# Drug Class Utilization and Age-Related Trends in Narcolepsy and Idiopathic Hypersomnia: A Claims Database Analysis

Rakesh Bhattacharjee, MD[1]; Michael J. Thorpy, MD[2]; Sarah D. Meskill, MD[3]; Murad C. Assaad, MD[4]; Anne Marie Morse, DO[5]; Jennifer Gudeman, PharmD[6,a]; Brian Abaluck, MD[7]

[1]University of California, San Diego, San Diego, CA, USA; [2]Albert Einstein College of Medicine, New York, NY, USA; [3]Tricoastal Narcolepsy and Sleep Disorder Center, Sugar Land, TX, USA; [4]Laureate Medical Group, Atlanta, GA, USA; [5]Geisinger Commonwealth School of Medicine, Geisinger Medical Center, Janet Weis Children's Hospital, Danville, PA, USA; [6]Avadel Pharmaceuticals, Chesterfield, MO, USA; [7]Alkermes, Inc., Waltham, MA, USA*; [a]At the time of the study

**Poster 376**

## INTRODUCTION

- Central disorders of hypersomnolence (CDoH), including narcolepsy type 1 (NT1), narcolepsy type 2 (NT2), and idiopathic hypersomnia (IH), are rare, chronic sleep disorders characterized by excessive daytime sleepiness (EDS)[1,2]
- Symptom management has included medications approved by the US Food and Drug Administration (FDA; eg, oxybates for narcolepsy and IH, wake-promoting agents for narcolepsy) and/or off-label therapies (eg, antidepressants, sedative hypnotics, dual orexin receptor antagonists)[2-10]
- As more therapies become available,[11] it is important to understand medication usage patterns
  - For narcolepsy, the last clinical practice guidelines (CPGs) released by the American Academy of Sleep Medicine (AASM) in 2021 included 4 strong recommendations for the treatment of EDS (modafinil, pitolisant, sodium oxybate [SXB], and solriamfetol) and 2 strong recommendations for the treatment of cataplexy (pitolisant and SXB); armodafinil, dextroamphetamine, and methylphenidate received conditional recommendations[12]
  - For IH, AASM strongly recommended modafinil and conditionally recommended SXB, clarithromycin, methylphenidate, and pitolisant[12]
  - The cutoff date for study inclusion in the AASM CPGs was August 2020[13]; since that time, 2 oxybate therapies have been approved by the FDA
    - Therefore, analyses of treatment use patterns of the time since the AASM CPGs were published may be warranted

## OBJECTIVE

- To assess medication usage patterns across different medication classes among patients with NT1, NT2, and IH

## METHODS

### DATA SOURCE AND PATIENT POPULATION

- Data from the Komodo Health claims database, comprising data from >330 million individuals in the US, were used to retrospectively identify patients with NT1, NT2, or IH in 2023 (ie, ≥1 *International Classification of Diseases,10th Revision* [ICD-10] diagnosis code in 2022 or 2023)
- The patient population was narrowed by defining a high-confidence diagnostic subset (**Table**)
  - High-confidence diagnosis was defined as ≥2 relevant ICD-10 codes for only 1 CDoH documented ≥30 days apart without any diagnoses of a different CDoH during the study period of 2018-2023

**TABLE: Inclusion and Exclusion Criteria for High-Confidence Diagnostic Subset**

| Inclusion criteria | Exclusion criterion |
|---|---|
| • 100% claim availability for 6 consecutive years (2018-2023)<br>• ≥2 claims documented ≥30 days apart with a relevant ICD-10 code<br>– NT1: G47.411, G47.421<br>– NT2: G47.419, G47.429<br>– IH: G47.11, G47.12 | • Multiple distinct diagnoses of NT1, NT2, or IH |

ICD-10, *International Classification of Diseases, 10th Revision*; IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- Treatment was defined as any paid prescription claim linked to a patient in the study cohort with National Drug Codes corresponding to narcolepsy or IH treatments after receiving a diagnosis code
- Valid age and sex data were required as the patients were grouped according to these categories

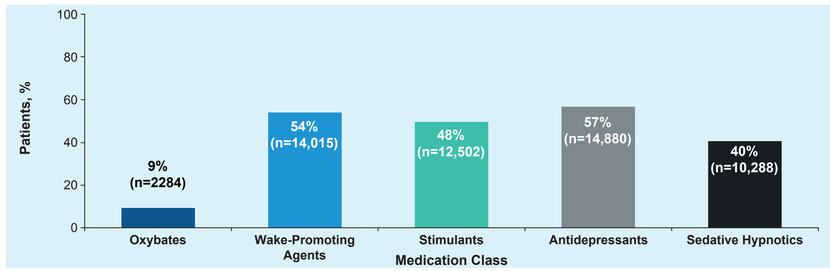
### DATA ANALYSIS

- The number (%) of patients with prescriptions for the following medication classes were calculated by diagnosis and age range
  - Oxybates (ie, immediate release [IR] SXB and IR calcium, magnesium, potassium, and sodium oxybates [mixed-salt oxybates])
  - Wake-promoting agents (eg, modafinil, armodafinil, pitolisant, solriamfetol)
  - Stimulants (eg, amphetamines, methylphenidate)
  - Antidepressants (eg, bupropion, sertraline)
  - Sedative hypnotics (eg, zolpidem, lorazepam)
- All data were analyzed descriptively

## RESULTS

- The Komodo database included 154,750 individuals with ≥1 NT1, NT2, or IH diagnosis in 2023
- The high-confidence diagnosis subset consisted of 26,003 patients
  - These patients were most commonly diagnosed with NT2 (65%; n=16,871), followed by IH (24%; n=6287) and NT1 (11%; n=2845)
- The age distribution was generally consistent among the diagnoses for each of the medication classes
  - The age group with the highest use across all medication classes was 45-64 years
- Antidepressants, wake-promoting agents, and stimulants were the medication classes used by the largest numbers of patients (**Figure 1**)

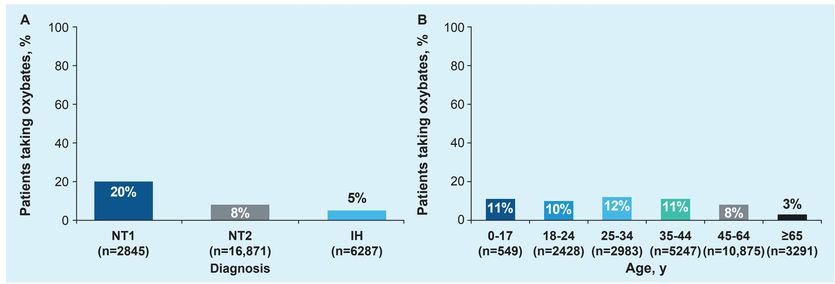
### FIGURE 1: Medication Use




Percentages were calculated based on the total number of patients with a high-confidence diagnosis (N=26,003), who may have received multiple medications across medication classes. 75 patients received dual orexin receptor antagonists (ie, daridorexant and lemborexant).

- 2284 (9%) patients were prescribed oxybates
  - 20% of patients with NT1 and 8% of patients with NT2 received oxybates (**Figure 2A**)
  - The proportion of patients who received treatment with oxybates was relatively consistent among age groups, with a trend toward less frequent use for adults aged ≥65 years (**Figure 2B**)

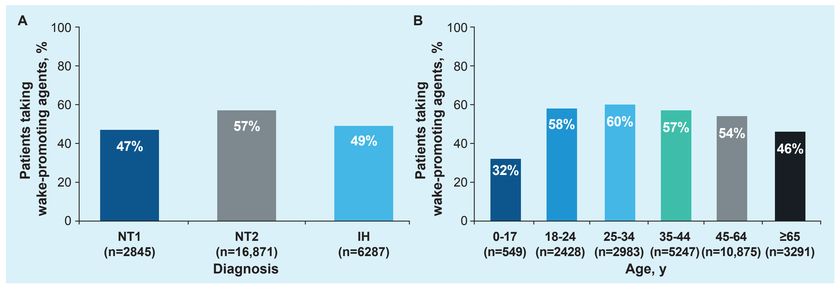
### FIGURE 2: Oxybate Use by (A) Diagnosis and (B) Age




n values represent the sample sizes of the subgroup populations. Sample size=26,003.
IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- 14,015 (54%) patients were taking wake-promoting agents
  - Wake-promoting agent use was relatively similar among diagnoses (**Figure 3A**) and across age groups, except for pediatric patients (**Figure 3B**)

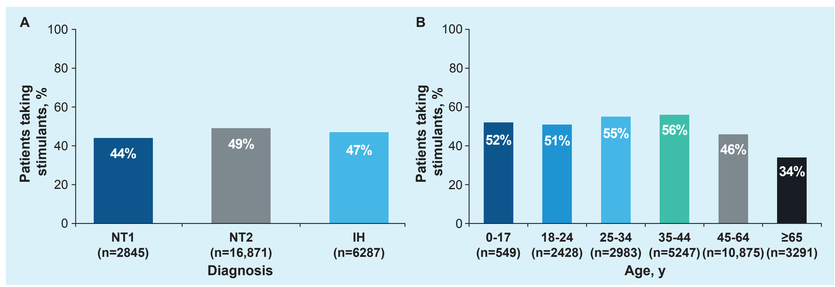
### FIGURE 3: Wake-Promoting Agent Use by (A) Diagnosis and (B) Age




n values represent the sample sizes of the subgroup populations. Sample size=26,003.
IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- 12,502 (48%) of patients were prescribed stimulants
  - Stimulant use was generally consistent among diagnoses (**Figure 4A**) and across age groups, with a trend toward less frequent use with older age (ie, ≥45 years; **Figure 4B**)

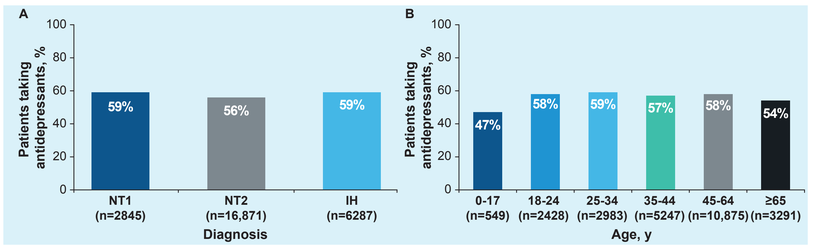
### FIGURE 4: Stimulant Use by (A) Diagnosis and (B) Age




n values represent the sample sizes of the subgroup populations. Sample size=26,003.
IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- 14,880 (57%) patients were prescribed antidepressants
  - Antidepressant use was consistent among diagnoses (**Figure 5A**) and across age groups (**Figure 5B**)

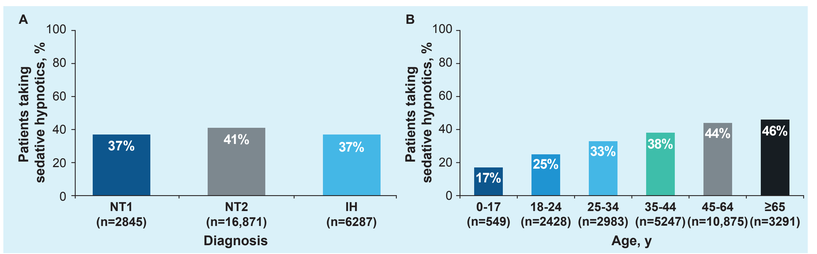
### FIGURE 5: Antidepressant Use by (A) Diagnosis and (B) Age




n values represent the sample sizes of the subgroup populations. Sample size=26,003.
IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- 10,288 (40%) patients received sedative hypnotics
  - Sedative hypnotic use was relatively consistent among diagnoses (**Figure 6A**) and exhibited a trend toward more frequent use throughout adulthood (**Figure 6B**)

### FIGURE 6: Sedative Hypnotic Use by (A) Diagnosis and (B) Age




n values represent the sample sizes of the subgroup populations. Sample size=26,003.
IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

## STUDY LIMITATIONS

- Available clinical information in claims databases limits the interpretation of these data
  - In particular, reliance on ICD-10 codes without clinical assessments confirming diagnoses of CDoH may have resulted in misclassification of NT1, NT2, and IH
  - Paid prescription claims do not confirm medication initiation, adherence, or persistence
  - Diagnosis for which medications were prescribed or when the medications were initiated was not documented; although some classes of medication may be used to treat symptoms of CDoH (eg, antidepressants for cataplexy and sedative hypnotics for nighttime symptoms) or comorbid conditions, the reason for their use across diagnoses remains unclear
- These treatment data only reflect 17% of patients diagnosed with NT1, NT2, or IH; thus, this subset may not represent the overall patient populations living with these CDoH
  - The study period for this analysis only included data up to 2023; current treatment use trends may be different with more recent approvals of medications, such as extended-release, once-nightly SXB

## CONCLUSIONS

- Despite the strong recommendation by the AASM for SXB as narcolepsy treatment, oxybates were used by <10% of patients in this population of people diagnosed with a CDoH and were used considerably less often than medications not approved by the FDA or recommended by the AASM for CDoH (eg, antidepressants and sedative hypnotics)
- Oxybate use by patients with NT2 was less than half that of patients with NT1 despite the strong recommendation by AASM for treatment of EDS; this disparity was not demonstrated by the treatment patterns for other medication classes
- Common use of antidepressants (57%) may suggest prevalence of mood disorders among patients with CDoH, even though clinical trial data are limited
  - Antidepressants may be prescribed to treat cataplexy in patients with NT1; however, their use was consistent across diagnoses
- Given the lifelong nature of CDoH, the gradual decline of wake-promoting agents and stimulant use observed among patients aged ≥35 years warrants further investigation to determine if these trends reflect evolving prescribing practices or variations in disease severity
- The widespread utilization of sedative hypnotics (40%) and their increased utilization with age underscores the prevalence and need for management of nighttime symptoms, including fragmented sleep, across CDoH
  - Clinician preference for off-label sedative hypnotic use over FDA-approved oxybate therapies merits further discussion and investigation into the primary factors contributing to this disparity

### ACKNOWLEDGMENTS

The authors acknowledge Johanna Hertel of Alkermes, Inc. (Waltham, MA) for contributions to data analysis. Medical writing support was provided by Kelby Killoy, PhD, from Citrus Health Group, Inc. (Chicago, IL) and was funded by Avadel Pharmaceuticals (Chesterfield, MO).

### DISCLOSURES

**RB** has served as a consultant, speaker, and/or on an advisory board for Avadel Pharmaceuticals, Harmony Biosciences, and Jazz Pharmaceuticals. **MJT** has served as a consultant or on advisory boards for Avadel Pharmaceuticals, Axsome Therapeutics, Balance Therapeutics, Eisai, Harmony Biosciences, Jazz Pharmaceuticals, NLS Pharmaceuticals, Suven Life Sciences Ltd., and Takeda Pharmaceutical Co. **SDM** has received funding for conducting research studies from Alkermes, Inc., Avadel Pharmaceuticals, Axsome Therapeutics, and Jazz Pharmaceuticals and has served on an advisory board for Avadel Pharmaceuticals. **MCA** has served as a consultant, speaker, and/or on an advisory board for Avadel Pharmaceuticals, Axsome Therapeutics, and Jazz Pharmaceuticals. **AMM** has served as an investigator, consultant, speaker, and/or on advisory boards for Alkermes, Inc., Aprinnel, Avadel Pharmaceuticals, Axsome Therapeutics, Eisai, Harmony Biosciences, Jazz Pharmaceuticals, Lilly, Noble Pharmaceuticals, Novartis, and Takeda Pharmaceutical Co.; has received grant funding from the National Institutes of Health, UCB Pharmaceuticals, Jazz Pharmaceuticals, ResMed Foundation, Coverys Community Healthcare Foundation, Harmony Biosciences, and Geisinger Health Plan; is the Chief Executive Officer of DAMM Good Sleep, LLC; and serves as an advisor for Neura Health, OpenEvidence, and FloraWorks. **JG** was an employee of Avadel Pharmaceuticals and is a consultant to Alkermes, Inc. **BA** is an employee of Alkermes, Inc.

### FUNDING

This study was funded by Avadel Pharmaceuticals (Chesterfield, MO). *Avadel Pharmaceuticals Limited (formerly Avadel Pharmaceuticals plc) is an affiliate of Alkermes plc.

### REFERENCES

1. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*. 3rd ed. American Academy of Sleep Medicine; 2014.
2. Dauvilliers Y, et al. *Sleep Med Rev*. 2022;66:101709.
3. Thorpy MJ, Dauvilliers Y. *Sleep Med*. 2015;16(1):9-18.
4. LUMRYZ® (sodium oxybate for extended-release oral suspension, CIII). Full Prescribing Information. Avadel Pharmaceuticals; 2025.
5. DAYVIGO® (lemborexant). Full Prescribing Information. Eisai Inc.; 2025.
6. QUVIVIQ (daridorexant). Full Prescribing Information. Idorsia Pharmaceuticals US Inc.; 2022.
7. Xywav® (calcium, magnesium, potassium, and sodium oxybate). Full Prescribing Information. Jazz Pharmaceuticals, Inc; 2025.
8. Xyrem® (sodium oxybate oral solution, CIII). Full Prescribing Information. Jazz Pharmaceuticals, Inc; 2025.
9. Wakix (pitolisant). Full Prescribing Information. Harmony Biosciences, LLC; 2024
10. Provigil (modafinil). Full Prescribing Information. Teva Pharmaceuticals; 2022.
11. Biscarini F, et al. *J Sleep Res*. 2025;34(5):e70118.
12. Maski K, et al. *J Clin Sleep Med*. 2021;17(9):1881-1893.
13. Maski K, et al. *J Clin Sleep Med*. 2021;17(9):1895-1945.

Copies of this poster can be obtained through this QR (Quick Response) code