

# Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan (H8H-MC-B005)

**First published:** 16/03/2023

**Last updated:** 22/11/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/1000000091>

### EU PAS number

EUPAS45442

### Study ID

1000000091

### DARWIN EU® study

No

## Study countries

☐ United States

---

## Study description

This is a retrospective cohort database study evaluating real-world utilization patterns among patients treated with lasmiditan in the US using IBM® MarketScan commercial administrative claims. This study will describe real-world utilization patterns for patients treated with lasmiditan and patient characteristics including demographics, comorbidities, and concomitant medication use.

---

## Study status

Finalised

# Research institutions and networks

## Institutions

[Eli Lilly and Company](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Nicole Kellier-Steele

#### Study contact

[Kellier\\_Nicole\\_A@lilly.com](mailto:Kellier_Nicole_A@lilly.com)

#### Primary lead investigator

Nicole Kellier-Steele

#### Primary lead investigator

## Study timelines

#### Date when funding contract was signed

Actual: 02/02/2022

---

#### Study start date

Planned: 31/01/2022

Actual: 22/05/2023

---

#### Date of final study report

Planned: 31/12/2023

Actual: 18/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

## Regulatory

### **Was the study required by a regulatory body?**

No

---

### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

##### **Study type:**

Non-interventional study

---

##### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

##### **Main study objective:**

This study aimed to describe utilization patterns in the US for patients treated with lasmiditan in

routine clinical practice using administrative claims data.

The primary objectives of this study are to: describe real-world utilization of

lasmiditan using prescription data over a period of 3 years after market availability to identify potential patterns of drug misuse or abuse; identify patients treated for longer than 1 year and describe treatment patterns; assess off-label treatment with lasmiditan among paediatric and adolescent patients with migraine, and; describe characteristics of lasmiditan-treated patients, including patients treated beyond 1year.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Name of medicine**

RAYVOW

---

### **Study drug International non-proprietary name (INN) or common name**

LASMIDITAN

---

### **Anatomical Therapeutic Chemical (ATC) code**

(N02CC08) lasmiditan

lasmiditan

---

### **Medical condition to be studied**

Migraine

## Population studied

## Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population ( $\geq 18$  years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly ( $\geq 65$  years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

## Study design details

### Outcomes

Misuse/abuse, off-label treatment in pediatric & adolescent patients, drug-utilization characteristics

---

### Data analysis plan

All data will be summarized using descriptive statistics. Categorical variables will be presented using percentages and frequencies. Continuous variables will be presented as means and medians with associated standard deviations.

## Documents

### Study report

[LY573144 B005 Noninterventional PASS Final Study Report – Basic Version 1\\_Redacted.pdf](#)(373.42 KB)

## Data management

## Data sources

## **Data sources (types)**

Administrative healthcare records (e.g., claims)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

---

### **Check completeness**

Unknown

---

### **Check stability**

Unknown

---

### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No