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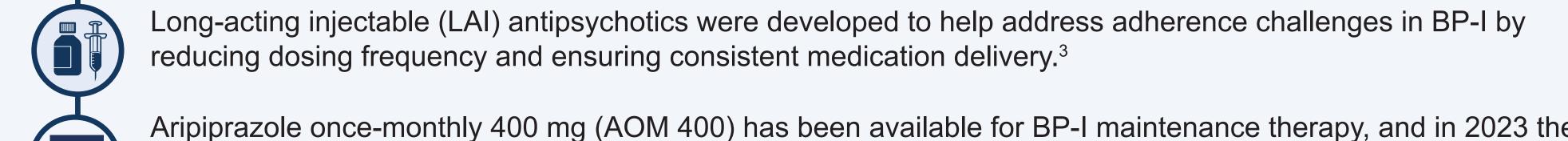
Enclosure:

POSTER: Nag S, Urganus A, Awasthi S et al. Presented at Psych Congress, September 17-19, 2025, San Diego, CA

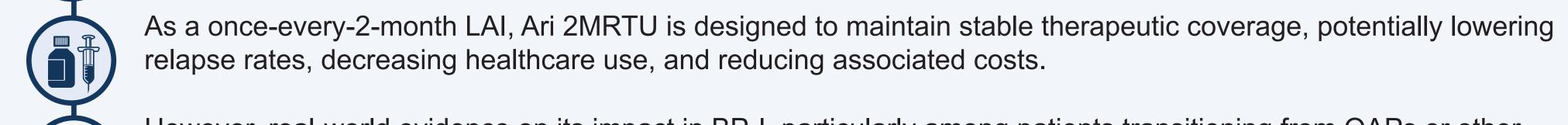
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Background



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}



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

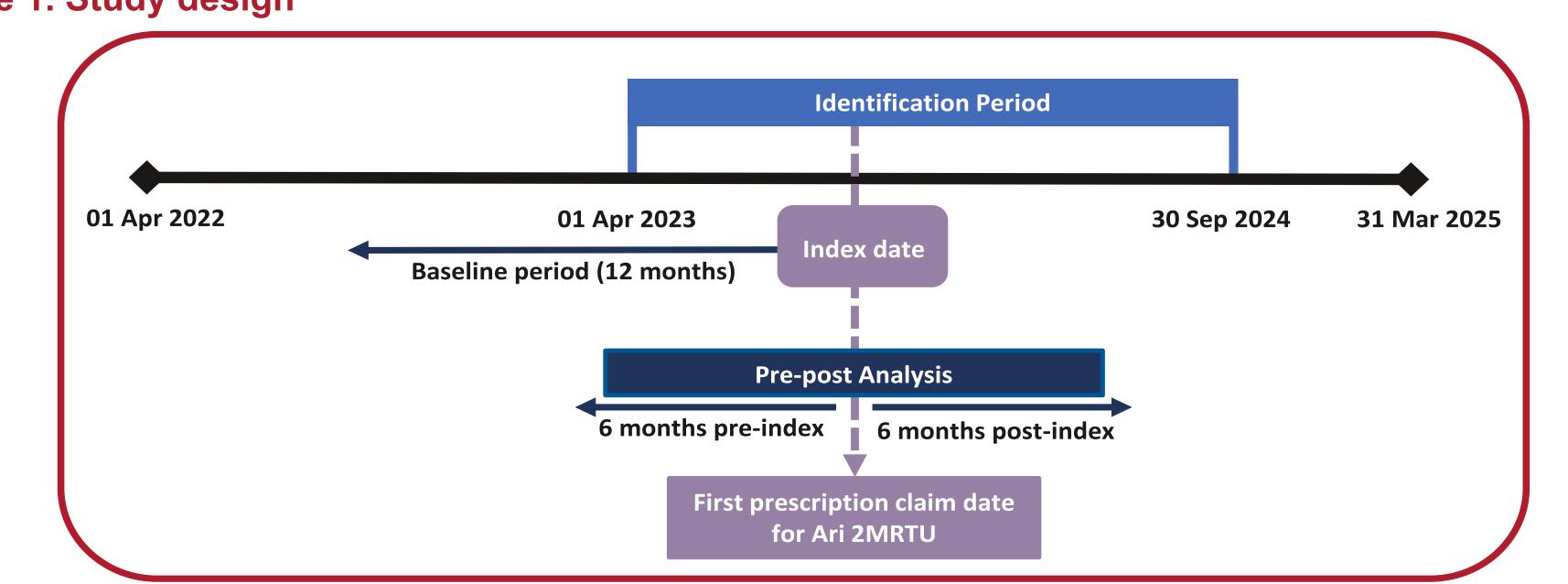


STUDY AIM: To describe patient profiles, adherence, HCRU, and costs in adults diagnosed with BP-I who transitioned from OAPs or aripiprazole once-monthly (AOM) to Ari 2MRTU, using a pre-post-analysis design.

Methods

• 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 demograph and clinical variables, including prescriber specialty and comorbidity, including the updated Charlson Comorbidity Index (CCI) to proxy for
- Mental health-specific and systemic health comorbidities were

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
- 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%

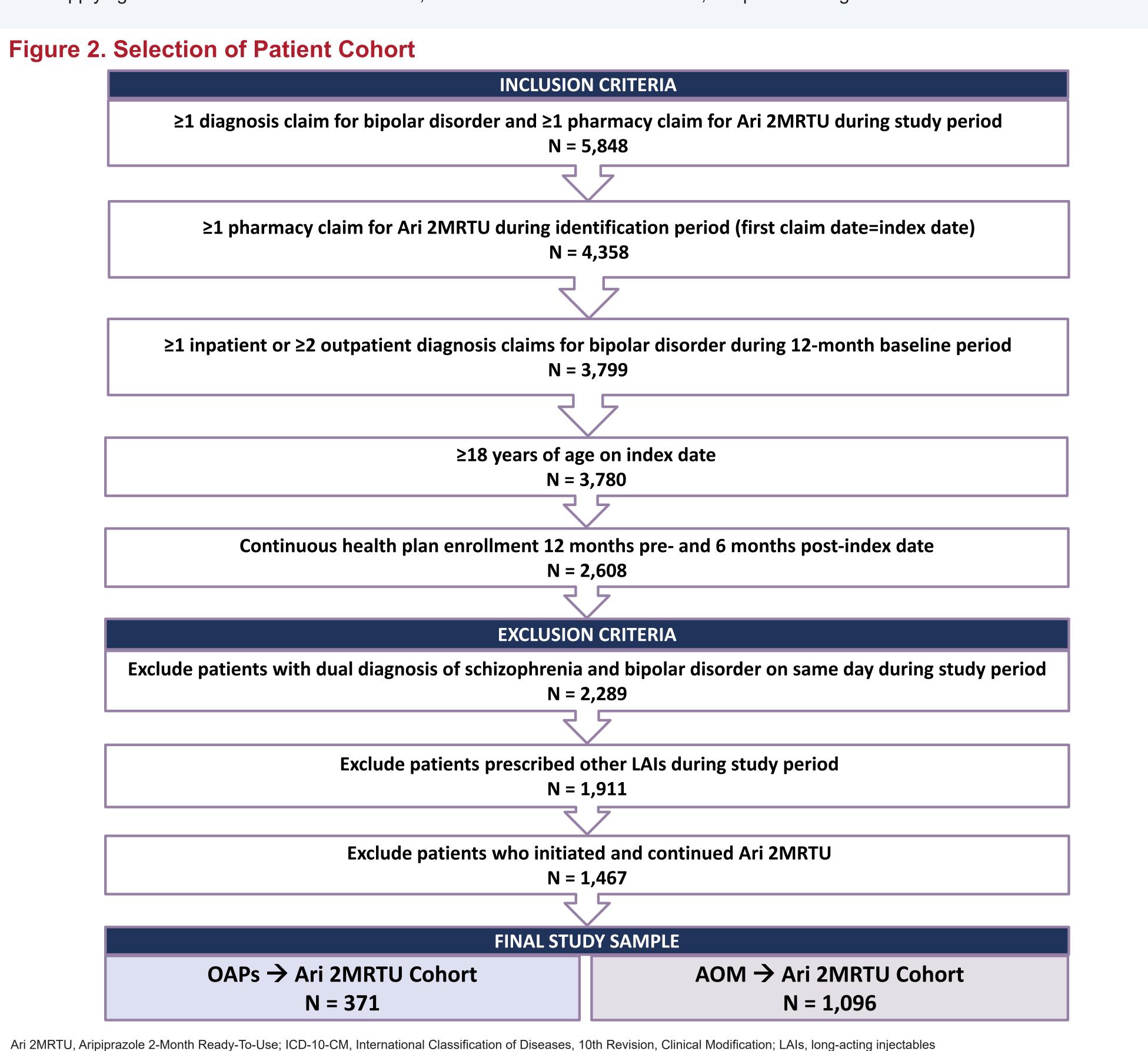
Healthcare Utilization & Costs: All-cause, Psychiatry-

- # 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).





	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%
OM, Aripiprazole once-monthly; Ari 2MRTU: A APs, oral antipsychotics; SD: standard deviat		-Month Ready-1	ō-Use;	

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 dherence Improved Post-Index OAPs → Ari 2MRTU Adherence (MPR ≥0.8) ↑ 75% MPR ↑ 27% (p<0.0001) PDC ↑ 26% (p<0.0001) rence (MPR ≥0.8) ↑ 54% MPR ↑ 44% (p<0.0001) ■ OAPs ■ AOM ■ Ari 2MRTU

Figure 4A. All-cause and BP-I-related Mean Number of Visits and Length of Stay (Days) 6 Months Pre- and

*Indicates statistically significant differences at the 95% confidence level.

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AOM, Aripiprazole once-monthly; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; MPR, medication possession ratio; OAPs, oral antipsychotics

Ari 2MRTU. Aripiprazole 2-Month Ready-To-Use; ED, emergency department; IP, inpatient, LOS, length of stay; OAPs, oral antipsychotics; OP, outpatient

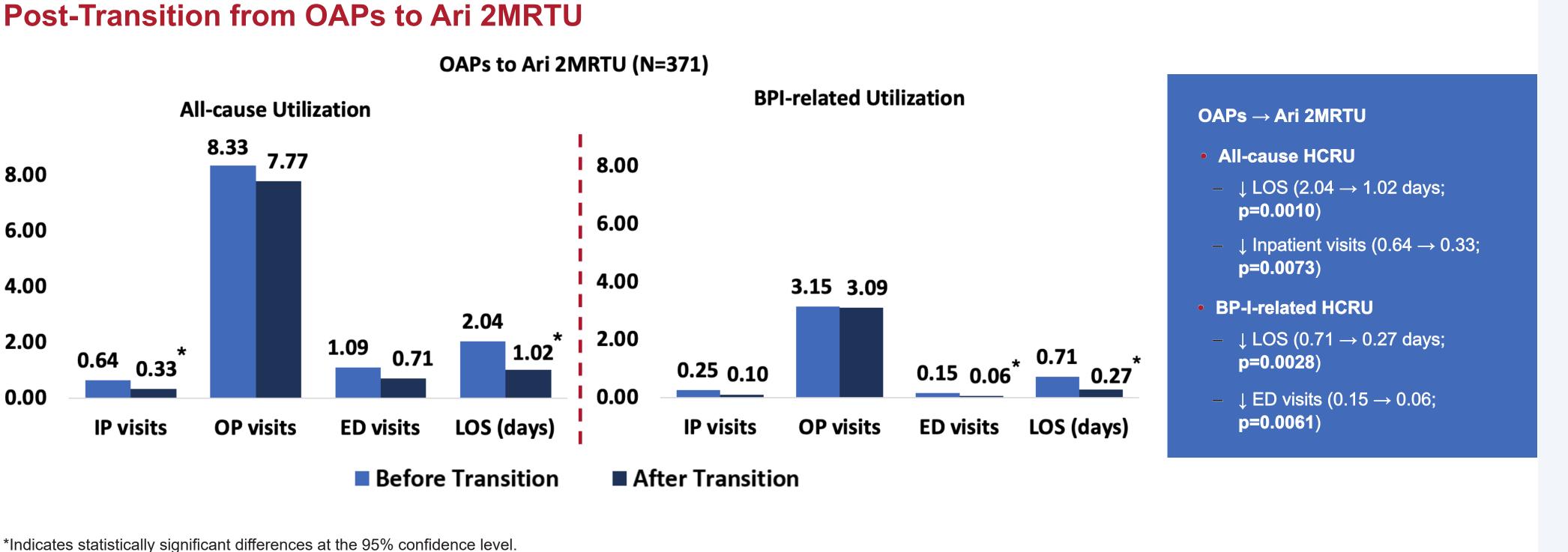
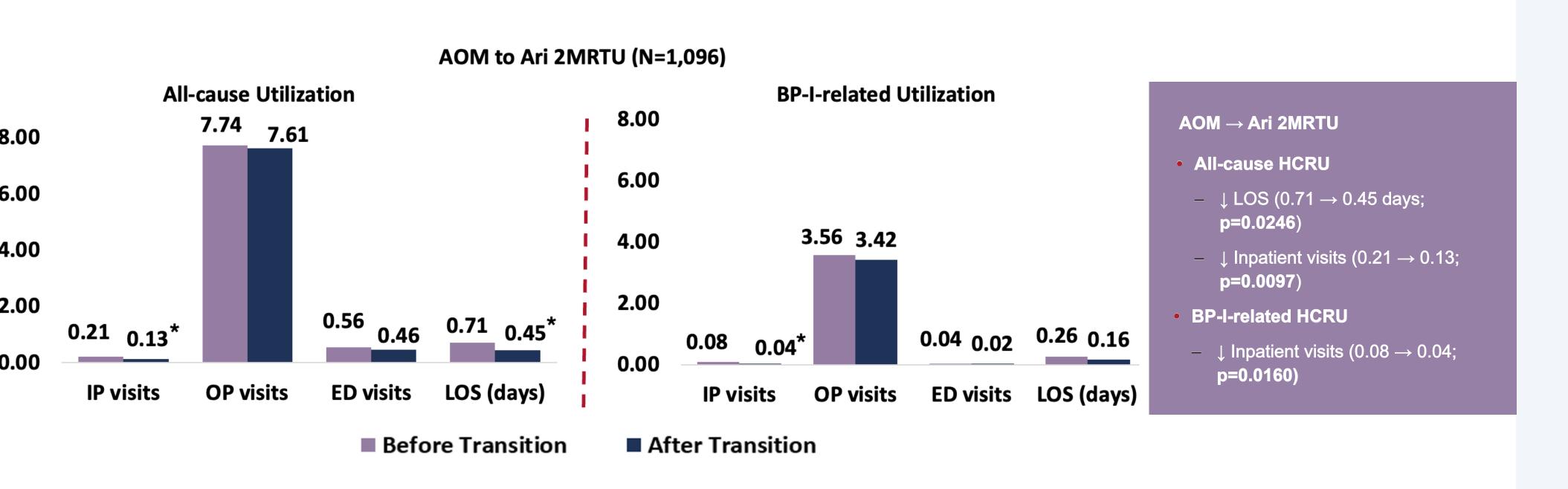
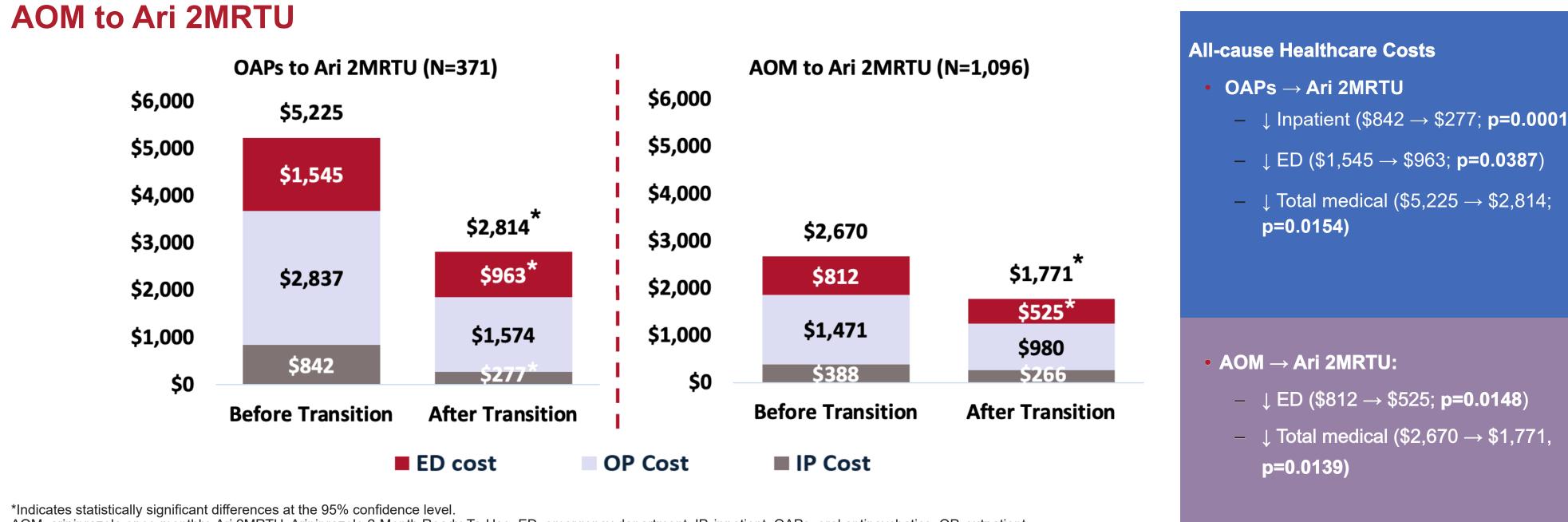


Figure 4B. All-cause and BP-I-related Mean Number of Visits and Length of Stay (Days) 6 Months Pre- and **Post-Transition from AOM to Ari 2MRTU**



AOM, 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



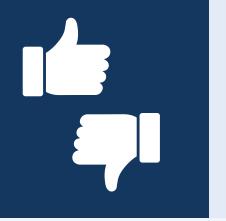
Limitations

- 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

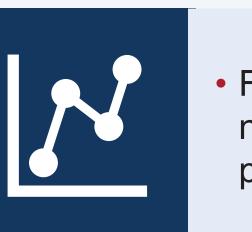
Conclusions



- In this pre-post descriptive study, among patients diagnosed with BP-I in a real-world setting, transitioning to
- 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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OB, KR: employee of Columbia Data Analytics, a consultant for Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ, USA) and H. Lundbeck A/S (Valby, Denmark).

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