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Enclosure:

POSTER: Nag S, Urganus A, Awasthi S, et al. Presented at: Psych Congress, September 17-21, 2025, San Diego, CA, USA..

Real-World Healthcare Resource Utilization and Costs Among US Individuals Living with Bipolar-I Disorder Who Transitioned to Aripiprazole 2-Month Ready-To-Use Formulation

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Background

Nonadherence to oral antipsychotics (OAPs) among patients diagnosed with bipolar I disorder (BP-I) is associated with an increased risk of relapse, greater healthcare resource utilization (HCRU), and higher medical costs.[1,2]

Long-acting injectable (LAI) antipsychotics were developed to help address adherence challenges in BP-I by reducing dosing frequency and ensuring consistent medication delivery.[3]

Aripiprazole once-monthly 400 mg (AOM 400) has been available for BP-I maintenance therapy, and in 2023 the 2-Month Ready-To-Use formulation (Ari 2MRTU) was approved.[4,5,6]

As a once-every-2-month LAI, Ari 2MRTU is designed to maintain stable therapeutic coverage, potentially lowering relapse rates, decreasing healthcare use, and reducing associated costs.

However, real-world evidence on its impact in BP-I, particularly among patients transitioning from OAPs or other LAIs, remains limited.

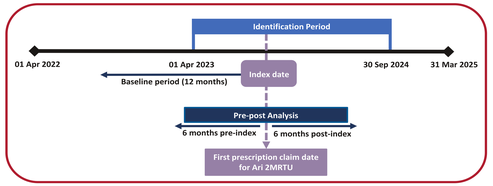
STUDY AIM: To describe patient profiles, adherence, HCRU, and costs in adults diagnosed with BP-I who transitioned from OAPs or aripiprazole once-monthly (AOM) to Ari 2MRTU, using a pre-post-analysis design.

Methods

Data

- Retrospective non-interventional database cohort study using Kythera Labs closed claims dataset from 1 April 2022 to 31 March 2025
- Commercial and Medicaid-insured US adults (≥18 years) diagnosed with BP-I who transitioned from OAPs or AOM to Ari 2MRTU

Figure 1. Study design



Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use

Cohort Assignment

- **OAPs → Ari 2MRTU Cohort:** Patients diagnosed with BP-I who initiated treatment with OAPs prior to transitioning to Ari 2MRTU
- **AOM → Ari 2MRTU Cohort:** Patients diagnosed with BP-I who were treated with AOM prior to transitioning to Ari 2MRTU

Baseline Characteristics

- Baseline characteristics were analyzed descriptively by demographic and clinical variables, including prescriber specialty and comorbidity, including the updated Charlson Comorbidity Index (CCI) to proxy for disease severity.
- Mental health-specific and systemic health comorbidities were identified using appropriate ICD-10 codes.

Outcomes Pre- and Post-Transition of Treatment Adherence

- **Proportion of days covered (PDC):** Ratio of days covered by the medication (without overlap) to total days in the pre-/post-transition period
- **Medication possession ratio (MPR):** Ratio of the number of days' supply to the total number of days in the pre-/post-transition period
- **Adherence:** Measured using MPR ≥0.8 (medication available ≥80% of days)

Healthcare Utilization & Costs: All-cause, Psychiatry-related

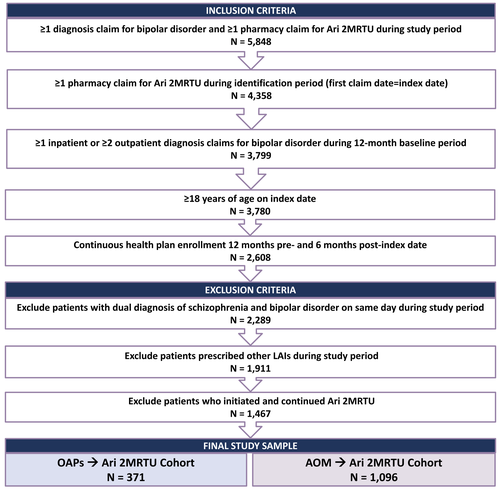
- # inpatient, outpatient, emergency department (ED) visits per patient
- Hospital length of stay (LOS)
- All-cause Inpatient/outpatient/ED/total medical costs per patient

Outcomes were assessed 6 months pre- and post-transition. All variables were analyzed descriptively.

Results

- After applying the inclusion and exclusion criteria, the cohort consists of a total of 1,467 patients diagnosed with BP-I who transitioned to Ari 2MRTU from either OAPs or AOM (**Figure 2**).

Figure 2. Selection of Patient Cohort



Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; LAIs, long-acting injectables

Table 1. Baseline Demographics of Patients Diagnosed with BP-I who Transitioned from OAPs and AOM to Ari 2MRTU

	OAPs to Ari 2MRTU (N=371)		AOM to Ari 2MRTU (N=1,096)	
Characteristics	N/Mean	%/SD	N/Mean	%/SD
Age (Mean)	38.46	13.53	39.60	13.33
Sex				
Female	192	51.75%	543	49.54%
Male	123	33.15%	383	34.95%
Unknown	56	15.09%	170	15.51%
Payer Type				
Commercial	278	74.93%	836	76.28%
Medicaid	93	25.07%	260	23.72%
US Geographic Region				
Northeast	53	14.29%	130	11.86%
North Central	89	23.99%	337	30.75%
South	131	35.31%	397	36.22%
West	94	25.34%	222	20.26%
Specialty Type Prescribing Medication				
Psychiatrists	235	63.34%	585	53.38%
Primary Care Physicians	53	14.29%	120	10.95%
Physician Assistants	18	4.85%	69	6.30%
Other	65	17.52%	322	29.38%

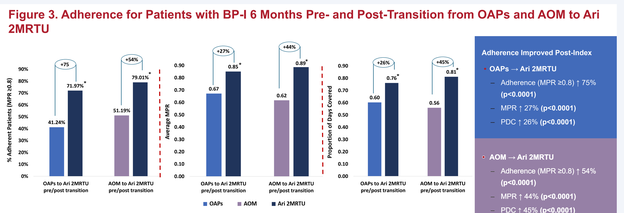
AOM, Aripiprazole once-monthly; Ari 2MRTU; Aripiprazole 2-Month Ready-To-Use; OAPs, oral antipsychotics; SD: standard deviation

Table 2. Baseline Clinical Characteristics for Patients Diagnosed with BP-I who Transitioned from OAPs and AOM to Ari 2MRTU

	OAPs to Ari 2MRTU (N=371)		AOM to Ari 2MRTU (N=1,096)	
Characteristics	N/Mean	%/SD	N/Mean	%/SD
Charlson Comorbidity Index score categories				
0	233	62.80%	684	62.41%
1	80	21.56%	232	21.17%
≥2	58	15.63%	180	16.42%
Mental Health Comorbidities				
Major depressive disorder	127	34.23%	272	24.82%
Anxiety disorders	206	55.53%	503	45.89%
Post-traumatic stress disorder	108	29.11%	258	23.54%
Any substance use disorders	218	58.76%	501	45.71%
Any mental health comorbidity	306	82.48%	793	72.35%
Systemic Health Comorbidities				
Diabetes	82	22.10%	278	25.36%
Obesity	60	16.17%	183	16.70%
Hypertension	116	31.27%	287	26.19%
Dyslipidemia	70	18.87%	259	23.63%
Sleeping disorders	86	23.18%	239	21.81%
Any systemic health comorbidity	217	58.49%	621	56.66%

AOM, Aripiprazole once-monthly; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use, OAPs, oral antipsychotics; SD, standard deviation

Figure 3. Adherence for Patients with BP-I 6 Months Pre- and Post-Transition from OAPs and AOM to Ari 2MRTU

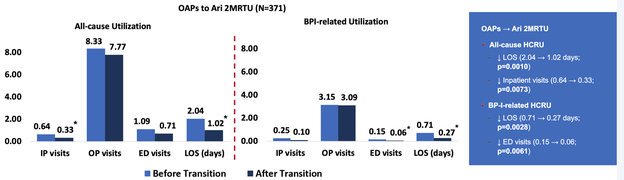


Adherence Improved Post-Index

- OAPs → Ari 2MRTU
  - Adherence (MPR ≥0.8) ↑ 75% (p<0.0001)
  - MPR ↑ 27% (p<0.0001)
  - PDC ↑ 26% (p<0.0001)
- AOM → Ari 2MRTU
  - Adherence (MPR ≥0.8) ↑ 54% (p<0.0001)
  - MPR ↑ 44% (p<0.0001)
  - PDC ↑ 45% (p<0.0001)

*Indicates statistically significant differences at the 95% confidence level.
AOM, Aripiprazole once-monthly; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; MPR, medication possession ratio; OAPs, oral antipsychotics

Figure 4A. All-cause and BP-I-related Mean Number of Visits and Length of Stay (Days) 6 Months Pre- and Post-Transition from OAPs to Ari 2MRTU

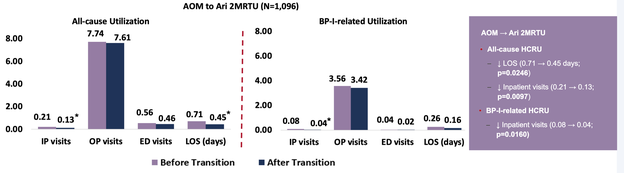


OAPs → Ari 2MRTU

- All-cause HCRU
  - ↓ LOS (2.04 → 1.02 days; p=0.0010)
  - ↓ Inpatient visits (0.64 → 0.33; p=0.0073)
- BP-I-related HCRU
  - ↓ LOS (0.71 → 0.27 days; p=0.0028)
  - ↓ ED visits (0.15 → 0.06; p=0.0061)

*Indicates statistically significant differences at the 95% confidence level.
Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; ED, emergency department; IP, inpatient, LOS, length of stay; OAPs, oral antipsychotics; OP, outpatient

Figure 4B. All-cause and BP-I-related Mean Number of Visits and Length of Stay (Days) 6 Months Pre- and Post-Transition from AOM to Ari 2MRTU

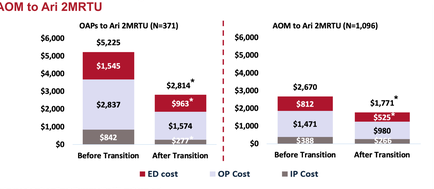


AOM → Ari 2MRTU

- All-cause HCRU
  - ↓ LOS (0.71 → 0.45 days; p=0.0246)
  - ↓ Inpatient visits (0.21 → 0.13; p=0.0097)
- BP-I-related HCRU
  - ↓ Inpatient visits (0.08 → 0.04; p=0.0160)

*Indicates statistically significant differences at the 95% confidence level.
AOM, Aripiprazole once-monthly; BP-I, bipolar disorder; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; ED, emergency department; IP, inpatient, LOS, length of stay; OP, outpatient

Figure 5. All-cause Average Medical Costs per Patient 6 Months Pre- and Post-Transition from OAPs and AOM to Ari 2MRTU



All-cause Healthcare Costs

- OAPs → Ari 2MRTU
  - ↓ Inpatient ($842 → $277; p=0.0001)
  - ↓ ED ($1,545 → $963; p=0.0387)
  - ↓ Total medical ($5,225 → $2,814; p=0.0154)
- AOM → Ari 2MRTU:
  - ↓ ED ($812 → $525, p=0.0148)
  - ↓ Total medical ($2,670 → $1,771, p=0.0139)

*Indicates statistically significant differences at the 95% confidence level.
AOM, aripiprazole once-monthly; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; ED, emergency department; IP, inpatient; OAPs, oral antipsychotics; OP, outpatient

Limitations

- Claims data may be incomplete or misclassified despite quality checks.
- Diagnosis codes do not confirm disease (possible miscoding or rule-out codes).
- Limited clinical detail (e.g., severity, lab values) may affect interpretation.
- This analysis is focused on a short 6-month pre-post framework. This is likely resulting in the small sample sizes that may be related to reduction in power and lack of significance, thus underestimating the effect of pre-post changes in HCRU.[10]

Conclusions

- In this pre-post descriptive study, among patients diagnosed with BP-I in a real-world setting, transitioning to Ari 2MRTU resulted in:
  - Improved adherence, consistent with prior studies showing benefits of less frequent LAI dosing;[2,8] and
  - Fewer ED visits, fewer inpatient admissions, and shorter hospital stays, reflecting significant reductions in HCRU, aligning with published evidence of LAI benefits.[7,8,11]
- The findings of this study highlight the potential role of Ari 2MRTU with a 2 monthly dosing interval in lowering HCRU burden among patients diagnosed with BP-I in a real-world setting.
- Further research with larger and more diverse patient populations and a longer-term follow-up period is needed to provide additional evidence on the impact on HCRU burden and related costs of Ari 2MRTU among patients diagnosed with BP-I in a real-world setting.

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Disclosures

SA, KSBL, NA: employees of Otsuka Pharmaceutical Development & Commercialization, Inc.
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Sponsorship

This work was supported by Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ, USA) and H. Lundbeck A/S (Valby, Denmark).