Treatment Access for Narcolepsy Across Patient Demographic Characteristics: A Claims Database Analysis

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INTRODUCTION

- Narcolepsy is a rare, chronic sleep disorder characterized by excessive daytime sleepiness (EDS) that impacts patients of all ages across race and ethnicity[1,2]
- Medications approved by the US Food and Drug Administration (FDA) for the treatment of EDS and/or cataplexy include oxybates and wake-promoting agents[3-7]
- The 2021 American Academy of Sleep Medicine (AASM) clinical practice guidelines included the following recommendations for narcolepsy symptom management[8]:
  - 4 strong recommendations for the treatment of EDS (modafinil, pitolisant, sodium oxybate [SXB], and solriamfetol)
  - 2 strong recommendations for the treatment of cataplexy (pitolisant and SXB)
  - Conditional recommendations for armodafinil, dextroamphetamine, and methylphenidate for the treatment of EDS and/or cataplexy
- There are 3 formulations of oxybate available in the US: immediate-release SXB, immediate-release mixed-salt oxybates, and extended-release SXB[3-5]
- As more narcolepsy therapies become available, it is important to understand medication usage patterns, including across the lifespan in diverse patient populations

OBJECTIVE

- To characterize narcolepsy treatment patterns among patients of different races and ethnicities and age groups

METHODS

DATA SOURCE AND PATIENT POPULATION

- Retrospective analysis of data from the Komodo Health claims database, which comprises data from >330 million individuals in the United States
  - The closed claims data set was used to identify patients with narcolepsy type 1 (NT1) or narcolepsy type 2 (NT2) in 2023
- The patient population was narrowed by defining a high-confidence diagnostic subset (**Table**)
  - High-confidence diagnosis was defined as ≥2 relevant *International Classification of Diseases, 10th Revision* (ICD-10) codes documented ≥30 days apart, with the first of such claims prior to 2023
  - The diagnosis of a different narcolepsy type or idiopathic hypersomnia (IH) was exclusionary
- Treatment was defined as any paid prescription claim linked to a patient in the study cohort with National Drug Codes corresponding to narcolepsy treatments after receiving a diagnosis code
- Self-reported race or ethnicity data and age data were required

DATA ANALYSIS

- The proportions of patients who received the following narcolepsy treatments were calculated:
  - Strongly recommended narcolepsy treatment per 2021 AASM clinical practice guidelines (modafinil, pitolisant, solriamfetol, and SXB; other oxybates; and armodafinil)
    - Oxybate treatment
  - No indicated treatment for EDS
- All data were stratified by race and ethnicity (Black or African American, Hispanic or Latino, and white), and age and reported descriptively
  - Two-sided z-tests were used to compare Black or African American, or Hispanic or Latino categories to the reference category (white) within each age group for each treatment category
  - Due to very small sample size, patients who did not self-report as Black or African American, Hispanic or Latino, or white were excluded from the analysis

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

Inclusion criteria	Exclusion criteria
• Exactly 1 NT1 or NT2 diagnosis prior to 2023: – ≥2 claims with a relevant ICD-10 code ≥30 days apart, with the first such claim prior to 2023: ▪ NT1: G47.411, G47.421 ▪ NT2: G47.419, G47.429 • 100% claim availability (continuously enrolled) in 2023 • ≥1 claim for the diagnosed narcolepsy type in 2023	• Multiple distinct diagnoses of IH, NT1, or NT2 at any time • No medical or prescription claims for the diagnosed narcolepsy type in 2023

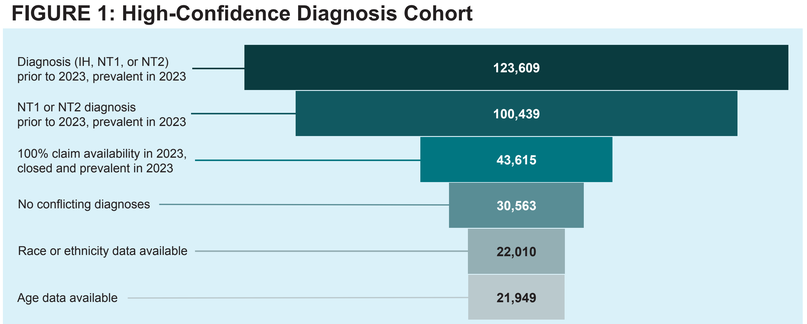
ICD-10, *International Classification of Diseases, 10th Revision*; IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

RESULTS

PATIENT CHARACTERISTICS

- The Komodo closed claims data set included 30,563 individuals with an NT1 or NT2 diagnosis in 2023; of these, 21,949 had race or ethnicity data and age data available **(Figure 1)**

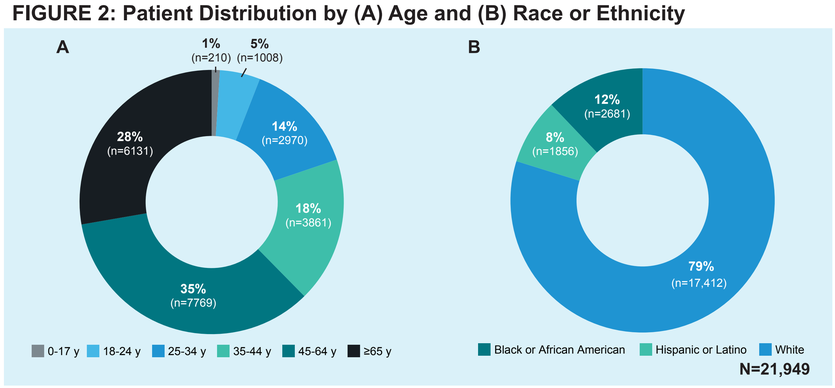
FIGURE 1: High-Confidence Diagnosis Cohort



IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- The majority of patients were aged 18-64 years (71%) and white (79%; **Figure 2**)

FIGURE 2: Patient Distribution by (A) Age and (B) Race or Ethnicity

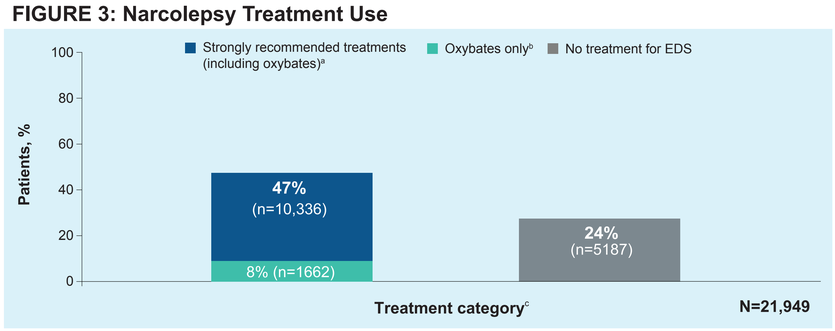


Percentages may not equal 100% due to rounding.

NARCOLEPSY TREATMENT PATTERNS

- Overall, 47% (n=10,336) of patients received a strongly recommended narcolepsy treatment in 2023 (**Figure 3**)
  - In the subset of those who received a strongly recommended treatment (n=10,336), 16% (n=1662) were treated with oxybates
- 24% (n= 5187) of patients did not receive any treatment for EDS

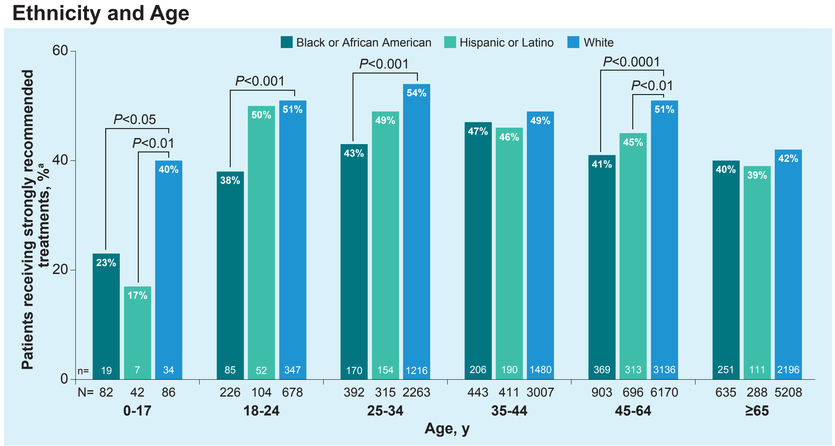
FIGURE 3: Narcolepsy Treatment Use



EDS, excessive daytime sleepiness.
[a]Strongly recommended treatments included modafinil, pitolisant, solriamfetol, armodafinil, and oxybates.
[b]Patients who received oxybates are a subset of those who received strongly recommended narcolepsy treatments.
[c]Patients receiving medications outside of those categorized as strongly recommended are not depicted.

- Among patients aged ≤64 years, receipt of strongly recommended narcolepsy treatments was significantly lower among Black or African American patients compared with white patients (**Figure 4**)
- Black or African and Hispanic or Latino pediatric patients (aged 0-17 years) were significantly less likely to receive a strongly recommended narcolepsy treatment compared with white pediatric patients

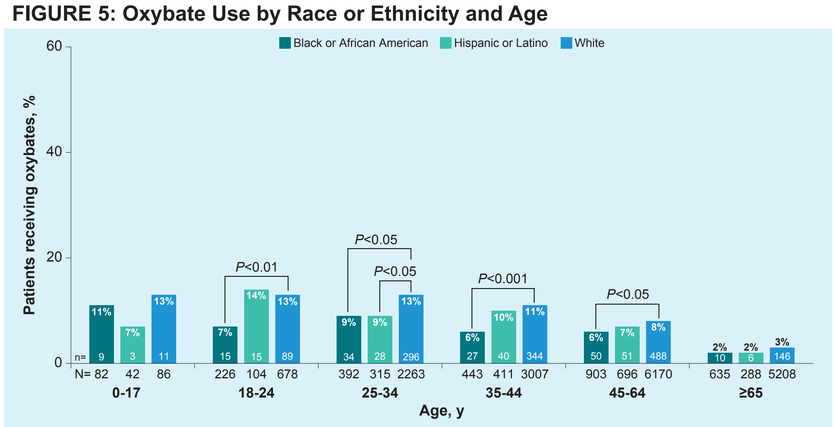
FIGURE 4: Strongly Recommended Narcolepsy Treatment Use by Race or Ethnicity and Age



[a]Strongly recommended treatments included modafinil, pitolisant, solriamfetol, armodafinil, and oxybates.

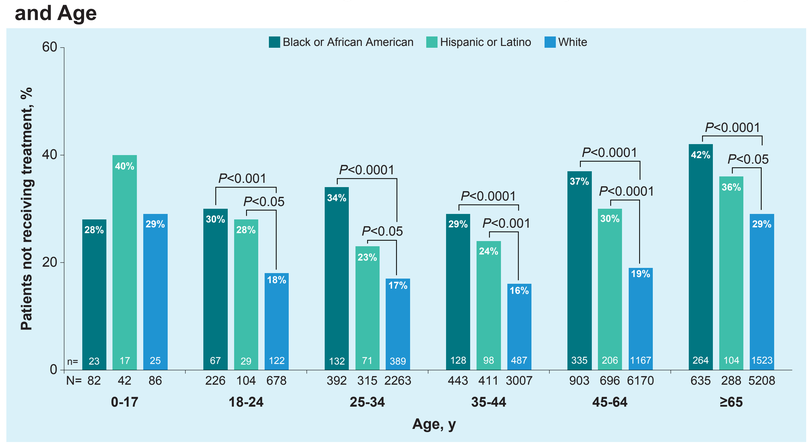
- Oxybate use was numerically lowest among patients aged ≥65 years compared with patients in other age groups, regardless of race or ethnicity (**Figure 5**)
- Among patients 18-64 years old, Black or African American patients were significantly less likely to receive oxybates compared with white patients

FIGURE 5: Oxybate Use by Race or Ethnicity and Age



- Hispanic or Latino pediatric patients (aged 0-17 years) and Black or African American senior patients (aged ≥65 years) were numerically less likely to receive a treatment for EDS compared with patients in other race or ethnicity and age groups (**Figure 6**)
- Among patients ≥18 years old, both Black or African American and Hispanic or Latino patients were significantly less likely to receive an oxybate treatment compared with white patients

FIGURE 6: Patients Not Receiving Treatment for EDS by Race or Ethnicity and Age



EDS, excessive daytime sleepiness.

STUDY LIMITATIONS

- Reliance on ICD-10 codes without clinical validation may have resulted in misclassification of NT1, NT2, and IH diagnoses; however, select patients with stable diagnoses over time may have mitigated some misclassification concerns
- Additional clinical and demographic factors that were not included in this analysis (eg, disease severity, symptom burden, comorbidities, and socioeconomic status) may influence treatment selection
- As a claims database analysis, demographic characteristics of this study population may not be representative of the overall population of patients with narcolepsy
- Paid claims do not confirm medication initiation, adherence, or persistence
- The limited timeframe of this analysis (2023) did not allow longitudinal assessment of treatment patterns
- Requirement for continuous claim availability may have excluded patients who were more vulnerable or intermittently insured and may have led to underestimated differences based on race and ethnicity, or age
- The healthcare-seeking behaviors of the patient population in this study could have affected the differences observed across race and ethnicity, or age

CONCLUSIONS

- Disparities in strongly recommended narcolepsy treatment were found for Black or African American and Hispanic or Latino patients compared with white patients, regardless of age
  - Black or African American and Hispanic or Latino adult patients (aged ≥18 years) were least likely to receive a narcolepsy treatment compared with white patients, highlighting potential gaps in care
  - Among subgroups, Hispanic or Latino pediatric patients (aged 0–17 years) and Black or African American senior patients (aged ≥65 years) were the most likely to not receive a narcolepsy treatment
- Despite being approved by the FDA[3-5] for treatment of cataplexy or EDS for >20 years and being a guideline recommendation by the AASM for treatment of EDS in narcolepsy since 2007,[9] oxybate use was consistently low (≤14%) across all race and ethnicity and age groups, highlighting a potential opportunity to improve patient care

ACKNOWLEDGMENTS

Medical writing support was provided by Marina Wylie, PhD, from Citrus Health Group, Inc. (Chicago, IL) and was funded by Avadel Pharmaceuticals (Chesterfield, MO).

FUNDING

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

DISCLOSURES

ABP served as a local principal investigator in the PMLUM-2402 open-label, observational study of once-nightly sodium oxybate (LUMRYZ®) for the treatment of narcolepsy. The study was sponsored by Avadel Pharmaceuticals. **RB** has served as a consultant, speaker, and/or on advisory boards for Avadel Pharmaceuticals, Harmony Biosciences, and Jazz Pharmaceuticals. **ML** has served as a consultant, speaker, and/or has received consulting fees for participation on advisory boards for Avadel Pharmaceuticals, Axsome Therapeutics, Harmony Biosciences, and Jazz Pharmaceuticals and is Sleep Medicine Advanced Practice Provider (SMAPP) President and Founder. **AB** has served as a consultant, speaker, and/or on advisory boards for Avadel Pharmaceuticals. **JG** was an employee of Avadel Pharmaceuticals and is a consultant to Alkermes, Inc. **JH** and **BA** are employees of Alkermes, Inc.

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