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Enclosure:

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Real-world Impact of Transitioning from Oral or Once-monthly Injectable Aripiprazole to a 2-Month Ready-To-Use Aripiprazole Formulation on Adherence and Healthcare Utilization in US Adults Diagnosed with Schizophrenia

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Background

Oral antipsychotics, such as aripiprazole (Ari), are commonly used to manage schizophrenia.[1]

However, adherence in patients living with schizophrenia, as with many chronic conditions, is often poor, with estimates ranging from 34% to 81%.[2-5]

Nonadherence can lead to serious consequences, including relapse, increased risk of hospitalization, and increased rates of suicide.[6]

Long-acting injectable antipsychotics (LAIs) were developed, in part, to address challenges due to nonadherence and reduce overall healthcare resource utilization (HCRU) burden.[7]

Aripiprazole once-monthly 400 mg (AOM 400) was approved in 2013 for the treatment of schizophrenia.[8]

In 2023, the once every 2-month ready-to-use formulation of aripiprazole (Ari 2MRTU) was approved, offering the potential to further improve adherence/persistence and reduce HCRU in this population.[9,10]

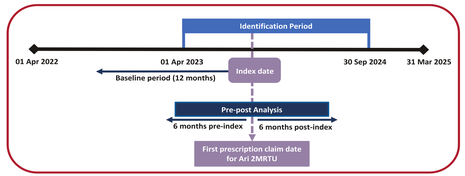
STUDY AIM: Characterize patient profiles, treatment adherence, HCRU, and related costs among individuals diagnosed with schizophrenia and transitioned from oral Ari or once-monthly aripiprazole (AOM) to Ari 2MRTU based on a pre-post design.

Methods

Data

- A retrospective non-interventional database cohort study was conducted using the Kythera Labs closed claims dataset from 1 April 2022 to 31 March 2025.
- Commercial and Medicaid-insured US adults (≥18 years) diagnosed with schizophrenia who transitioned from oral Ari or AOM to Ari 2MRTU

Figure 1. Study design



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

Cohort Assignment

- **Oral Ari → Ari 2MRTU Cohort:** Patients diagnosed with schizophrenia who initiated treatment with oral Ari prior to transitioning to Ari 2MRTU
- **AOM → Ari 2MRTU Cohort:** Patients diagnosed with schizophrenia who were treated with AOM prior to transitioning to Ari 2MRTU

Descriptive Baseline Characteristics

- Baseline characteristics for each group were analyzed descriptively by demographic and clinical variables, including payer type, geographic region, prescriber specialty, and comorbidities/Charlson Comorbidity Index (CCI).

Outcomes Measured 6 Months 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:** Percentage of patients with MPR ≥0.8 (medication available ≥80% of days)

HCRU: All-Cause and Schizophrenia-Related

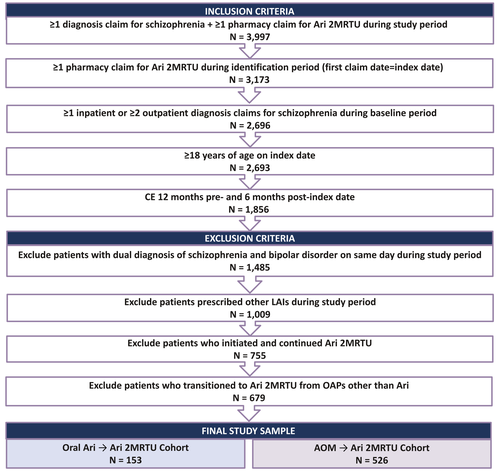
- # inpatient/outpatient/emergency department (ED) visits per patient
- Hospital length of stay (LOS)

All variables were analyzed descriptively.

Results

- After applying the inclusion and exclusion criteria, the cohort consists of a total of 679 patients diagnosed with schizophrenia, who transitioned to Ari 2MRTU from either oral Ari or AOM (Figure 2).

Figure 2. Selection of Patient Cohort



Ari, Aripiprazole; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; AOM, Aripiprazole once-monthly; CE, continuous enrollment; LAIs, long-acting injectables; OAPs, oral antipsychotics

Table 1. Baseline Demographics of Patients Diagnosed with Schizophrenia who Transitioned from Oral Ari and AOM to Ari 2MRTU

	Oral Ari to Ari 2MRTU (n=153)		AOM to Ari 2MRTU (n=526)	
Characteristics	N/Mean	%/SD	N/Mean	%/SD
Age (Mean)	40.41	13.61	42.37	13.72
Sex				
Female	51	33.33%	172	32.70%
Male	75	49.02%	275	52.28%
Unknown	27	17.65%	79	15.02%
Payer Type				
Commercial	118	77.12%	415	78.90%
Medicaid	35	22.88%	111	21.10%
US Geographic Region				
Northeast	14	9.15%	61	11.60%
Midwest	31	20.26%	124	23.57%
South	62	40.52%	197	37.45%
West	46	30.07%	139	26.43%
Specialty Type Prescribing Medication				
Psychiatrists	95	62.09%	267	50.76%
Primary Care Physicians	23	15.03%	57	10.84%
Physician Assistants	5	3.27%	23	4.37%
Other	30	19.61%	179	34.03%

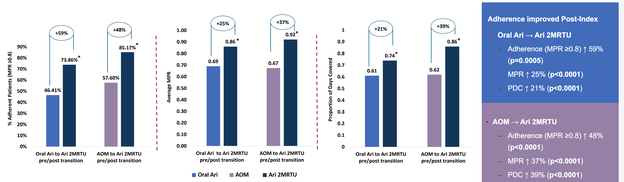
AOM, Aripiprazole once-monthly; Ari, aripiprazole; Ari 2MRTU: Aripiprazole 2-Month Ready-To-Use; SD: standard deviation

Table 2. Baseline Clinical Characteristics of Patients Diagnosed with Schizophrenia who Transitioned from Oral Ari and AOM to Ari 2MRTU

	Oral Ari to Ari 2MRTU (n=153)		AOM to Ari 2MRTU (n=526)	
Characteristics	N/Mean	%/SD	N/Mean	%/SD
Charlson Comorbidity Index score categories				
0	88	57.52%	327	62.17%
1	36	23.53%	100	19.01%
≥2	29	18.95%	99	18.82%
Mental Health Comorbidities				
Major depressive disorder	49	32.03%	110	20.91%
Anxiety disorders	74	48.37%	160	30.42%
Post-traumatic stress disorder	28	18.30%	61	11.60%
Any substance use disorders	90	58.82%	229	43.54%
Any mental health comorbidity	121	79.08%	323	61.41%
Systemic Health Comorbidities				
Diabetes	43	28.10%	139	26.43%
Obesity	31	20.26%	107	20.34%
Hypertension	47	30.72%	166	31.56%
Dyslipidemia	35	22.88%	129	24.52%
Sleeping disorders	26	16.99%	96	18.25%
Any systemic health comorbidity	96	62.75%	313	59.51%

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

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



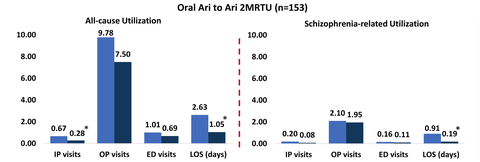
Adherence improved Post-Index

Oral Ari → Ari 2MRTU
- Adherence (MPR ≥0.8) ↑ 59% (p=0.0005)
- MPR ↑ 25% (p<0.0001)
- PDC ↑ 21% (p<0.0001)

AOM → Ari 2MRTU
- Adherence (MPR ≥0.8) ↑ 48% (p<0.0001)
- MPR ↑ 37% (p<0.0001)
- PDC ↑ 39% (p<0.0001)

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

Figure 4A. All-cause and Schizophrenia-related Average Number of Visits and Length of Stay 6 Months Pre- and Post-Transition from Oral Ari to Ari 2MRTU



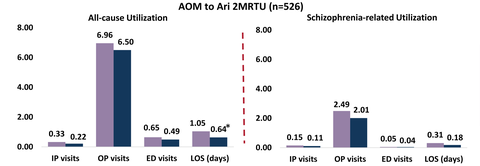
Oral Ari → Ari 2MRTU

All-cause HCRU
- ↓ Inpatient visits (0.67 → 0.28; p=0.0186)
- ↓ LOS (2.63 → 1.05 days; p=0.0081)

Schizophrenia-related HCRU
- ↓ LOS (0.91 → 0.19 days; p=0.0307)

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

Figure 4B. All-cause and Schizophrenia-Related Average Number of Visits and Length of Stay 6 Months Pre- and Post-Transition from AOM to Ari 2MRTU



AOM → Ari 2MRTU

All-cause HCRU
- ↓ LOS (1.05 → 0.64 days; p=0.0466)

*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, LOS, length of stay; OP, outpatient

Limitations

- Claims data may be incomplete or misclassified despite quality checks.
- A diagnosis code does not confirm disease due to possible miscoding or rule-out coding.
- Limited clinical and disease-specific details (e.g., severity, lab values) may affect interpretation of outcomes.
- 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 potentially underestimating the effect of pre-post changes in HCRU.[11]

Conclusions

- In this pre-post descriptive study, among patients diagnosed with schizophrenia in a real-world setting, transitioning to Ari 2MRTU resulted in:
  - Improved treatment adherence, consistent with prior evidence that less frequent dosing supports adherence;[12]
  - Reductions in all-cause and schizophrenia-related HCRU, consistent with prior research showing that improved adherence can lead to lower utilization.[13,14]
- The findings of this study highlight the potential role of Ari 2MRTU, with its once every 2-month dosing interval, to lower HCRU burden among patients diagnosed with schizophrenia in a real-world setting.
- Larger studies with longer follow-up periods are needed to provide additional evidence on the impact on HCRU burden of Ari 2MRTU among patients diagnosed with schizophrenia in a real-world setting.

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Disclosures

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