experience with narcolepsy type 1 on treatment value, shared decision-making, and access to care.
4. Discuss the impact of soon-to-emerge narcolepsy type 1 therapies and evolving guidelines on clinical practice, focusing on how these advances may reshape patient expectations, access, and health outcomes.

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Continuing Pharmacy Education Credit

The Academy of Managed Care Pharmacy (AMCP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity is accredited to provide 1.25 contact hours of continuing pharmacy education (CPE) credit.

- ✓ Instructions to claim credit can be found in the app
- ✓ Obtain the session access code
- ✓ Login to amcplearn.org
- ✓ Submit by Monday, May 11, 2026

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This activity is supported by an educational grant from Takeda Pharmaceuticals U.S.A., Inc.

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Participate in Polls and Ask Questions

https://amcp26.cnf.io/sessions/kgtn

Download Handouts in App

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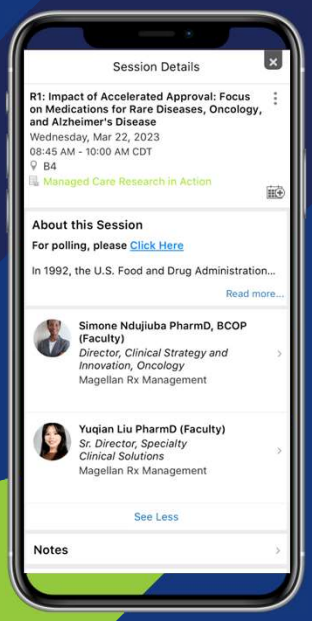

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Faculty

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Interactive Question

Word Cloud

In one word, what is the BIGGEST challenge you face when managing patients with narcolepsy?

Epidemiology

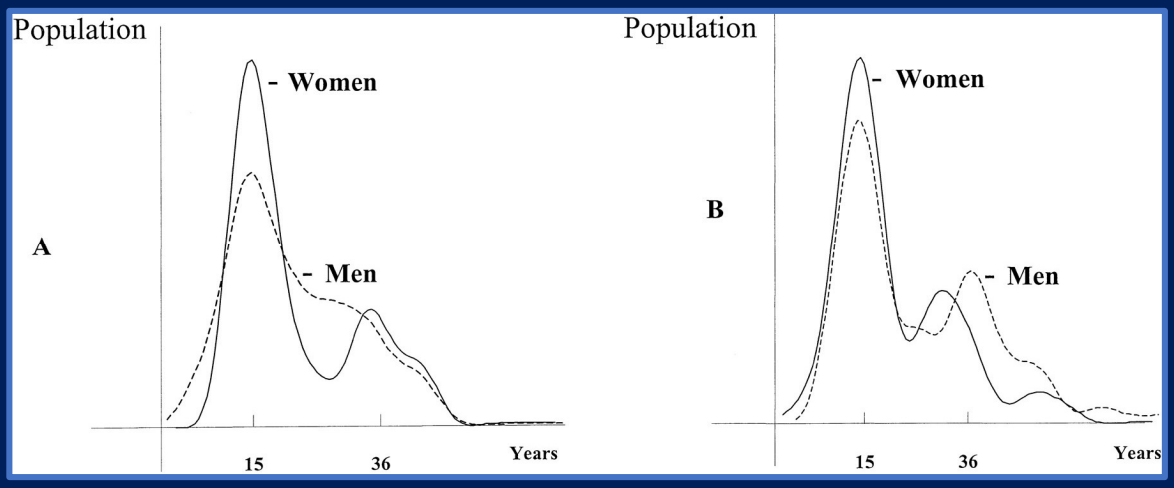
Narcolepsy Type 1 (NT-1) (with cataplexy)

Irrepressible urges to sleep + skeletal muscle weakness in response to strong emotions

- Incidence:
  - 1.2 per 100,000 persons each year
- Prevalence:
  - 0.02-0.18% of U.S. and Western European states
  - Slight preponderance for males
  - 1% to 2% risk in first-degree relatives of affected persons

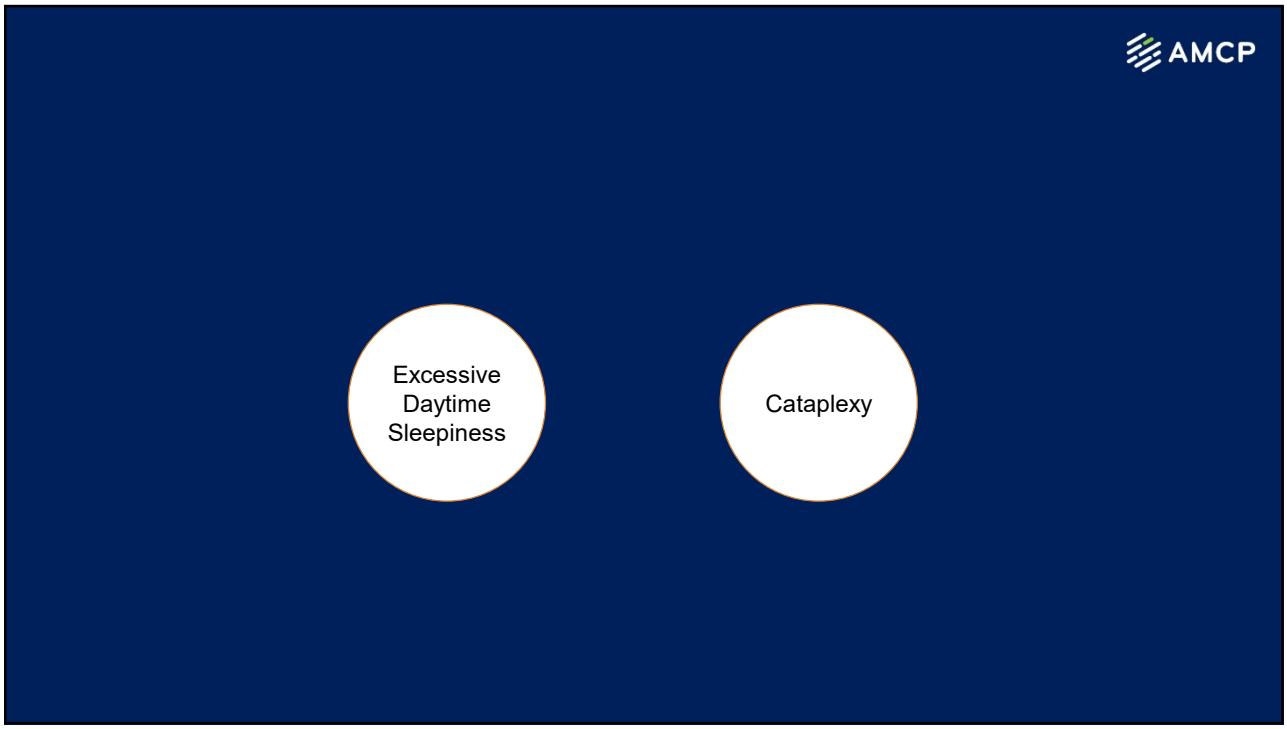
Dauvilliers, et al. *Neurology*. 2001;57(11):2029-2033.

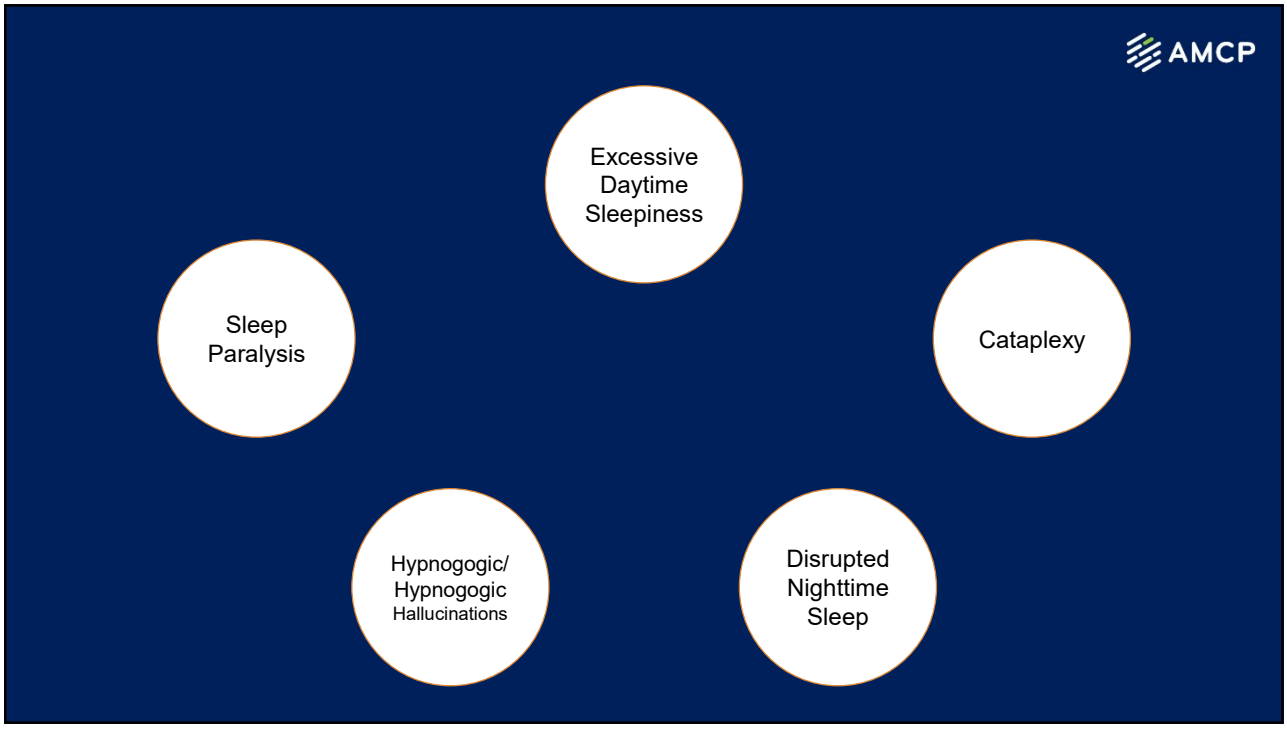
Age of Onset

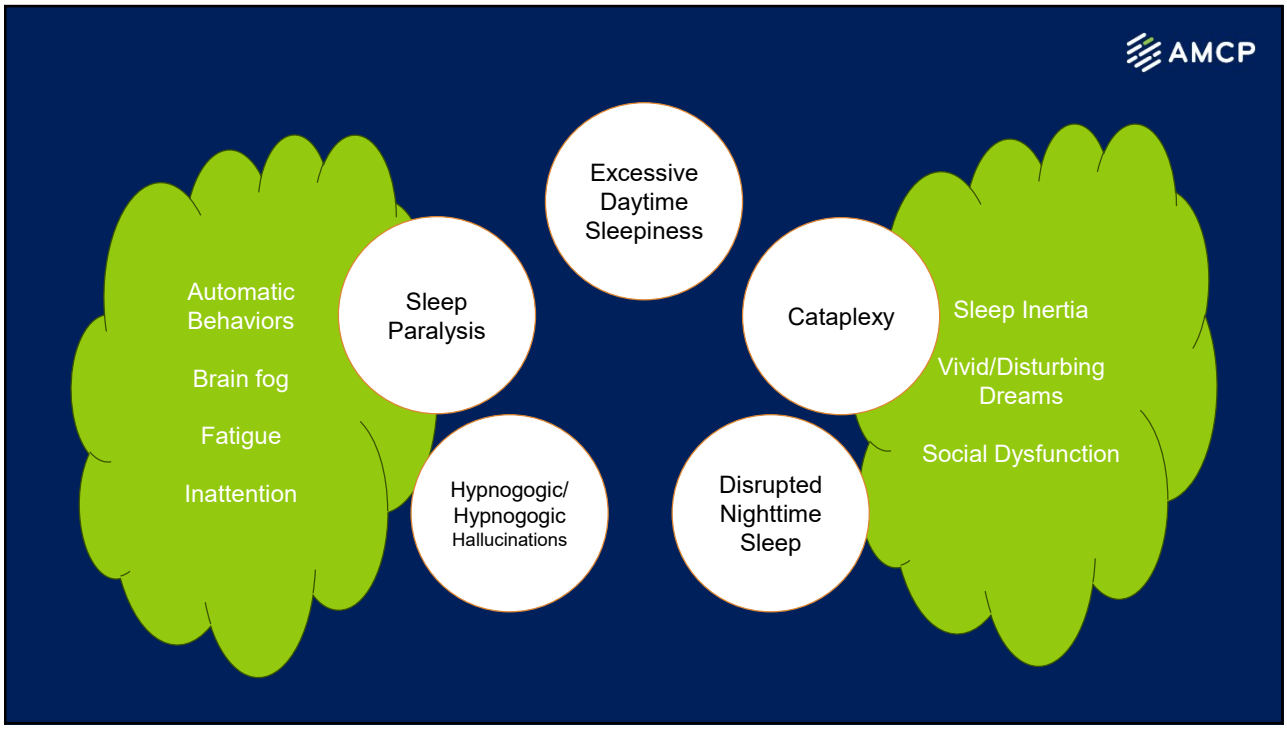


Dauvilliers Y, Montplaisir J, Molinari N, Carlander B, Ondze B, Besset A, Billiard M. Age at onset of narcolepsy in two large populations of patients in France and Quebec. Neurology. 2001 Dec 11;57(11):2029-33. doi: 10.1212/wnl.57.11.2029. PMID: 11739821. Permission of use granted 4/9/2026.

Excessive Daytime Sleepiness


AMCP
Excessive Daytime Sleepiness
Cataplexy


AMCP
Excessive Daytime Sleepiness
Sleep Paralysis
Cataplexy
Hypnogogic/ Hypnogogic Hallucinations
Disrupted Nighttime Sleep



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Disease Burden

- Prospective cohort of 171 patients with narcolepsy compared with 680 controls (Denmark)
- Comparing the narcolepsy patient vs controls @ age 20:
  - Lower educational level
  - Lower grade point averages
  - Lower employment rate
  - Lower income
  - Higher health costs
- Results were independent of parent educational and social level

Jennum, et al. *Sleep Med*. 2020;67:23-27.

Social Burden

Decreased Quality of Life	Both physical (fatigue or sleepiness) & mental (anxiety or depression) domains contribute
Higher Healthcare Utilization	More likely to be hospitalized or undergo procedures
Decreased Productivity	Absenteeism & Presenteeism Decreased overall productivity
Cost of treatment	Personal & System Costs Provider time getting authorizations for medication

Bassi C, et al. *J Sleep Res*. 2024;33(3):e14087

Burden of Narcolepsy Disease (BOND) Study

- Retrospective Study
- Based on medical claims data
  - Narcolepsy and Comorbid Conditions were based on ICD codes
- 9312 Subjects (>18 yo)
  - 20% Had a diagnosis of cataplexy
- 46,559 controls, matched 5:1 based on age, sex, geographic region, and payer
- Looked at 5 years between 2006-2010

Black, et al. *Sleep Med*. 2014;15(5):522-529.

Narcolepsy Comorbidity (BOND Study)

Narcolepsy has been associated with an excess prevalence for:

Black, et al. *Sleep Med*. 2014;15(5):522-529.

Cardiovascular Risk & Narcolepsy

Narcolepsy itself can increase risk of cardiovascular disease by 20%

Heart Failure	Coronary Artery Disease	Common Comorbidities	Stimulant Risk
OR 1.714 (95% CI 1.031–2.849; P=0.037)	OR 1.702 (95% CI 1.011–2.864; P=0.045)	HTN, obesity, DM, HLD	May increase BP and arrhythmia risk

Recommendations for Reducing CV Risk

- Monitor blood pressure, weight, and waist circumference in patients without CV disease
- Screen for lipids and A1c; increase monitoring frequency with co-occurring CV conditions
- Educate patients on narcolepsy–CV risk association; counsel on sodium reduction
- Tailor pharmacotherapy: use low-sodium LXB for sodium-sensitive conditions (HF, refractory HTN)
- Pitolisant: monitor QTc interval; avoid with other QTc-prolonging medications

Franceschini, et al. *Neurotherapeutics*. 2021;18:6-19. Krahn, et al. *Adv Ther*. 2022;39:221-243. Gudka , et al. *Sleep Med Rev*. 2022;65:101669.
Tao, et al. *Sleep Med*. 2024;113:6-12. Kwon, et al. *J Am Heart Assoc*. 2024;13:e.035168.

Diagnosis

Diagnostic Delay

- Mean time gap of 3-5 years between onset and 1st consultation
- Awareness of narcolepsy among primary care physicians tends to be very low
- Estimated diagnostic delay **8-15 years** after symptom onset

Taddei, et al. J *Sleep Res*. 2016;25(6):709-715.
Rosenberg, et al. *Postgrad Med*. 2014;126(1):78-86.
Thorpy, et al. *Sleep Med*. 2014;15(5):502-507.
Maski K, et al. *Lancet*. 2016;15(11):1170-81.
Ohayon MM, et al. *Sleep Med*. 2021;84:405-414.

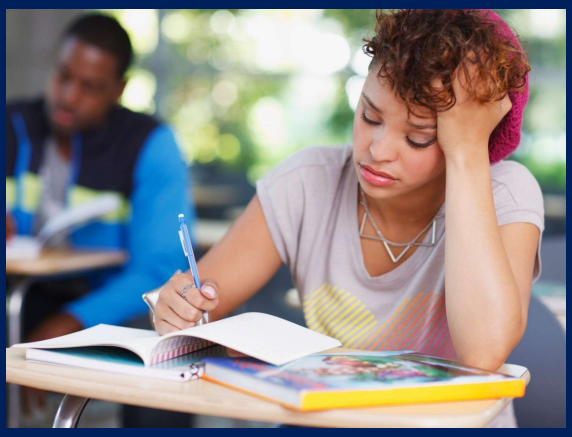
Diagnostic Delay

- Strongest predictor of diagnostic delay is pediatric onset
- Factors that contribute to delay:
  - Mild initial or gradual onset of symptoms
  - Lack of recognition of symptoms
  - Mistaken diagnosis (OSA, circadian rhythm d/o)
  - Misdiagnosis/co-diagnosis (depression, ADHD)

Maski, et al. *J Clin Sleep Med*. 2017;13(3):419-425.
OSA = Obstructive Sleep Apnea; ADHD = Attention-Deficit/Hyperactivity Disorder

Evaluation of Narcolepsy (is difficult!)

- Screen for pentad symptoms
- Timing of symptoms
- Screen for metabolic etiology (anemia, hypothyroid, electrolyte imbalance, etc.)
- Difficulty when dealing with conditions that have overlapping presentations but can also be comorbid (depression, ADHD, insufficient sleep due to sleep disruptions, OSA, etc.)



Evaluation of Narcolepsy

- Actigraphy
- Overnight PSG
- Urine Drug Testing
- Multiple Sleep Latency Test (MSLT)
- HLA Testing
- CSF Hypocretin levels

Photo credit: Luis Ortiz

PSG = Polysomnography; HLA = Human Leukocyte Antigen; CSF = Cerebrospinal Fluid

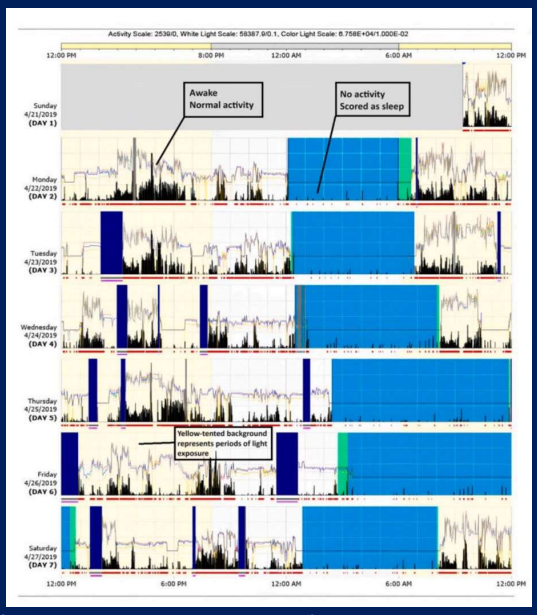
Diagnosis

ICSD–3–TR	DSM–5–TR
Daily periods of irrepressible need to sleep or daytime lapses into drowsiness or sleep.	Recurrent periods of an irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day occurring 3 times/week, >3 months
The presence of ***one or both*** of the following: 1. Cataplexy *and* either: a. Mean sleep latency of ≤ 8 minutes and two or more sleep-onset REM periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) preformed in accordance with current recommended protocols. b. A SOREMP (within 15 minutes of sleep onset) on nocturnal polysomnogram. 2. CSF Hypotretin-1 concentration of ≤110 pg/mL or less than one-third of the mean values obtained in normal subjects with the same standardized assay.	The presence of at least ***one*** of the following: 1. Episodes of cataplexy, defined as either (a) or (b), occurring at least a few times per month 2. Nocturnal sleep PSG showing REM sleep latency ≤ 15 minutes, or an MSLT showing a mean sleep latency ≤ 8 minutes and ≥ 2 SOREMPs 3. Hypocretin deficiency, as measured using CSF hypocretin-1 immunoreactivity values (≤ 1/3 of values obtained in healthy subjects tested using the same assay, or ≤ 110 pg/mL).

ICSD-3-TR = International Classification of Sleep Disorders, Third Edition, Text Revision, https://aasm.org/clinical-resources/international-classification-sleep-disorders/
DSM-5-TR = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision, https://doi.org/10.1176/appi.books.9780890425787
NT1 = Narcolepsy Type 1; NT2 = Narcolepsy Type 2; CSF = Cerebrospinal Fluid; SOREM = Sleep-Onset Rapid Eye Movement; MSLT = Multiple Sleep Latency Test

Actigraphy

- Non-invasive method used to monitor rest/activity cycles. Usually a small, wrist-mounted device that contains an accelerometer to record physical motion.
  - It provides a more reliable record of sleep duration than sleep diaries
  - Worn for 2 weeks prior to overnight sleep study
- While actigraphy cannot diagnose narcolepsy on its own, it is a **mandatory prerequisite** for valid diagnostic testing (the MSLT) according to ICSD-3-TR standards
  - Helps rule out sleep deprivation
  - Verifies sleep hygiene/sleep schedules
  - Assessment of Circadian Rhythm
  - Can identify sleep irregularity that is common in narcolepsy



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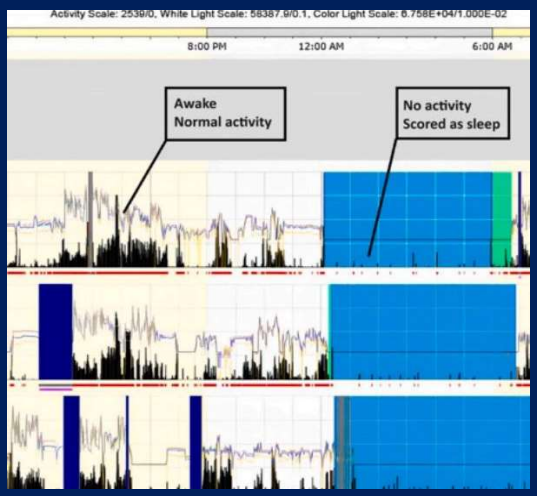

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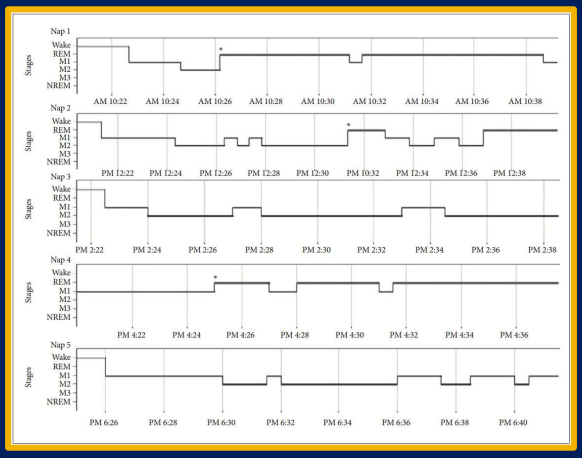
Polysomnography

- Comprehensive recording of biophysiological changes during sleep
- Gold Standard in diagnosing OSA
- Main goals:
  - Rule out other sleep disorders such as obstructive sleep apnea
  - Ensure adequate sleep before MSLT
  - However, narcolepsy diagnosis possible with test

MSLT

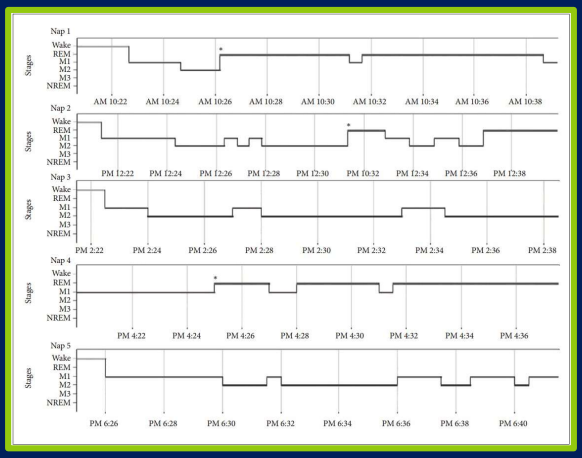
- Following overnight PSG
- Patient given 5, 20 minute opportunities to fall asleep
- If the patient falls asleep, the patient will be allowed to sleep for 15 minutes
- Next nap opportunity 2 hours after arousal
- How quickly the patient falls asleep and if they enter REM sleep determines diagnosis



Baek JH, et al. *Sleep Med Res* 2016; 7(2):74-77
MSLT = Multiple Sleep Latency Test

MSLT

- A diagnosis of narcolepsy requires:
  - Mean Sleep Latency of <8 minutes
  - At least 2 sleep onset REM periods (SOREMs)



Baek JH, et al. *Sleep Med Res* 2016; 7(2):74-77
MSLT = Multiple Sleep Latency Test

MSLT is Not Fool Proof!

False Positives

- Insufficient sleep the night before
- Untreated sleep disorder
- Medications that can cause increased REM sleep or REM rebound or increased sleepiness
- Poor adherence to protocol

False Negatives

- Anxiety
- REM Suppressing medications
- Wake Promoting Medications
- Poor testing conditions
- Age of patient

Guidelines

Goals of Therapy

- Staying awake
  - Decreasing episodes of sleepiness
  - Decreasing limitations due to sleepiness
- Decreasing frequency/severity of cataplexy
- Waking up easier
- Going to sleep
- Staying asleep
- Decrease Brain fog
- ADHD Symptoms
- Co-existing Depression or Anxiety

Maski, et al. *J Clin Sleep Med*. 2021;17(9):1881-1893.

AASM Guidelines (2021)

Intervention	Strength of Recommendation	Critical Outcomes Showing Clinically Significant Improvement			
		EDS*	Cataplexy	Disease Severity	QoL**
NARCOLEPSY					
Modafinil	Strong	X		X	X
Pitolisant	Strong	X	X	X	
Sodium Oxybate	Strong	X	X	X	
Solriamfetol	Strong	X		X	X
Armodafinil	Conditional	X		X	
Dextroamphetamine	Conditional	X	X		
Methylphenidate	Conditional			X	

*EDS = Excessive Daytime Sleepiness
**QoL = Quality of Life

Maski, et al. *J Clin Sleep Med*. 2017;13(3):419-425.

AASM Recommendations (2021) Pediatric

Intervention	Strength of Recommendation	Critical Outcomes Showing Clinically Significant Improvement			
		EDS	Cataplexy	Disease Severity	QOL
NARCOLEPSY					
Modafinil	Conditional	X			
Sodium Oxybate	Conditional	X	X	X	

Maski, et al. *J Clin Sleep Med*. 2017;13(3):419-425.

EUROPEAN GUIDELINE:

Management of Narcolepsy in Adults & Children

Written by EAN, ESRS and EU-NN

NARCOLEPSY is an uncommon disorder of presumed autoimmune origin that usually requires lifelong treatment. Narcolepsy typically has a pleomorphic clinical presentation and produces a considerable variety of different symptoms with a variable clinical course.

TREATMENT RECOMMENDATION

The management of narcolepsy involves non-pharmacological and pharmacological approaches, with an increasing number of symptomatic treatment options for adults and children.

ADULTS

Excessive daytime sleepiness / Disturbed nocturnal sleep

- Regular sleep-wake schedule & scheduled daytime naps (strong recommendation)
- Wake promoting agents during the day: Modafinil, pitolisant & solriamfetol (strong recommendation)
- Sodium oxybate during the night (strong recommendation)
- Wake promoting during the day: Methylphenidate & amphetamine-derivates (weak recommendation)

Cataplexy

- Sodium oxybate during the night (strong recommendation)
- Venlafaxine & clomipramine during the day (strong recommendation)
- Pitolisant during the day (weak recommendation)

CHILDREN

Excessive daytime sleepiness / Disturbed nocturnal sleep

- Regular sleep-wake schedule & scheduled daytime naps (strong recommendation)
- Sodium oxybate during the night (strong recommendation)
- Wake promoting during the day: Modafinil, methylphenidate, pitolisant & amphetamine-derivates during the day (weak recommendation)

Cataplexy

- Sodium oxybate during the night (strong recommendation)
- Antidepressants during the day (weak recommendation)

Read the full guideline in the European Journal of Neurology: https://doi.org/10.1111/ene.14888

When using GRADE, panels make strong recommendation when most clinicians and patients would choose the recommended course of action. Weak recommendation indicates that clinicians and patients should consider the recommended course of action, but the final decision should be based on discussion, case-by-case risks and preferences.

Treatment choices should be tailored to each patient's symptoms, needs, comorbidities and risk of potential drug interactions.

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A Patient's Journey

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Patient Journey

- Narcolepsy is more than just being tired. Living with narcolepsy means waking up tired even after a full night of sleep and facing sudden sleep attacks that can strike anytime. It affects my focus, memory, and energy, but it has also taught me resilience, self-advocacy, and the importance of finding support and understanding along the way.

Securing My Narcolepsy Diagnosis

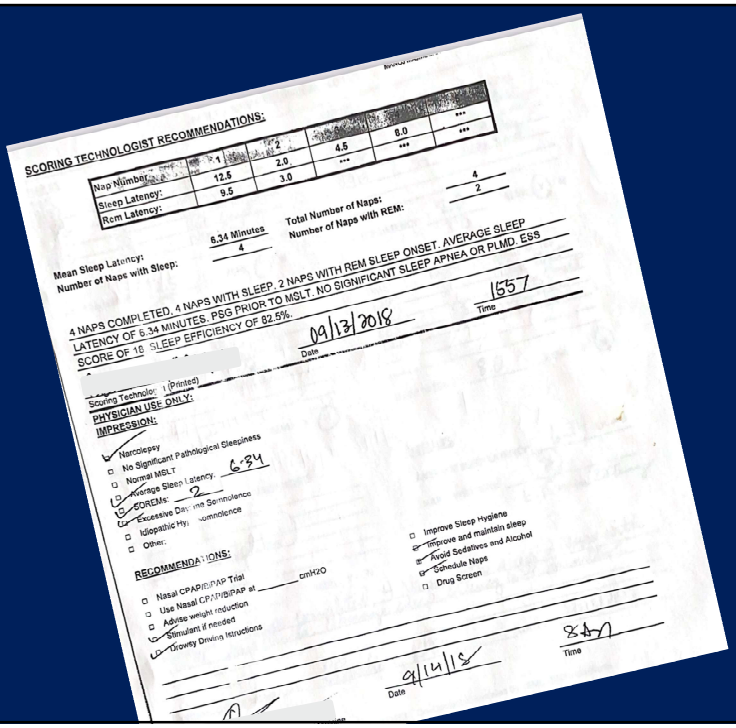
- It took almost two years to be diagnosed with Narcolepsy Type 1 with cataplexy. As a nurse, I was able to advocate for the correct testing — without that, it likely would have taken even longer.

Photo credit:

Patient Journey

- My MSLT in September 2018 finally gave me validation. While there's no cure, having a diagnosis brought hope through available treatments.
- Finding the right medication was a long process of trial and error, delayed by insurance denials/approvals, prior authorizations and high costs. Even when I found one that worked, delivery and safety were major concerns. Even now, I'm facing current barriers to treatment.
- Value of Treatment: Treatment has been life-changing for me — the difference is night and day. It allows me to be functional, safe, and fully present in my life and with my family.

My MSLT



SCORING TECHNOLOGIST RECOMMENDATIONS:

Nap Number:	1	2	3	4	5
Sleep Latency:	12.5	2.0	4.5	6.0	***
Rem Latency:	9.5	3.0	***	***	***

Mean Sleep Latency: 6.34 Minutes
Number of Naps with Sleep: 4

Total Number of Naps: 4
Number of Naps with REM: 2

4 NAPS COMPLETED, 4 NAPS WITH SLEEP, 2 NAPS WITH REM SLEEP ONSET. AVERAGE SLEEP LATENCY OF 6.34 MINUTES. PSG PRIOR TO MSLT. NO SIGNIFICANT SLEEP APNEA OR PLMD. ESS SCORE OF 18. SLEEP EFFICIENCY OF 82.5%.

09/13/2018 Date
1557 Time

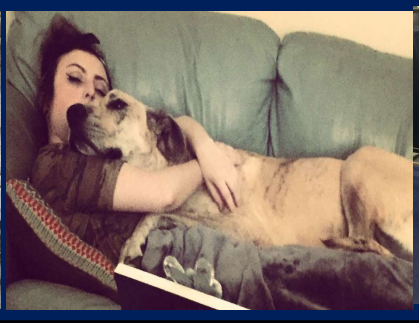
Scoring Technologist (Printed)
PHYSICIAN USE ONLY:
IMPRESSION:
- Narcolepsy
- No Significant Pathological Sleepiness
- Normal MSLT
- Average Sleep Latency: 6.34
- SOREMs: 2
- Excessive Daytime Somnolence
- Idiopathic Hypersomnolence
- Other:

RECOMMENDATIONS:
- Nasal CPAP/BiPAP Trial ____ cmH2O
- Use Nasal CPAP/BiPAP at ____
- Advise weight reduction
- Stimulant if needed
- Drowsy Driving Instructions
- Improve Sleep Hygiene
- Improve and maintain sleep
- Avoid Sedatives and Alcohol
- Schedule Naps
- Drug Screen

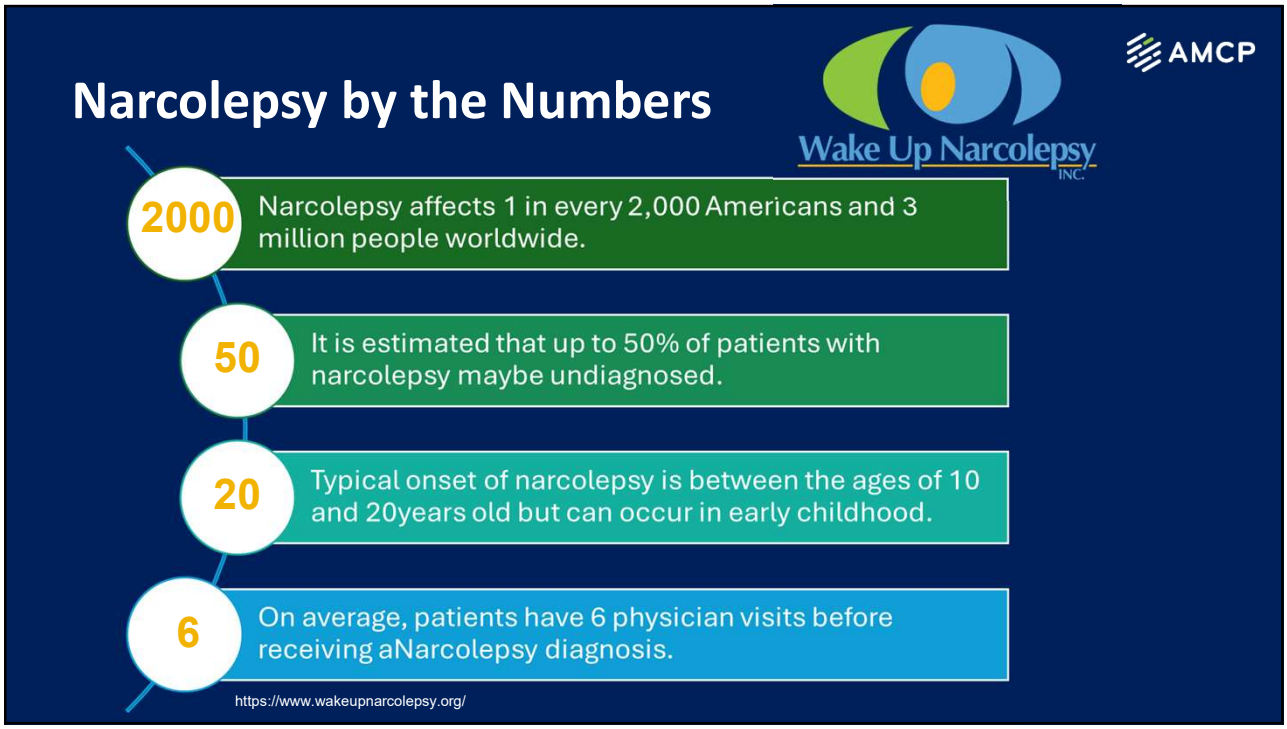
9/14/18 Date
Time

Message to Managed Care Professionals

Narcolepsy is more than sleepiness — it's a complex, lifelong condition that impacts safety, productivity, and quality of life. Timely diagnosis, access to treatment, and coverage for appropriate medications are critical. Your understanding, support, and advocacy can make a real difference in patients' daily lives- in my life.



Photos credit: Shelby Cole


Narcolepsy by the Numbers
Wake Up Narcolepsy INC.
AMCP
2000
Narcolepsy affects 1 in every 2,000 Americans and 3 million people worldwide.
50
It is estimated that up to 50% of patients with narcolepsy maybe undiagnosed.
20
Typical onset of narcolepsy is between the ages of 10 and 20years old but can occur in early childhood.
6
On average, patients have 6 physician visits before receiving aNarcolepsy diagnosis.
https://www.wakeupnarcolepsy.org/


Managed Care Impact
AMCP

Currently Available Agents

Drug	Brand	Generic	Approval	Patent Exp	MFR
modafinil	Provigil	Yes	1998	-	-
armodafinil	Nuvigil	Yes	2007	-	-
sodium oxybate	Xyrem	Yes (AG- Amneal, Hikma)	2002	-	Jazz
sodium oxybate /Ca/Mag/Pot	Xywav	**No**	2020	2033	Jazz
sodium oxybate XR	Lumryz	**No**	2023	2037	Avadel
solriamfetol	Sunosi	**No**	2019	2026	Axsome
pitolisant	Wakix	**No**	2019	2026	Harmony

Provigil. Product label. Teva Pharmaceuticals. Jan 2015.
Nuvigil. Product label. Teva Pharmaceuticals. Feb 2017.
Xyrem. Product label. Jazz Pharmaceuticals. April 2023.
Xywav. Product label. Jazz Pharmaceuticals. May 2025.

Lumryz. Product label. Avadel CNS. Oct 2024.
Sunosi. Product label. Axsome Therapeutics. June 2023.
Wakix. Product label. Harmony Biosciences. February 2026.

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Clinical Indications

Agent	Narcolepsy: Excessive daytime sleepiness (EDS)	Narcolepsy: Cataplexy	Obstructive Sleep Apnea (OSA)-Sleepiness	Idiopathic Hypersomnia (IH)	Shift Work Disorder
modafinil	≥18	-	✓	-	✓
armodafinil	≥18	-	✓	-	✓
sodium oxybate	**≥7**	**≥7**	-	-	-
sodium oxybate +	**≥7**	**≥7**	-	✓	-
sodium oxybate XR	**≥7**	**≥7**	-	-	-
solriamfetol	≥18	-	✓	-	-
pitolisant	**≥6**	≥18	-	-	-

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Pharmacology & Administration

	modafinil	armodafinil	sodium oxybate	mixed oxybate salts	sodium oxybate XR	solriamfetol	pitolisant
MOA	Unknown, sympathomimetic, inhibits DA reuptake?		Unknown, CNS depressant, GABA (via NE, DA)?			NE, DA reuptake inhibitors	H3R Inverse Agonist
Form	Tab (whole): 100, 200 mg	Tab (whole): 50, 150, 200, 250 mg	**Solution:** 0.5 g/mL	**Solution:** 0.5 g/mL	**Suspension:** 4.5/6/7.5/ 9 g pack	Tab (split): 75, 150 mg	Tab (whole): 4.45, 17.8 mg
Admin	Food delays Tmax by 1 hour, but no effect on bioavailability		2h after eating			-	-
Dose	QAM	QAM	**First dose at bedtime, second dose 2.5-4h later**		QHS	QAM	QAM

CNS=central nervous system; DA=dopamine; NE=norepinephrine; H3R=histamine H3 receptor

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Wakix. Product label. Harmony Biosciences. February 2026.

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Safety & Tolerability

	modafinil	armodafinil	sodium oxybate	sodium oxybate +	sodium oxybate XR	solriamfetol	pitolisant
C/I	hypersensitivity		use with sedatives, succinic deficiency			MAOI	hypersensitivity
Warnings	serious rash, drug reaction, anaphylaxis, psychiatric, CV disease		**BBW for CNS depression & abuse,** depression, suicidality, anxiety, confusion, parasomnias Xyrem and Lumryz: high sodium content			psychiatric, HTN, tachycardia	QT prolongation
AE (>5%)	HA, N/D, dizziness, insomnia, anxiety, rhinitis, back pain, dyspepsia	HA, nausea, dizziness, insomnia	N/V, dizziness, somnolence, enuresis, tremor	HA, N/V/D, dizziness, somnolence, insomnia, anxiety, sweating, anorexia, dry mouth, tremor	HA, N/V, dizziness, enuresis	HA, nausea, anorexia, insomnia, anxiety	nausea, insomnia, anxiety

C/I=contraindication; CV=cardiovascular; HTN=hypertension; HA=headache; N=nausea; V=vomiting; D=diarrhea; BBW=black box warning; CNS=central nervous system; MAOI=monoamine oxidase inhibitor

Provigil. Product label. Teva Pharmaceuticals. Jan 2015.
Nuvigil. Product label. Teva Pharmaceuticals. Feb 2017.
Xyrem. Product label. Jazz Pharmaceuticals. April 2023.
Xywav. Product label. Jazz Pharmaceuticals. May 2025.

Lumryz. Product label. Avadel CNS. Oct 2024.
Sunosi. Product label. Axsome Therapeutics. June 2023.
Wakix. Product label. Harmony Biosciences. February 2026.

Safety & Tolerability

	modafinil	armodafinil	sodium oxybate	sodium oxybate +	sodium oxybate XR	solriamfetol	pitolisant
Special Pops	• pregnancy: N/A* • peds: N/A • **geri: dec dose** • **hepatic: sev, dec** • renal: N/A		• pregnancy: N/A • **peds: ≥7y** • geri: N/A • **hepatic: dec** • renal: N/A			• pregnancy: N/A • peds: N/A • **geri: no change** • hepatic: N/A • **renal: sev, avoid**	• pregnancy: N/A • peds: **: ≥6y** • geri: N/A • **hepatic: severe, avoid** • **renal: severe, avoid**
D/I	Steroidal contraception, cyclosporine, CYP2C19		divalproex		sedatives	Any drugs which increase BP or DA	CYP2D6, CYP3A4
Schedule	**IV (low)**		**III (moderate potential for abuse)**			**IV (low)**	-
REMS	No		**Yes**			No	No

C/I=contraindication; CV=cardiovascular; HTN=hypertension; HA=headache; N=nausea; V=vomiting; D=diarrhea; DA=dopamine; BBW=black box warning; CNS=central nervous system; MAOI=monoamine oxidase inhibitor; N/A=not applicable

Provigil. Product label. Teva Pharmaceuticals. Jan 2015.
Nuvigil. Product label. Teva Pharmaceuticals. Feb 2017.
Xyrem. Product label. Jazz Pharmaceuticals. April 2023.
Xywav. Product label. Jazz Pharmaceuticals. May 2025.
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Comparative Efficacy & Safety

Systematic Reviews and Metanalysis

Measures of Efficacy

Measure	Description
Epworth sleepiness scale (ESS)	• An **8-item, patient-rated** questionnaire which assesses perceived likelihood of falling asleep during usual daily life activities (range 0 to 24, with higher scores indicating a higher sleep propensity) • ESS scores of **0 to 10 indicate normal** levels of daytime sleepiness, and scores of **11 to 24** demonstrate **increasing** levels of excessive daytime sleepiness, with scores of **16 to 24** representing **severe** sleepiness
Maintenance of wakefulness test (MWT)	• MWT **measures a patient's ability to remain awake during the daytime** in a darkened, quiet environment • Patients instructed to remain awake for as long as possible during 40-minute test sessions; sleep latency was determined as the mean # of minutes patients could remain awake in the first 4 of 5 test sessions. • A **MWT sleep latency of ≤ 8 minutes is indicative of narcolepsy**

Gonçalves, et al. *Sleep Med*. 2023;109:261-269.
Sagaspe, et al. *Sleep Med*. 2019;55:1-5.

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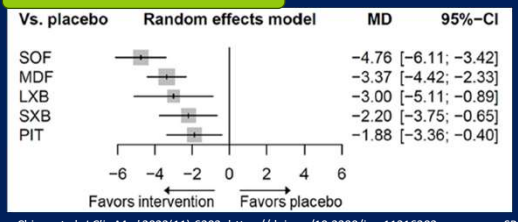
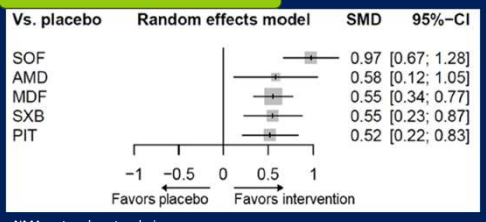
SR & NMA on EDS in Adults with Narcolepsy

Study Design	Treatments	Primary Endpoints
Network metanalysis 19 RCTs (n=2504 patients) ❑ 5 RCTs for ESS ❑ 5 RCTs for MWT	• solriamfetol (SOF) • modafinil (MDF) • lower-sodium oxybate (LXB) • sodium oxybate (SXB) • pitolisant (PIT)	• Epworth Sleepiness Scale (ESS) • Maintenance of Wakefulness Test (MWT) Numerous secondary endpoints • Safety (Adverse events)
ESS Results: **Solriamfetol** achieved the highest ranking and was **superior to PIT and SXB** MWT Results: **Solriamfetol** achieved the **highest ranking** and was **superior to PIT and MDF**		
Clustered ranking plot supported that efficacy–safety profiles of PIT, SXB, and MDF are more balanced than solriamfetol → choice of medication for EDS in narcolepsy should be made on an individual basis		

Results: ESS



Results: MWT

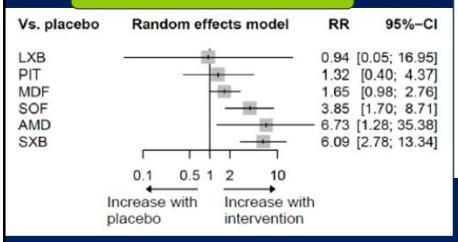


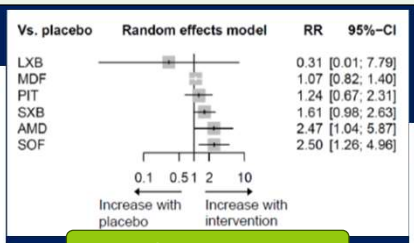
Chien, et al. *J Clin Med* 2022(11);6302. https://doi.org/10.3390/jcm11216302. SR=systematic reviews; NMA=network metanalysis

NMA: Safety Analysis for Narcolepsy

Study Design	Treatments	Endpoints
Network metanalysis 19 RCTs (n=2504 patients) – 5 RCTs for ESS – 5 RCTs for MWT	• solriamfetol (SOF) • modafinil (MDF) • lower-sodium oxybate (LXB) • sodium oxybate (SXB) • pitolisant (PIT)	Numerous secondary endpoints • **Safety (Adverse events)**
Clustered ranking plot supported that **efficacy–safety profiles of PIT, SXB, and MDF are more balanced than solriamfetol** → choice of medication for EDS in narcolepsy should be made on an individual basis		

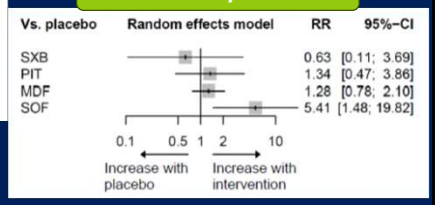
Results: GI ADEs





Results: Neuro ADEs

Results: Psych ADEs

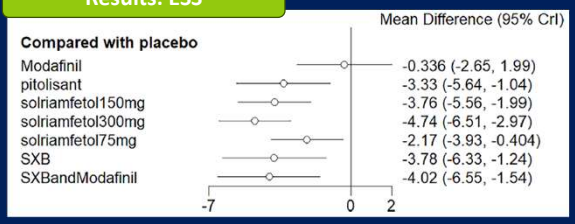


Chien, et al. *J Clin Med* 2022(11);6302. https://doi.org/10.3390/jcm11216302. NMA=network metanalysis

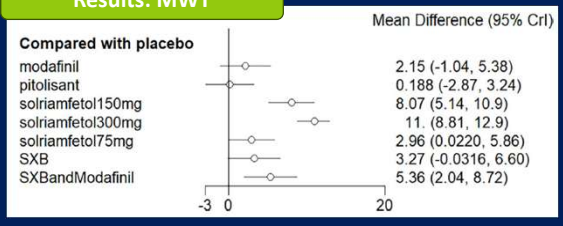
NMA of Wake-Promoting Agents for Narcolepsy

Study Design	Treatments	Endpoints
Network metanalysis 13 RCTs	• solriamfetol • armodafinil/modafinil • sodium oxybate (SXB) • pitolisant	• Epworth Sleepiness Scale (ESS) • Maintenance of Wakefulness Test (MWT) • Cataplexy frequency, # of subjects with ESS scores < 10, SD of lane position (SDLP) score, and ADRs
Results: All drugs > PBO in efficacy; **solriamfetol 300mg > other drugs** in ↓ ESS scores and prolonging sleep latency ADRs: SXB → diarrhea/vomiting; pitolisant → nausea; SXB + modafinil → dizziness		

Results: ESS



Results: MWT



Yan, et al. *BMC Neurology* 2025(25):466. https://doi.org/10.1186/s12883-025-04328-9.

Sodium Oxybate Comparison

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Sodium oxybate and Sodium Content

At rec dose of 9g/night	sodium oxybate	sodium oxybate +	sodium oxybate
Sodium Content/night	1640 mg	131 mg	1640 mg
MFR	Jazz		Avadel
CV outcomes in trials	**3 trials pooled data, NR**	**1 trial, NR**	**1 trial, NR**

American Heart Association Sodium Recs: <2300 mg/day, <1500 mg/day with hypertension

https://www.heart.org/en/health-topics/high-blood-pressure/changes-you-can-make-to-manage-high-blood-pressure/shaking-the-salt-habit-to-lower-high-blood-pressure

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Indirect Comparison Sodium oxybate

	sodium oxybate		sodium oxybate +		sodium oxybate XR	
Trial	R, DB, PC		2-week R, DB withdrawal		R, DB, PC	
	placebo	Xyrem	placebo	Xywav	placebo	Lumryz
Δ from baseline: **Epworth Sleepiness Scale**	18 → Δ -1	19→ Δ -5	B: 13→Δ +3	B: 14→Δ 0	18→ Δ -3	17→ Δ -7
	Tx vs PBO: Δ -4 (p<0.001)		-		**Tx vs PBO: Δ -4 (p<0.001)**	
Δ from baseline: **cataplexy attacks per week**	21→ Δ -4	24→Δ -16	B: 7→Δ +12	B: 9→Δ +0.1	B: 20→Δ -5	B: 19→Δ -12
	Tx vs PBO: Δ -12 (p=0.0016)		-		**Tx vs PBO: Δ -7 (p<0.001)**	

R=randomized; DB=double-blind; PC=placebo-controlled; PBO=placebo; TX=treatment

Xyrem. Product label. Jazz Pharmaceuticals. April 2023.
Xywav. Product label. Jazz Pharmaceuticals. May 2025.
Lumryz. Product label. Avadel CNS. Oct 2024.

SXB Limitations & Newer Formulations

Key Limitations of SXB

- HIGH sodium content — 1,640 mg at maximum dose
- WPA onset may take 4–8 weeks
- ~70–75% of patients miss the 2nd dose
- 80% who miss 2nd dose have reduced next-day function
- ~59% take 2nd dose late (>4 hours)
- 92% get out of bed after 2nd dose — risk of falls
- 8% experience falls; 4–32% sustain injuries

Low-Sodium Oxybate (LXB / Xywav)

- Calcium, Magnesium, Potassium, & Sodium Oxybates
- 92% LESS sodium (131 mg at max dose)
- FDA-designated 'superior' due to lower sodium
- Gram-for-gram transition from SXB
- Liver impairment: ↓ initial nightly dose by half

Once-Nightly SXB (ON-SXB / Lumryz)

- Extended-release: single dose at bedtime
- Mix 80 mL water; do not use hot water
- Gram-for-gram transition from SXB
- Same HIGH sodium as original SXB
- Avoid in liver impairment

SXB=sodium oxybate; WPA=wakefulness-promoting agent

Managed Care Considerations

- Pharmacy benefit issues
  - Coordination of care
  - Access
- New drug reviews
- Drug class reviews
- Clinical effectiveness
  - Head-to-head studies
  - Systematic reviews
  - Meta-analysis
- Cost effectiveness
  - Cost-minimization analysis (CMA)
  - Cost-effectiveness analysis (CEA)
  - Cost-utility analysis (CUA)
  - Budget impact analysis (BIA)
  - Sensitivity analysis
- Utilization management
  - Prior authorization (PA)
  - Quantity limits (QL)
  - Restricted distribution (RD)
- Pipeline (Emerging Therapies)

Likely Prior Authorization Requirements
pitolisant, solriamfetol

- Age requirement
- FDA-approved indications
- Prescribed by a specialist
  - Neurologist, psych, sleep medicine
- Dx based on objective testing
- Intolerant to, contraindication, or insufficient response to:
  - Modafinil or armodafinil
  - Stimulant-based therapy
- No concurrent use with CNS depressants and/or oxybates
- Initial approval with an expiration; renewal criteria
  - Attestation regarding continued clinical improvement

Reference: Adapted from publicly available health plan PA criteria.

Likely Prior Authorization Requirements
sodium oxybates

- Age requirement
- FDA-approved indications
- Prescribed by a specialist
  - Neurologist, psych, sleep medicine
- Dx based on objective testing
- Generic sodium oxybate preferred
- Intolerant to, contraindication, or insufficient response to:
  - Modafinil or armodafinil
  - Stimulant-based therapy
- No concurrent use with CNS depressants
- Initial approval with an expiration; renewal criteria
  - Attestation regarding continued clinical improvement

Reference: Adapted from publicly available health plan PA criteria.

Specialty Pharmacy Considerations

- Limited distribution drugs and thus can only be dispensed from specialty pharmacies
- "Specialty tier" co-pays likely from many health plans/PBMs
- May provide additional "handholding" to help improve adherence, provide detailed administration instructions, manage REMS requirements, and mitigate AEs
- Aid in cold chain management
- May monitor therapeutic outcomes, quality of life, and patient satisfaction metrics

Emerging Therapies

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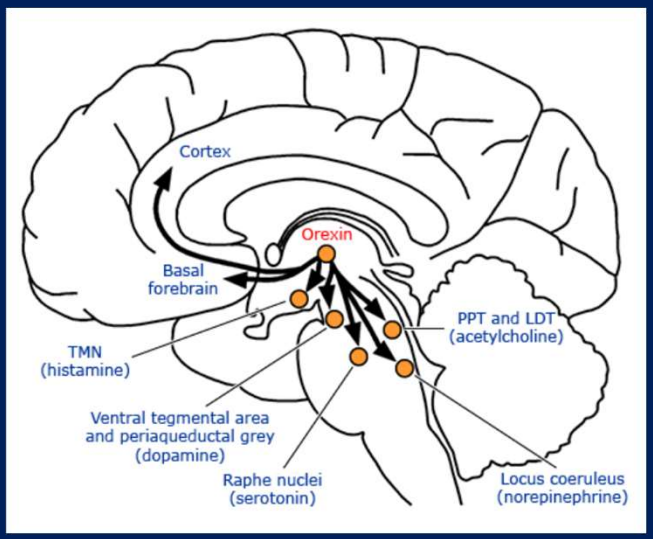
Narcolepsy Medication Targets



Graphic 73012 Version 1.0

What are Orexins?

- Neuropeptides produced exclusively in the lateral hypothalamus
  - Two peptides (orexin-A and orexin-B); also called hypocretins
- Released during wakefulness and increase the activity of many brain regions that promote wakefulness
- Healthy individuals = orexin signaling normally stabilizes wakefulness and prevents inappropriate transitions into sleep
- NT1 individuals = loss of orexin neurons allows rapid transitions into sleep and REM sleep-related phenomena (e.g., cataplexy, sleep paralysis)

Orexin-A (OX-A)
- 33 amino acids, more stable
- Higher CNS penetration
- Larger, cyclic structure

Orexin-B (OX-B)
- 28 amino acids
- Linear peptide, shorter t1/2
- Lower CNS penetration

Receptors	Orexin-A affinity	Orexin-B affinity	Primary Locations
OX_1R	High	Lower (~10-fold less)	Locus coeruleus, prefrontal cortex
OX_2R	High	Equally high	Tuberomammillary nucleus, ventral tegmental area, nucleus accumbens

Both are G-protein-coupled receptors (primarily Gq-coupled), and their activation increases neuronal excitability

Scammell T, et al. *Neuron*. 2017;93(4)747.

Dual Orexin Receptor Antagonists (DORAs)

Drug	Target	Approved for Insomnia	Notes
Suvorexant (Belsomra)	Dual OX_1R/OX_2R	2014	First approved DORA; Half-life = 12 hours
Lemborexant (Dayvigo)	Dual OX_1R/OX_2R	2019	Longest half-life = 17-19 hours
Daridorexant (Quviviq)	Dual OX_1R/OX_2R	2022	Half-life = 8 hours

Contraindicated in Narcolepsy

Emerging Therapies
Orexin 2 Receptor Agonists (OX2R)

Drug	Target	Status
oveporexton	OX2R	• Anticipated approval: Jan 12, 2027; specialty drug
alixorexton	OX2R	• Jan 2026: given breakthrough designation • Starting phase 3 studies (VIBRANCE study program)
ORX750	OX2R	• In phase 2 studies

Source: clinicaltrials.gov 3-15-26
NT=narcolepsy type; IH=Idiopathic Hypersomnia

Emerging OX2R Therapies

OX2R	Sponsor	Conditions	NCT/Acronym	Phase	Completion	Details
oveporexton TAK-861	Takeda	NT1	NCT05816382	3	2028	• **Anticipated approval: 2027** • **Oral selective OX2R** • Specialty drug; Priority review
		NT1; Narcolepsy + Cataplexy	NCT07363720	3	Oct 2026	
alixorexton ALKS 2680	Alkermes	NT1	Brilliance NT1	3	May 2027	• **Q12026 phase 3 studies to start** • **Oral selective OX2R** • Vibrance study program
ORX750	Centessa	NT1; NT2; IH	Phase 2			• **Oral selective OX2R**

NT1=narcolepsy type 1; NT2=narcolepsy type 2; IH=idiopathic hypersomnia

Other Emerging Therapies

Investigational Agent	Sponsor	Conditions	NCT/Acronym	Phase	Completion	Details
reboxetine AXS-12	Axsome	NT1	SYMPHONY ENCORE	3	Completed	• NE reuptake inhibitor
mazindol ER NLS-1021	NLS	NT1; Narcolepsy + Cataplexy	AMAZE	3	Not yet recruiting	• Triple monoamine reuptake inhibitor + partial OX2R
samelisant SUVN-G3031	Suven	Narcolepsy	NCT04072380	2	Completed	• Potent/selective histamine-3 receptor inverse agonist

Source: clinicaltrials.gov 3-15-26; Individual manufacturer websites
NT=narcolepsy type; IH=Idiopathic Hypersomnia; NE=norepinephrine

Corser, et al. *SLEEP*. 2023;46:A257; ClinicalTrials.gov identifier NCT04923594.
Nirogi, et al. *Sleep Med.* 124:618-626. https://doi.org/10.1016/j.sleep.2024.10.037

Oveporexton — Phase 2 Trial in NT1

Study Overview

Study Design:
R, DB, PC phase 2 study in adults with NT1 for 8 weeks

Doses Studied:
0.5mg, 2mg, 5mg, and 7mg BID
Oral (taken at 8 AM and 11 AM)

Population:
Adults (n=112) with NT1
Avg age = 34 years
85.7% Caucasian

Most common AEs:
insomnia (48%)
urinary urgency (33%)
urinary frequency (32%)

Results vs Placebo

Dose	Sleep Latency	ESS Score	Cataplexy Rate
0.5 mg BID	+12.5 min	−8.9	3.3/wk
2 mg BID	+23.5 min	−13.8	3.2/wk
2 → 5 mg	+25.4 min	−12.8	2.1/wk
7 mg QD	+15 min	−11.3	5.89/wk

Dauvilliers, et al. *N Engl J Med* 2025;392:1905-16.

ICER: Cost Analysis and Value Draft

Study Design	Drugs Included	Outcomes
Effectiveness and value of **oveporexton** for narcolepsy **Time horizon**: Lifetime **Health States**: Initial treatment, subsequent treatment, and death **Perspective**: Health system	oveporexton 1 mg BID or 2 mg BID	• Daytime symptoms (e.g., EDS, cataplexy) • REM-related symptoms (e.g., sleep paralysis, sleep-related hallucinations) • Work or school performance • QoL measure (e.g., cognitive and fatigue symptoms) • ADEs

RESULTS

- A NMA comparing oveporexton to modafinil/armodafinil, sodium oxybates, and pitolisant showed that treatment with **oveporexton resulted in statistically significant and clinically meaningful differences in MWT scores and ESS scores vs all other treatments**
- Overall, treatment with oveporexton resulted in statistically significant and clinically meaningful improvements in NT1 symptoms, as well as HRQoL, with few serious harms. The **cost-effectiveness of oveporexton** compared with no pharmacological therapy or other active treatments **will depend on its actual price**.

HRQoL=health-related quality of life; ADE=adverse drug events; EDS=excessive daytime sleepiness

Lin, et al. Oveporexton for Narcolepsy: Effectiveness and Value; Draft Report. Institute for Clinical and Economic Review, March 12, 2026. https://icer.org/assessment/narcolepsy-2026/

Interactive Question

If oveporexton receives FDA approval in 2027, what do you anticipate will be the PRIMARY barrier to patient access at your institution?

a) High acquisition cost / formulary placement
b) REMS program requirements
c) Lack of clinical familiarity with orexin agonists
d) Payer prior authorization criteria
e) Patient hesitancy toward new agents

The Role of the Pharmacist in Narcolepsy

Medication Access	Drug Interactions	Safety Monitoring
• Navigate **REMS** programs for oxybates. • Connect patients with **specialty pharmacies** for pitolisant. • Identify **co-pay assistance** programs.	• Monitor for **CYP interactions** (modafinil, pitolisant) • Counsel on **hormonal contraceptive efficacy** ↓ • Manage **CNS depressant** combos.	• **Monitor BP/HR with stimulants and solriamfetol.** • Watch for **QTc with pitolisant.** • Counsel on **fall risk** with 2nd SXB dose; screen for **skin reactions** with modafinil.

Cardiovascular Risk	Adherence Support	Reproductive Counseling
• **Narcolepsy increases CV disease risk by 20%.** • **Monitor** BP, weight, lipids, A1c. • **Individualize** oxybate formulation based on **sodium tolerance.**	• **Adherence** ~55% with WPAs. 77% of forgetfulness-driven non-adherence. • **Counsel** on importance; **manage adverse effects** early.	• Many narcolepsy medications carry **pregnancy risks**. • **Discontinue** for planned pregnancy. • **Counsel** on **contraceptive interactions**.

Key Takeaways

- Evidence-based guidelines support pharmacotherapy for NT1 with agent selection individualized based on clinical judgment, comorbidities, safety profile, and patient preference.
- For EDS, guidelines recommend comprehensive medical evaluation prior to initiating pharmacotherapy; management by sleep specialists is preferred.
- NT1 diagnosis: Cataplexy is measured using a patient diary/patient report.; clinical guidelines ICSD-3-TR and DSM-5-TR specify diagnostic criteria.
- Diagnostic delay averages 8-10 years; EDS and cataplexy are frequently misattributed to psychiatric, behavioral, or metabolic conditions, highlighting the need for increased clinical awareness.
- Patient-reported outcomes (ESS, NSS, FOSQ, PGI-C/S) capture disease burden and are essential to diagnosis, treatment monitoring, and shared decision-making in both clinical and managed care settings.

Key Takeaways

- In a NMA, solriamfetol, sodium oxybate, pitolisant, and armodafinil demonstrated statistically significant and clinically meaningful ESS reductions vs. placebo
  - Solriamfetol ranked highest for both ESS and MWT outcomes; however, treatment selection should remain individualized given differences in safety and adherence profiles
  - For cataplexy: pitolisant and sodium oxybate significantly reduced cataplexy rate vs. placebo; sodium oxybate agents were comparable in ESS reductions across formulations
- Common AEs across agents include neurologic (headache, dizziness), gastrointestinal (nausea, vomiting), and psychiatric (anxiety, insomnia) symptoms; none of the approved agents resulted in a significantly increased risk for serious ADEs
- When choosing an agent, clinicians must consider warnings, precautions, REMS, and scheduling and abuse potential
- Narcolepsy is independently associated with a ~20% increased cardiovascular risk; clinicians should monitor labs and individualize oxybate formulation selection based on sodium tolerance (HTN, heart failure)

Key Takeaways

- Several orexin 2 agonists (OX2R) are in the pipeline and may change the narcolepsy treatment paradigm since they directly address NT1 pathophysiology
- Oveporexton demonstrated significant improvements in MWT, ESS, and cataplexy rate
  - FDA approval anticipated January 2027
  - ICER NMA showed superior MWT and ESS vs. all current agents
  - Anticipated specialty drug
- Managed care strategies for NT1 should incorporate clinical evidence, safety profiles, and cost-effectiveness
  - Formulary placement, PA criteria, and step therapy policies should avoid creating additional access barriers
  - Payers should proactively develop evidence-based PA criteria for oveporexton, leverage co-pay assistance, and prepare for potential formulary disruption upon FDA approval
- Pharmacists are central to REMS navigation, DDI monitoring, AE management, adherence support (~55% with WPAs), and reproductive and CV risk counseling

Questions

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Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Shelby Cole *Faculty*	Disclosed no relevant financial relationships.
Amy Lugo *Faculty*	Disclosed no relevant financial relationships.
Luis Ortiz *Faculty*	Advisor: Alkermes, Avadel, Harmony Biosciences, Jazz Pharmaceuticals; Individual Stocks/Stock Options: Ascendis; AstraZeneca; Moderna; Pfizer; Faculty/Speaker: Takeda
Drake Reiter *Peer Reviewer*	Advisor and/or Consultant: Avalon Healthcare Solutions, BioMedical Insights, Capyision, COEUS, Comprehensive Care Sustainability Collaborative, Eversana, GLG, Havas, Health Institutes Research Center (HIRC), Impact Education, MMIT, SUN Pharma
Jennifer L. Evans *Planner*	Disclosed no relevant financial relationships.

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FACULTY BIOGRAPHY

Shelby Cole **RN, BSN; Patient Advocate** **Wake Up Narcolepsy**	Shelby Cole, RN, BSN is a registered nurse, patient advocate, and speaker living with narcolepsy type 1. After years of unexplained symptoms prior to diagnosis, Shelby became passionate about raising awareness and helping healthcare professionals better understand the real-life impact of narcolepsy. By combining her clinical background with lived experience, she offers a unique perspective that helps bridge the gap between patients and providers, emphasizing earlier recognition, compassionate care, and improved quality of life for those living with sleep disorders. Shelby works from home as a clinical QA registered nurse and is actively involved in advocacy and education efforts within the narcolepsy community. She lives with her husband, a ln ironworker, and their three children. She enjoys spending time with family. Through speaking and community outreach, she is committed to sharing her story to reduce stigma, support others navigating narcolepsy, and help advance understanding of the condition among healthcare professionals.
Amy Lugo, PharmD, BCPS, BC-ADM, FAPhA **Founder & CEO** **LoneStar Health Solutions**	Dr. Lugo is the Founder and CEO of LoneStar Health Solutions, providing managed care pharmacy consulting. She has 16 years of managed care experience in consulting and with the DoD and TRICARE, managing the pharmacy benefit via formulary management, pharmacoeconomics, benefit design, data analytics, and utilization management. She also has experience in a variety of practice settings, including academia and health-system pharmacy, as a clinical specialist in primary care, inpatient medicine, as a clinical coordinator, and director of pharmacy residency programs. Dr. Lugo is passionate about giving back to the profession and has many years of volunteer service with AMCP, APhA, and ASHP. She received her PharmD from University of Florida, completed a primary care residency in Asheville, NC and is board certified in Pharmacotherapy and advanced diabetes management. She enjoys mentoring students and residents, photography, being mom to 14-year-old Emma Grace, playing tennis, and cheering on her Gators.
Luis E. Ortiz, MD **Assistant Professor of Pediatrics** **Johns Hopkins School of Medicine**	Dr. Luis Ortiz is an Assistant Professor of Pediatrics at Johns Hopkins University School of Medicine and a sleep medicine physician at Johns Hopkins All Children's Hospital in St. Petersburg, FL. After earning his medical degree from the University of Rochester School of Medicine & Dentistry in 2010. He completed a combined internal medicine & pediatrics residency at Charleston Area Medical Center/West Virginia University (Charleston Division) in 2014 followed by fellowships in pediatric pulmonology at Johns Hopkins University School of Medicine and sleep medicine at the Children's Hospital of Philadelphia, completed in 2018. His clinical and research interests include narcolepsy, central hypersomnias, obstructive sleep apnea, and insomnia. Personally living with narcolepsy, Dr. Ortiz brings a unique, empathetic perspective to his clinical practice. This firsthand experience deeply informs his advocacy and educational work, allowing him to provide personalized care and support for patients and families navigating sleep disorders and rare diseases.