Impact of Sex and Race on Treatment of Narcolepsy: 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 across sex, race, and ethnicity[1,2]
- Symptom management for narcolepsy includes medications approved by the US Food and Drug Administration (FDA) for EDS or cataplexy (eg, oxybates, wake-promoting agents)[3-10]
- The 2021 American Academy of Sleep Medicine (AASM) clinical practice guidelines (CPGs) 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 for the treatment of EDS and/or cataplexy[11]
- Since the cutoff date for inclusion in the AASM CPGs (August 2020),[12] the following oxybate therapies have been approved by the FDA for treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy:
  - Immediate-release calcium, magnesium, potassium, and sodium (mixed-salt) oxybates[5]
  - Extended-release, once-nightly sodium oxybate (ON-SXB)[6]
- As the treatment paradigm for narcolepsy advances, it is important to understand medication usage patterns, including across diverse patient populations

OBJECTIVE

- To assess narcolepsy treatment patterns among male and female patients with narcolepsy of different races and ethnicities

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
- Valid race and ethnicity data (self-reported) and sex 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 sex 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 sex 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

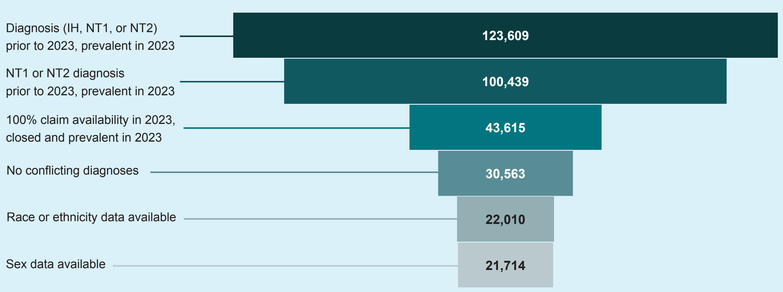
ICD-10, *International Classification of Diseases, 10th Revision*; IH, idiopathic hypersomnia; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

RESULTS

PATIENT CHARACTERISTICS

- The Komodo closed claims data set included 30,563 individuals with an NT1 or NT2 diagnosis in 2023; of these, 21,714 had race and ethnicity data and sex data available (**Figure 1**)

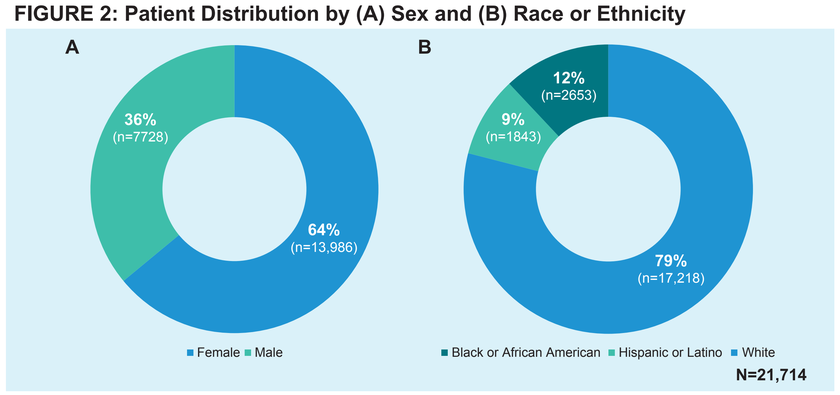
FIGURE 1: High-Confidence Diagnosis Cohort



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

- The majority of patients were female (64%) and white (79%; **Figure 2**)

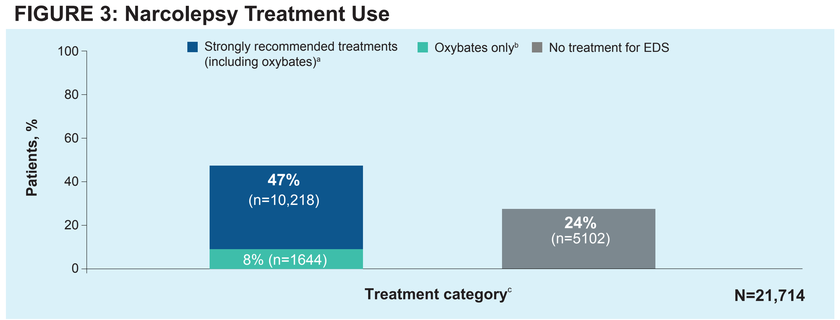
FIGURE 2: Patient Distribution by (A) Sex and (B) Race or Ethnicity



NARCOLEPSY TREATMENT PATTERNS

- Overall, 47% (n=10,218) of patients received a strongly recommended narcolepsy treatment in 2023 (**Figure 3**)
  - In the subset of those who received a strongly recommended treatment (n=10,218), 16% (n=1644) were treated with oxybates
- 24% (n=5120) of patients did not receive any treatment for EDS

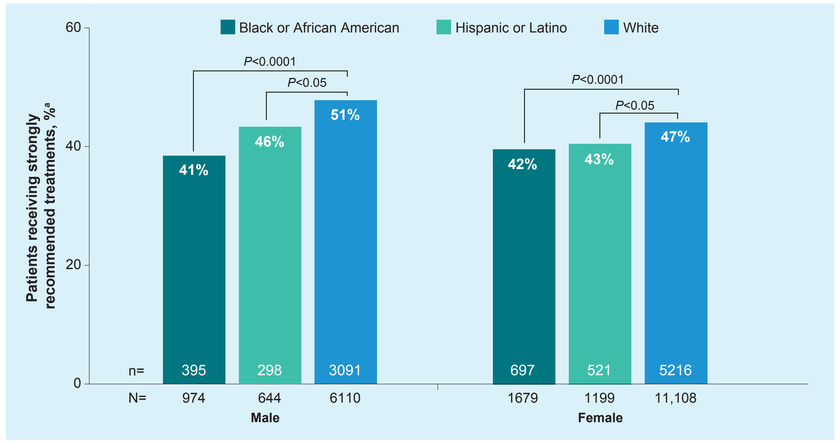
FIGURE 3: Narcolepsy Treatment Use



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.

- For both sexes, receipt of strongly recommended narcolepsy treatments was significantly lower among Black or African American patients and Hispanic or Latino patients compared with white patients (**Figure 4**)

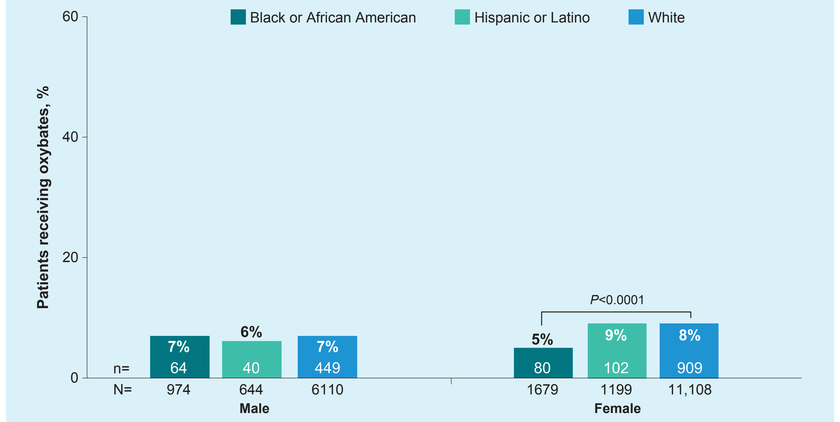
FIGURE 4: Strongly Recommended Narcolepsy Treatment Use by Race or Ethnicity and Sex



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

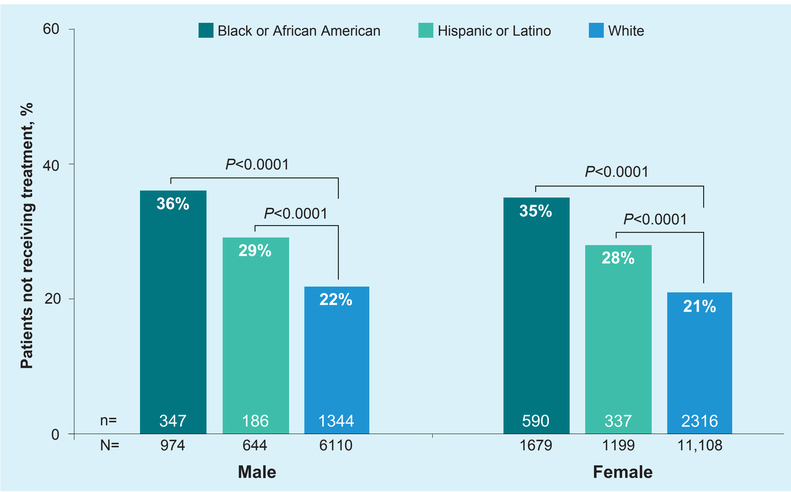
- Oxybate use was significantly lower among Black or African American female patients compared with white female patients (**Figure 5**)

FIGURE 5: Oxybate Use by Race or Ethnicity and Sex



- For both sexes, Black or African American and Hispanic or Latino patients were significantly less likely to receive a treatment for EDS compared with white patients (**Figure 6**)

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



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, age, 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 sex
- The healthcare-seeking behaviors of the patient population in this study could have affected the differences observed across race and ethnicity, or sex

CONCLUSIONS

- Disparities in receipt of strongly recommended narcolepsy treatments and any treatment for EDS were observed for Black or African American patients compared with patients of other races and ethnicities, regardless of sex
- Despite being approved by the FDA[4-6] for treatment of cataplexy or EDS for >20 years and being strongly recommended by the AASM for treatment of EDS in narcolepsy since 2007,[13] oxybate use was consistently low (<10%) across race and ethnicity groups for both sexes, highlighting a potential opportunity to improve patient care

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DISCLOSURES

RB has served as a consultant, speaker, and/or on advisory boards for Avadel Pharmaceuticals, Harmony Biosciences, and Jazz Pharmaceuticals. **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. **CM** has received consulting fees for participation on advisory boards for Avadel Pharmaceuticals, Axsome Therapeutics, and Harmony Biosciences and has served on speakers bureaus for Avadel Pharmaceuticals, Axsome Therapeutics, and Jazz 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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