Real-World Lumateperone Dosing Patterns and Treatment Duration in Bipolar Depression

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Introduction

- Depressive episodes are a core feature of bipolar disorder and are associated with increased suicide risk and impaired quality of life[1,2]
- Lumateperone, a second-generation antipsychotic, has demonstrated efficacy in improving depressive symptoms in adults with bipolar I or bipolar II depression in clinical trials[3,4]
- However, real-world evidence on lumateperone use remains limited

Objective

- This study aims to characterize real-world lumateperone dosing patterns and treatment duration in patients with bipolar depression

Methods

Study design and data source

- A retrospective observational cohort study using deidentified MarketScan (MS) and HealthVerity (HV) commercial claims data (1/1/2022–1/30/2026)

Study population

- Adult patients (≥18 years) were eligible if they met the following criteria:
  - Initiated lumateperone between 1/1/2022 and 1/30/2026
  - Had ≥2 lumateperone prescription claims; the date of the first prescription claim was defined as the index date
  - Had ≥12 months of continuous pre-index commercial medical and pharmacy enrollment (baseline period) and ≥3 months of continuous post-index enrollment
  - Had a diagnosis of bipolar depression (ICD-10: F31.3, F31.30, F31.31, F31.32, F31.4, F31.5, F31.75, F31.76, F31.81) during the baseline period or on the index date
  - Patients with any schizophrenia diagnosis (ICD-10: F20.x, F21.x) during baseline or on the index date were excluded
  - Among patients with an index dose <42 mg, those with a hepatic impairment diagnosis during the baseline period or on the index date, or with a moderate-to-strong CYP3A inhibitor use within 6 months before or on the index date, were excluded

Outcome measures

- Continuous use of lumateperone was assessed from the index date by rolling forward days of supply across prescription fills, allowing for pill stockpiling and gaps up to 60 days, until the discontinuous rolled-out end date (DRED). The DRED was defined as the end of the available days of supply from the last prescription fill, including any accumulated stockpiled medication, or the end of continuous enrollment, whichever occurred first
- Discontinuation was defined when the DRED plus 60 days occurred on or before the end of continuous enrollment; the DRED was considered the discontinuation date. Otherwise, the patient was censored at the end of continuous enrollment

Data analysis

- Patients were categorized into 3 groups: Group 1, lumateperone initiation at 42 mg; Group 2, initiation at <42 mg with subsequent dose escalation to 42 mg; Group 3, initiation at <42 mg without escalation
- Baseline demographics and clinical characteristics were reported for each group
- Baseline characteristics were balanced using inverse probability of treatment weighting (IPTW) across the 3 groups. Stabilized weights were calculated and trimmed at the 1st and 99th percentiles of the propensity score distribution to limit the influence of extreme weights
- Follow-up continued until the earlier of disenrollment or treatment discontinuation
- Time to discontinuation (TTD) was estimated using Kaplan–Meier methods

Results

Patient characteristics

- A total of 7,024 patients were included (MS: 1,997; HV: 5,027). Patient baseline characteristics are summarized in **Table 1**

Table 1. Patient baseline characteristics

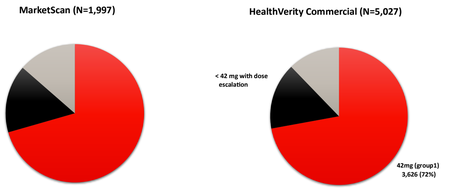
	MarketScan				HealthVerity			
	Group 1 (N=1,409)	Group 2 (N=317)	Group 3 escalation (N=271)	Total (N=1,997)	Group 1 (N=3,626)	Group 2 (N=787)	Group 3 (N=614)	Total (N=5,027)
Age, mean (SD), years	38.8 (12.5)	38.2 (12.8)	40.1 (14.0)	38.9 (12.8)	39.4 (12.8)	38.3 (12.8)	38.0 (13.5)	39.1 (12.9)
Female, n (%)	987 (70.0)	224 (70.7)	202 (74.5)	1,413 (70.8)	2,571 (70.9)	557 (70.8)	441 (71.8)	3,569 (71.0)
Year of index date, n (%)								
2022	349 (24.8)	21 (6.6)	6 (2.2)	376 (18.8)	989 (27.3)	38 (4.8)	26 (4.2)	1,053 (20.9)
2023	391 (27.8)	72 (22.7)	54 (19.9)	517 (25.9)	887 (24.5)	205 (26.0)	155 (25.2)	1,247 (24.8)
2024	336 (23.8)	114 (36.0)	86 (31.7)	536 (26.8)	901 (24.8)	278 (35.3)	191 (31.1)	1,370 (27.3)
2025	333 (23.6)	110 (34.7)	125 (46.1)	568 (28.4)	849 (23.4)	266 (33.8)	242 (39.4)	1,357 (27.0)
Region, n (%)								
Midwest	151 (10.7)	48 (15.1)	46 (17.0)	245 (12.3)	1,075 (29.6)	242 (30.7)	183 (29.8)	1,500 (29.8)
Northeast	335 (23.8)	72 (22.7)	73 (26.9)	480 (24.0)	463 (12.8)	135 (17.2)	91 (14.8)	689 (13.7)
South	751 (53.3)	146 (46.1)	116 (42.8)	1,013 (50.7)	1,538 (42.4)	281 (35.7)	251 (40.9)	2,070 (41.2)
West	172 (12.2)	51 (16.1)	36 (13.3)	259 (13.0)	550 (15.2)	129 (16.4)	89 (14.5)	768 (15.3)
QCCI, mean (SD)	0.5 (1.0)	0.3 (0.9)	0.3 (0.8)	0.4 (0.9)	0.6 (1.8)	0.4 (0.9)	0.4 (0.8)	0.6 (1.1)
Concomitant medications, n (%)								
Other atypical antipsychotics	1,113 (79.0)	250 (78.9)	183 (67.5)	1,546 (77.4)	2,862 (78.9)	618 (78.5)	433 (70.5)	3,913 (77.8)
Typical antipsychotics	50 (3.5)	10 (3.2)	5 (1.8)	65 (3.3)	122 (3.4)	14 (1.8)	5 (0.8)	141 (2.8)
Mood stabilizers	870 (61.7)	200 (63.1)	143 (52.8)	1,213 (60.7)	2,063 (56.9)	486 (61.8)	356 (58.0)	2,905 (57.8)
Anticonvulsant	854 (60.6)	199 (62.8)	148 (54.6)	1,201 (60.1)	2,137 (58.9)	492 (62.5)	361 (58.8)	2,990 (59.5)
Anxiolytics	1,050 (74.5)	225 (71.0)	195 (72.0)	1,470 (73.6)	2,720 (75.0)	550 (69.9)	428 (69.7)	3,698 (73.6)
Psychostimulants	439 (31.2)	78 (24.6)	74 (27.3)	591 (29.6)	988 (27.2)	230 (29.2)	167 (27.2)	1,385 (27.6)
Comorbidities, n (%)								
Anxiety disorder	1,144 (81.2)	252 (79.5)	223 (82.3)	1,619 (81.1)	2,841 (78.4)	606 (77.0)	471 (76.7)	3,918 (77.9)
Depressive disorder	729 (51.7)	151 (47.6)	130 (48.0)	1,010 (50.6)	1,791 (49.4)	377 (47.9)	311 (50.7)	2,479 (49.3)
Neurodevelopment disorders	462 (32.8)	95 (30.0)	87 (32.1)	644 (32.2)	1,169 (32.2)	264 (33.5)	202 (32.9)	1,635 (32.5)
Sleep-wake disorder	484 (34.4)	120 (37.9)	80 (29.5)	684 (34.3)	1,279 (35.3)	260 (33.0)	206 (33.6)	1,745 (34.7)
Trauma-stressor related disorder	411 (29.2)	113 (35.6)	72 (26.6)	596 (29.8)	1,090 (30.1)	226 (28.7)	192 (31.3)	1,508 (30.0)
Neurocognitive disorders	38 (2.7)	15 (4.7)	7 (2.6)	60 (3.0)	118 (3.3)	23 (2.9)	16 (2.6)	157 (3.1)
Obesity	454 (32.2)	97 (30.6)	79 (29.2)	630 (31.5)	1,279 (35.3)	252 (32.0)	164 (26.7)	1,695 (33.7)
Hypertension	415 (29.5)	81 (25.6)	63 (23.2)	559 (28.0)	1,124 (31.0)	181 (23.0)	127 (20.7)	1,432 (28.5)
Chronic pulmonary disease	223 (15.8)	42 (13.2)	42 (15.5)	307 (15.4)	713 (19.7)	137 (17.4)	98 (16.0)	948 (18.9)
Drug abuse	251 (17.8)	51 (16.1)	33 (12.2)	335 (16.8)	781 (21.5)	133 (16.9)	119 (19.4)	1,033 (20.5)
Diabetes	157 (11.1)	35 (11.0)	25 (9.2)	217 (10.9)	459 (12.7)	77 (9.8)	53 (8.6)	589 (11.7)
Psychoses	195 (13.8)	44 (13.9)	20 (7.4)	259 (13.0)	542 (14.9)	91 (11.6)	65 (10.6)	698 (13.9)

QCCI, Quan-Charlson Comorbidity Index; SD, standard deviation.

Dosing patterns

- In both databases, Group 1 was the most common (MS: 70%; HV: 72%), followed by Group 2 (MS: and HV: 16%) and Group 3 (MS: 14%; HV: 12%) (**Figure 1**)

Figure 1. More than two-thirds of patients initiated lumateperone at 42 mg dose

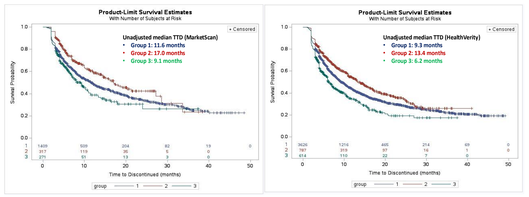


TTD, time to discontinuation.

TTD

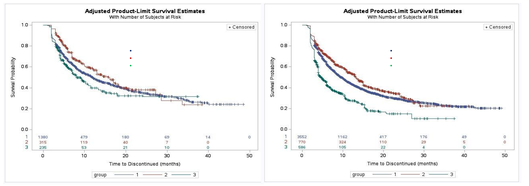
- IPTW adjusted analyses showed that median TTD was the longest for Group 2 (MS: 16.1 months; HV: 13.2 months) followed by Group 1 (MS: 12.0 months; HV: 9.6 months) and Group 3 (MS: 8.0 months; HV: 4.6 months) (**Figure 2**)
- Findings were consistent with unadjusted analyses (**Figure 3**)

Figure 2. Unadjusted median TTD



TTD, time to discontinuation.

Figure 3. Adjusted median TTD



TTD, time to discontinuation.

Conclusions

- In this study, approximately 70%-72% of patients initiated lumateperone at 42 mg. Patients who initiated or escalated to 42 mg had longer treatment durations compared with those remaining on lower doses
- By leveraging two large U.S. claims databases, this study yielded highly consistent findings across both data sources, strengthening confidence in the robustness of the results

Limitations

This study included only commercially insured US patients; findings may not be generalizable to broader patient populations

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Disclosures

Madhav Namjoshi, Zhiwen Liu, Zhongyun Zhao, and Camilo Obando are all employees of Johnson & Johnson and they all hold stock in Johnson & Johnson.

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