534

Real-World, Participant-Reported Effectiveness and Satisfaction with Low-Sodium Oxybate in Idiopathic Hypersomnia

Justin Yu, PharmD, MS[1]; Caroleen Drachenberg, PhD, MSPH[1]; Sarah C. Markt, ScD, MPH[1]; Jessica K. Alexander, PhD[1]; Marisa Whalen, PharmD[1]; Silky Beaty, PharmD, MSPH[1]; Brandon Foster, PhD[2]; Jamie Tock, PhD[2]; Elizabeth Hribal, BA[2]; Edward Mezerhane, MD, FAASM, FACP[3]

[1]Jazz Pharmaceuticals, Palo Alto, CA, USA; [2]Lumanity, Boston, MA, USA; [3]Sleep Medicine Specialists of South Florida, Miami, FL, USA

Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the US Food and Drug Administration to treat idiopathic hypersomnia in adults and excessive daytime sleepiness (EDS) or cataplexy in patients aged ≥7 years with narcolepsy[1-4]
- Limited evidence exists on the real-world patient experience of individuals with idiopathic hypersomnia taking LXB
- The **C**linical effectiveness, treatment ad**H**erence, and treatment satisfaction in adults with **I**diopathic hypersomnia and narcolepsy taking low-sodiu**M** oxybat**E** (CHIME) study evaluated real-world patient-reported outcomes, including clinical effectiveness, treatment adherence, and treatment satisfaction among adults with idiopathic hypersomnia or narcolepsy taking LXB
  - Results for individuals with narcolepsy are reported separately in **Poster 535**

Objective

- To evaluate real-world patient-reported outcomes, including treatment effectiveness, adherence, and satisfaction among adults with idiopathic hypersomnia taking LXB

Methods

- A cross-sectional, web-based survey was administered to US adults with narcolepsy or idiopathic hypersomnia taking LXB from 08/26/2024 to 12/12/2024
  - Participants had previously consented to outreach from the study sponsor with opportunities to participate in research
- Key inclusion criteria
  - US residents ≥18 years of age with a self-reported physician diagnosis of idiopathic hypersomnia
  - Currently taking LXB for treatment of idiopathic hypersomnia
  - Opted-in to receiving marketing/promotional communications from the study sponsor
- Key exclusion criteria
  - Current diagnoses of both narcolepsy and idiopathic hypersomnia
  - Cognitive difficulties or impairment that would make completing the survey challenging or prevent from completing the survey accurately
- Descriptive analyses were conducted on standardized patient-reported outcome measures (including the Epworth Sleepiness Scale [ESS; score range 0–24], Idiopathic Hypersomnia Severity Scale [IHSS; range 0–50], Visual Analog Scale–Sleep Inertia [VAS-SI; range 0–100], Patient Global Impression of Change [PGI-C]) and de novo questions to evaluate the experiences of individuals with idiopathic hypersomnia taking LXB

Results

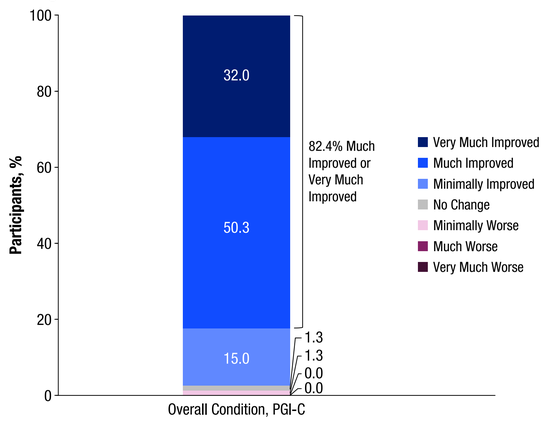
Table 1. Self-Reported Demographics and Clinical Characteristics

Characteristic	Participants With Idiopathic Hypersomnia (N=153)
Age (years)	
Mean (SD)	37.9 (12.1)
Median (min, max)	36.0 (19.0, 74.0)
Gender identity, n (%)	
Female	110 (71.9)
Male	31 (20.3)
Nonbinary	9 (5.9)
Gender nonconforming	1 (0.7)
Prefer not to answer	1 (0.7)
Other	1 (0.7)
Hispanic or Latino, n (%)	
Yes	6 (3.9)
No	147 (96.1)
Race, n (%)	
White	133 (86.9)
Multiple selected	11 (7.2)
Asian or Asian American	5 (3.3)
Black or African American	2 (1.3)
American Indian or Alaska Native	0
Native Hawaiian or other Pacific Islander	0
Prefer not to answer	2 (1.3)
Highest level of education, n (%)	
High school graduate or less	8 (5.2)
Associate's degree or some college (no degree)	34 (22.2)
Bachelor's degree	51 (33.3)
Master's degree or doctoral/doctorate degree	59 (38.6)
Other	1 (0.7)
Number of comorbidities, n (%)	
≥1	142 (92.9)
≥2	120 (78.5)
Most common comorbidities (≥15%), n (%)	
Anxiety	89 (58.2)
Depression	77 (50.3)
Migraine/headaches	42 (27.5)
Hypertension	37 (24.2)
ADD/ADHD	37 (24.2)
Obstructive sleep apnea	30 (19.6)
High cholesterol	29 (19.0)
Hypothyroidism	24 (15.7)
Obesity	24 (15.7)
Other	40 (26.1)
ESS total score[a]	
Mean (SD)	7.5 (4.6)
Median (min, max)	6.0 (0.0, 23.0)
IHSS total score[b]	
Mean (SD)	23.3 (8.2)
Median (min, max)	22.0 (8.0, 47.0)
VAS-SI total score	
Mean (SD)	31.2 (25.8)
Median (min, max)	25.0 (0.0, 100.0)
Time taking LXB, weeks	
Mean (SD)	128.1 (43.0)
Total nightly dosage of LXB, g, n (%)	
<2.5	1 (0.7)
2.5 to 4	6 (3.9)
>4 to 6	45 (29.4)
>6 to 9	98 (64.1)
>9	3 (2.0)
Taking ≥1 concomitant alerting agent,[c] n (%)	82 (53.6)

[a]ESS severity categories are: normal (0–10), mild (11–12), moderate (13–15), and severe (16–24). [b]IHSS severity categories are: mild (0–12), moderate (13–25), severe (26–38), and very severe (39–50). [c]Alerting agents were defined as wakefulness-promoting agents (ie, armodafinil, modafinil, pitolisant, solriamfetol) or traditional stimulants (ie, amphetamines, methylphenidate).
ADD, attention deficit disorder; ADHD, attention-deficit/hyperactivity disorder; ESS, Epworth Sleepiness Scale; IHSS, Idiopathic Hypersomnia Severity Scale; LXB, low-sodium oxybate; max, maximum; min, minimum; SD, standard deviation; VAS-SI, Visual Analog Scale for Sleep Inertia.

- Among the 153 participants with idiopathic hypersomnia, the mean (standard deviation [SD]) time taking LXB was 128.1 (43.0) weeks, or 2.4 (0.8) years, with 71.2% taking LXB for >2 years
- Most participants were female (71.9%) and White (86.9%); mean (SD) age was 37.9 (12.1) years

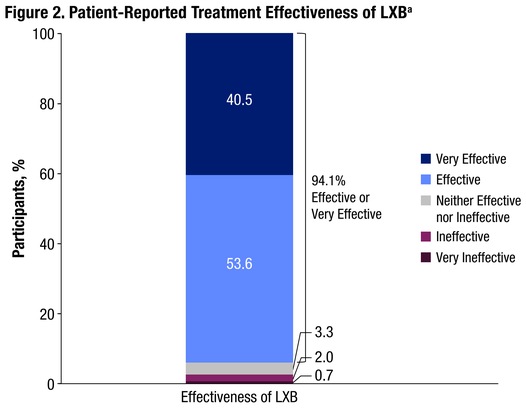
Figure 1. Patient Global Impression of Change in Overall Condition Since Starting LXB[a]



[a]Participants were asked, "Since you started LXB, what is your overall condition?"
LXB, low-sodium oxybate; PGI-C, Patient Global Impression of Change.

- On the PGI-C, 82.4% of participants reported their overall condition was "much improved" or "very much improved" since starting LXB

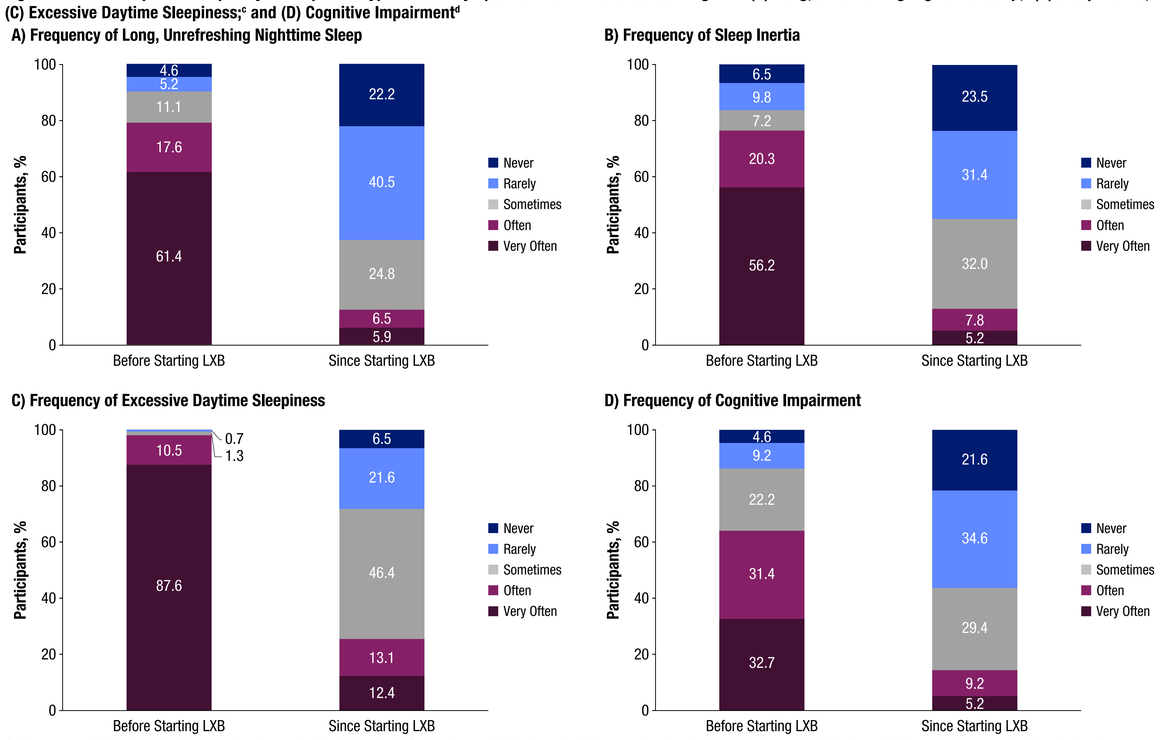
Figure 2. Patient-Reported Treatment Effectiveness of LXB[a]



[a]Participants were asked, "Overall, how effective is LXB at managing your symptoms?"
LXB, low-sodium oxybate.

- Most participants (94.1%) reported LXB was "effective" or "very effective" at managing their idiopathic hypersomnia symptoms
- Since starting LXB, 56.2% of participants reported they stopped taking, reduced the dosage, or reduced the frequency of taking alerting agents (either a wakefulness-promoting agent or a traditional stimulant)

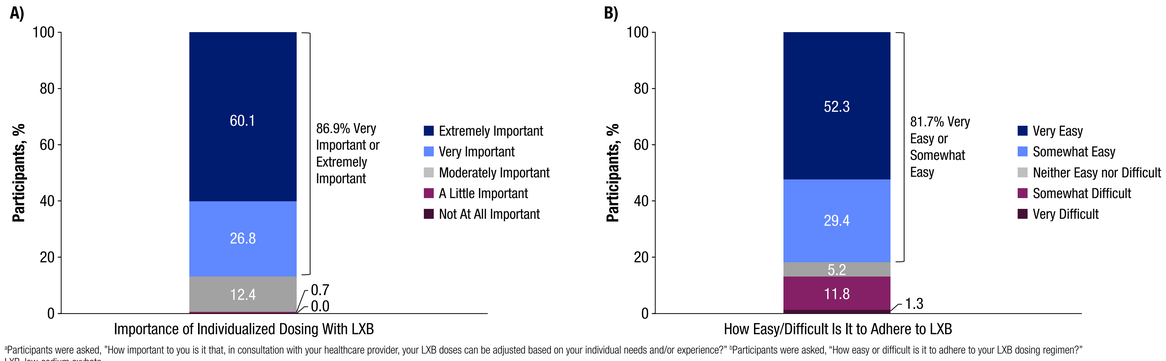
Figure 3. Patient-Reported Frequency of Idiopathic Hypersomnia Symptoms Before and Since Starting LXB: (A) Long, Unrefreshing Nighttime Sleep;[a] (B) Sleep Inertia;[b] (C) Excessive Daytime Sleepiness;[c] and (D) Cognitive Impairment[d]



[a]Participants were asked, "How frequently did/do you experience long, unrefreshing nighttime sleep?" [b]Participants were asked, "How frequently did/do you experience sleep inertia?" [c]Participants were asked, "How frequently did/do you experience excessive daytime sleepiness?" [d]Participants were asked, "How frequently did/do you experience cognitive impairment?"
LXB, low-sodium oxybate.

- Since starting LXB, the percentage of participants who reported experiencing idiopathic hypersomnia symptoms "often" or "very often" decreased from 79.1% to 12.4% for long, unrefreshing nighttime sleep; 76.5% to 13.1% for sleep inertia; 98.0% to 25.5% for EDS; and 64.1% to 14.4% for cognitive impairment

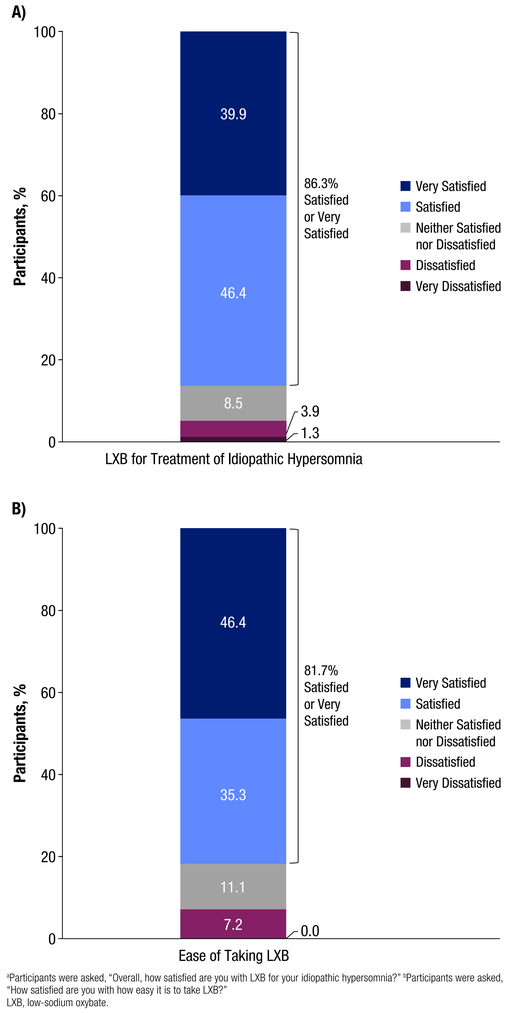
Figure 4. (A) Importance of Individualized Dosing With LXB[a] and (B) Ease of Adherence to Dosing Regimen[b]



[a]Participants were asked, "How important to you is it that, in consultation with your healthcare provider, your LXB doses can be adjusted based on your individual needs and/or experience?" [b]Participants were asked, "How easy or difficult is it to adhere to your LXB dosing regimen?"
LXB, low-sodium oxybate.

- 86.9% of participants reported that it was "very important" or "extremely important" that LXB dosing could be adjusted in consultation with their provider based on individual needs and/or experience
- 81.7% of participants reported that it was "somewhat easy" or "very easy" to adhere to their LXB dosing regimen

Figure 5. (A) Overall Satisfaction With LXB for Treatment of Idiopathic Hypersomnia[a] and (B) Ease of Taking LXB[b]



[a]Participants were asked, "Overall, how satisfied are you with LXB for your idiopathic hypersomnia?" [b]Participants were asked, "How satisfied are you with how easy it is to take LXB?"
LXB, low-sodium oxybate.

- 86.3% of participants reported they were "satisfied" or "very satisfied" with LXB for treating their idiopathic hypersomnia
- 81.7% of participants reported that they were "satisfied" or "very satisfied" with how easy it was to take LXB

Conclusions

- This analysis from CHIME, the largest real-world survey of LXB patients to date, suggests that participants taking LXB experienced improvement in nighttime and daytime symptoms of idiopathic hypersomnia, including long, unrefreshing nighttime sleep; sleep inertia; EDS; and cognitive impairment; and many stopped taking, reduced the dosage, or reduced the frequency of alerting agents for idiopathic hypersomnia after starting LXB
- According to the CHIME survey findings, the ability to individualize dosing with LXB was highly important, and the majority of participants reported satisfaction with the ease of taking LXB
- Limitations of this analysis include the cross-sectional design and the potential for selection bias limiting generalizability, as participants who are satisfied with LXB may be more likely to enroll in the study

References: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Szarfman A, et al. *N Engl J Med.* 1995;333(19):1291. **3.** US Food and Drug Administration. Clinical review for Binosto, NDA 202344. 2012. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202344Orig1s000MedR.pdf. **4.** US Food and Drug Administration. Quantitative labeling of sodium, potassium, and phosphorus for human over-the-counter and prescription drug products. Guidance for industry. 2022. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quantitative-labeling-sodium-potassium-and-phosphorus-human-over-counter-and-prescription-drug.

Support and Acknowledgments: This study was supported by Jazz Pharmaceuticals. Under the direction of the authors, Kim Tran-Kerr, MD, and Eleanor Bush, MA, of Peloton Advantage, LLC, an OPEN Health company, provided medical writing and editorial support for this poster, which was funded by Jazz Pharmaceutical.

Disclosures: J Yu is a consultant/contractor for Jazz Pharmaceuticals. **C Drachenberg, SC Markt, JK Alexander, M Whalen,** and **S Beaty** are full-time employees of Jazz Pharmaceuticals who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. **B Foster, J Tock,** and **E Hribal** are full-time employees of Lumanity, which has received consulting fees from Jazz Pharmaceuticals, plc. **E Mezerhane** is a consultant/contractor for Avadel, Axsome, Eli Lilly, Harmony Biosciences, and Jazz Pharmaceuticals.

Scan this code to access this poster online.
This code is not for promotional purposes.

Presented at SLEEP 2025, the 39th Annual Meeting of the Associated Professional Sleep Societies, LLC (APSS); June 8–11, 2025; Seattle, WA, USA