

Real-World, Long-Term Impact of Transitioning From Oral Antipsychotics or Aripiprazole Once-Monthly to Aripiprazole 2-Month Ready-To-Use in Adults Diagnosed with Bipolar I Disorder: Exploratory Outcomes from the REAL-BD Study

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Background

- Optimal management of bipolar I disorder (BP-I) typically involves long-term maintenance therapy aimed at preventing relapse and restoring functioning and quality of life.¹
- However, adherence to oral antipsychotic formulations in patients living with BP-I is suboptimal, and this can lead to higher rates of psychiatric hospitalization and greater total psychiatric inpatient costs.²⁻⁵
- Long-acting injectable (LAI) antipsychotics provide sustained medication exposure and facilitate adherence.⁴
- Aripiprazole monohydrate is an atypical antipsychotic approved in the United States (US) for the maintenance treatment of patients diagnosed with BP-I, with aripiprazole once-monthly (AOM) and aripiprazole 2-month ready-to-use (Ari 2MRTU) LAI formulations.^{1,6}
- A long-term, real-world study (REAL-BD) showed that patients diagnosed with BP-I who transitioned from an oral antipsychotic or AOM to Ari 2MRTU had a significantly lower risk of psychiatric hospitalization (poster 59).

The aims of this analysis of exploratory endpoints from the REAL-BD study were to determine if patients diagnosed with BP-I who transitioned to Ari 2MRTU had (1) reduced concomitant psychotropic medication prescriptions, (2) reduced healthcare resource utilization, and (3) reduced psychiatric hospitalizations in clinically relevant subgroups.

Methods

Study design and patients

- REAL-BD was a retrospective, non-interventional, pre-post chart review study performed in multiple centers in the US over an observational period from May 15, 2025, to April 21, 2026.
- The study comprised a 12-month pre-index period and a 12-month post-index period, with Ari 2MRTU initiation as the index date (Figure 1).
- Eligible patients were adults aged 19–64 years with a confirmed primary diagnosis of BP-I (for ≥1 year), who initiated Ari 2MRTU after receiving an oral antipsychotic (non-clozapine) or AOM for ≥1 year.
- Patients were excluded if they had diagnoses of schizophrenia, bipolar II disorder, or schizoaffective disorder; or if they had a substance use disorder within 30 days of baseline (nicotine⁷, alcohol⁸, and cannabis-related substance disorders were allowed).

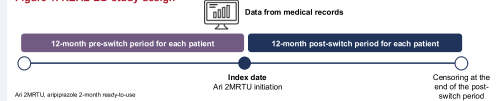
Exploratory outcomes

- Psychotropic medication prescriptions:**
 - Change in the cumulative burden of concomitant psychotropic medication prescriptions (i.e., total number of medications).
 - Change in concomitant psychotropic medication treatment patterns (initiation, augmentation, switch, discontinuation, or dose adjustment).
- Healthcare resource utilization:**
 - Change in healthcare resource utilization, defined as psychiatric healthcare visits (scheduled or unscheduled) plus psychiatric/non-psychiatric hospitalizations.
- Psychiatric hospitalizations by subgroup:**
 - Change in inpatient psychiatric hospitalizations in subgroups relating to demographics (age, sex, and race), social determinants of health (education level, employment status, primary health insurance, and US geographic region), substance use history, and lead-in medication for BP-I.

Data analysis

- Exploratory outcomes were evaluated with descriptive statistics for the 12 months before versus after the index date.
- Paired t-tests (2-sided alpha=0.05) were used for analyses of prescriptions and healthcare resource utilization, and McNemar's tests (2-sided alpha=0.05) were used for analyses of hospitalizations by subgroup.

Figure 1. REAL-BD study design



Results

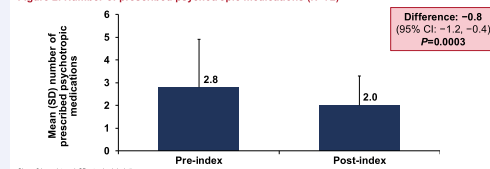
Patients

- Data were available for 72 patients diagnosed with BP-I.
- The mean (standard deviation [SD]) age at index was 32.4 (11.4) years [median 30.6 years]; 45 (62.5%) patients were female, and 40 (55.6%) patients were White. The mean (SD) age at diagnosis of BP-I was 27.7 (10.1) years. Subgroups are listed in Table 1.
- Overall, 61 (84.7%) patients completed 12 months of follow-up, and 56 (77.8%) patients completed 12 months of continuous treatment with Ari 2MRTU.

Psychotropic medication prescriptions

- The mean number of prescribed concomitant psychotropic medications significantly decreased from 2.8 pre-index to 2.0 post-index (P=0.0003) (Figure 2).
- The mean total number of concomitant psychotropic treatment changes numerically decreased from 1.8 pre-index to 1.1 post-index (P=0.058) (Table 2). The mean number of initiations, augmentations, switches, and dose adjustments each significantly decreased, whereas discontinuations numerically increased (Table 2).

Figure 2. Number of prescribed psychotropic medications (N=72)

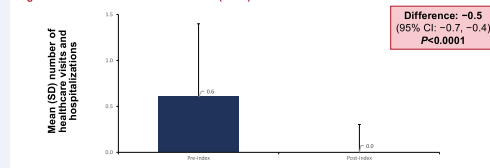


CI, confidence interval; SD, standard deviation

Healthcare resource utilization

- Mean healthcare resource utilization significantly decreased from 0.6 pre-index to 0.0 post-index (P<0.0001) (Figure 3).

Figure 3. Healthcare resource utilization (N=72)



CI, confidence interval; SD, standard deviation

Psychiatric hospitalizations by subgroup

- No patients in any of the subgroups had a post-index inpatient psychiatric hospitalization (Table 1).
- Pre-post index differences in psychiatric hospitalizations by demographics, social determinants of health, and lead-in medications for BP-I (including individual antipsychotics with n=5) are shown in Table 1.
- Due to the low number of patients with substance use history (1), no analysis of hospitalizations by substance use history was performed.

Table 1. Inpatient psychiatric hospitalizations in patient subgroups (N=72)

Subgroup	n (%) ^a	Pre-index hospitalization, n (%)	Post-index hospitalization, n (%)	Difference (95% CI)
Age				
≤Median (30.6 years)	39 (54.2)	10 (25.6)	0	-25.6 (-39.4, -11.9); P=0.002
>Median (30.6 years)	33 (45.8)	3 (9.1)	0	-9.1 (-18.9, 0.72); P=0.25
Sex				
Male	27 (37.5)	7 (25.9)	0	-25.9 (-42.5, -9.4); P=0.016
Female	45 (62.5)	6 (13.3)	0	-13.3 (-23.3, -3.4); P=0.031
Race				
Asian	4 (5.6)	1 (25.0)	0	-25.0 (-67.4, 17.4); P=1
Black or African American	15 (20.8)	5 (33.3)	0	-33.3 (-57.2, -9.5); P=0.063
White	40 (55.6)	5 (12.5)	0	-12.5 (-22.8, -2.3); P=0.063
More than one race	3 (4.2)	0	0	-
Other	2 (2.8)	0	0	-
Not reported	8 (11.1)	2 (25.0)	0	-25.0 (-55.0, 5.0); P=0.50
Education level				
Master's degree or higher	1 (1.4)	1 (100)	0	-100 (-100, -100); P=1
Bachelor's degree	8 (11.1)	2 (25.0)	0	-25.0 (-55.0, 5.0); P=0.50
Some college education	18 (25.0)	2 (11.1)	0	-11.1 (-25.6, 3.4); P=0.50
High school or less	37 (51.4)	8 (21.6)	0	-21.6 (-34.9, -8.4); P=0.008
Unknown	8 (11.1)	0	0	-
Employment status				
Full-time	13 (18.1)	3 (23.1)	0	-23.1 (-46.0, -0.2); P=0.25
Part-time	13 (18.1)	6 (46.2)	0	-46.2 (-73.3, -19.1); P=0.031
Self-employed	1 (1.4)	0	0	-
Student	6 (8.3)	0	0	-
Other	29 (40.3)	1 (3.5)	0	-3.5 (-10.1, 3.2); P=1
Unknown	10 (13.9)	3 (30.0)	0	-30.0 (-58.4, -1.6); P=0.25
Primary health insurance				
Employer-sponsored	8 (11.1)	1 (12.5)	0	-12.5 (-35.4, 10.4); P=1
Marketplace/exchange plans	1 (1.4)	0	0	-
Medicaid	7 (9.7)	1 (14.3)	0	-14.3 (-40.2, 11.6); P=1
Medicare	1 (1.4)	0	0	-
Private insurance	9 (12.5)	3 (33.3)	0	-33.3 (-64.1, -2.5); P=0.25
Other	12 (16.7)	1 (8.3)	0	-8.3 (-24.0, 7.3); P=1
Unknown	34 (47.2)	7 (20.6)	0	-20.6 (-34.2, -7.0); P=0.016
US geographic region				
Northeast	52 (72.2)	13 (25.0)	0	-25.0 (-36.8, -13.2); P=0.002
South	11 (15.3)	0	0	-
West	9 (12.5)	0	0	-

Lead-in medication for BP-I

Any antipsychotic	58 (80.6)	12 (20.7)	0	-20.7 (-31.1, -10.3); P=0.0005
Aripiprazole (oral)	17 (23.6)	1 (5.9)	0	-5.9 (-17.1, 5.3); P=1
Olanzapine (oral)	21 (29.2)	6 (28.6)	0	-28.6 (-47.9, -9.3); P=0.031
None ^a	14 (19.4)	1 (7.1)	0	-7.1 (-20.6, 6.4); P=1

^aNo lead-in medications reported as taken for at least 9 months

Table 2. Number of psychotropic treatment changes (N=72)

Category	Pre-index changes, mean (SD)	Post-index changes, mean (SD)	Difference (95% CI)
Any treatment change	1.8 (2.7)	1.1 (1.1)	-0.6 (-1.3, 0.0); P=0.058
Initiation	0.5 (1.0)	0.2 (0.4)	-0.3 (-0.6, 0.1); P=0.018
Augmentation	0.3 (0.7)	0.1 (0.4)	-0.2 (-0.4, 0.1); P=0.010
Switch	0.2 (0.6)	0.0 (0.2)	-0.2 (-0.3, 0.0); P=0.027
Discontinuation	0.6 (1.0)	0.8 (0.7)	+0.2 (-0.1, 0.5); P=0.12
Dose adjustment	0.2 (0.6)	0.0 (0.1)	-0.2 (-0.3, 0.0); P=0.021

CI, confidence interval; SD, standard deviation

Limitations

- The lack of a comparator group prevents causal relationships from being identified.
- There was no adjustment for multiplicity and all outcomes were exploratory; results should be interpreted as hypothesis generating unless confirmed in a controlled study.
- Subgroup analyses were limited by small sample sizes.
- While race/ethnicity balance aimed to be representative of the US patient population, enrollment was limited to 6 sites, with a disproportionate contribution from 1 site, potentially reducing generalizability or revealing site-specific treatment patterns.
- Retrospective studies may potentially include inaccurate, incomplete, or misclassified data.

Conclusions

- Exploratory analyses from a real-world study suggest that patients diagnosed with BP-I who transitioned to Ari 2MRTU had reduced cumulative burden of concomitant psychotropic medication prescriptions and healthcare resource utilization.
- These real-world findings support the value of Ari 2MRTU as a long-term maintenance treatment option for patients diagnosed with BP-I and the feasibility of transitioning from an oral antipsychotic or AOM to Ari 2MRTU in clinical practice.

References

- Keratanian K et al. Focus (Am Psychiatr Publ) 2023; 21 (4): 344–353.
 - Hong J et al. Psychiatry Res 2015; 190 (1): 110–114.
 - Hong J et al. Pharmacoeconomics 2010; 28 (7): 555–566.
 - McEvoy JP. J Clin Psychiatry 2006; 67 (Suppl 5): 15–18.
 - Otsuka America Pharmaceutical, Inc. Axiity Maltene® (aripiprazole). Prescribing information. <https://www.otsuka-us.com/media/axiity/Axiity-Maltene-Pf.pdf>. February 2026.
 - Otsuka America Pharmaceutical, Inc. Axiity Axiity® (aripiprazole). Prescribing information. <https://www.otsuka-us.com/media/axiity/Axiity-Axiity-Pf.pdf>. March 2025.
- Disclosures**
- JFG has served as a consultant for Abbvie, Akorn, Almaco, Alvogon, Compas Pathways, Genomind, Luye Pharmaceuticals, Neuritis, Neurona, Otsuka, Pureset, Sepracor Therapeutics, and Sunovion; is on speakers bureaus for Akorn, Almaco, Bristol Myers Squibb, Johnson and Johnson, and Vanda Pharmaceuticals; and has received royalties from American Psychiatric Publishing Inc. and Cambridge University Press. NA is a consultant for Otsuka Pharmaceutical Development & Commercialization Inc. KSB is an employee of Otsuka Pharmaceutical Development & Commercialization Inc. at the time of this analysis, and is currently an employee of Neurone Biosciences. AMW is an employee of Lundbeck LLC. ZZ, AMP, SSN, and AA are employees of Otsuka Pharmaceutical Development & Commercialization Inc. PP is on speakers bureaus for Bristol Myers Squibb, Abbvie, Akorn, and Teva Pharmaceuticals. TJB-D is on speakers bureaus for Akorn, Bristol Myers Squibb, and Teva Pharmaceuticals. KH is an employee of H. Lundbeck A/S.

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