Treatment Patterns and Healthcare Resource Utilization Following Initiation of Aripiprazole Lauroxil Using a 1-Day Initiation Regimen

Lauren N. Strand, PhD, MS[1]; Michael J. Doane, PhD[1]; James A. McGrory, PhD[1]; Alejandro G. Hughes, MPH[2]; John Lauriello, MD[3]

[1]Alkermes, Inc., Waltham, MA, USA; [2]Optum, Inc., Eden Prairie, MN, USA; [3]Department of Psychiatry and Human Behavior, Jefferson Health–Sidney Kimmel Medical College, Philadelphia, PA, USA

INTRODUCTION

- Aripiprazole lauroxil (AL) is an atypical long-acting injectable antipsychotic indicated for the treatment of adults with schizophrenia and is available with monthly, every-6-weeks, and every-2-months dosing options[1]
- Treatment with AL can be started in a single day using a one-time 675-mg injection of the AL NanoCrystal Dispersion initiation formulation (AL_{NCD}) and 30 mg of oral aripiprazole,[2,3] with the first AL dose given on the same day or up to 10 days later[4]
- In a previous retrospective observational cohort study, AL treatment initiation utilizing 21 days of oral aripiprazole supplementation resulted in significant reductions in all-cause inpatient (P=0.017) and mental health–related inpatient admissions per patient (P=0.011) and the proportion of patients with at least 1 mental health–related emergency department visit (P=0.025) between baseline and 6 months of follow-up[5]

OBJECTIVE

- To examine treatment patterns and healthcare resource utilization (HCRU) among patients with schizophrenia before and after initiating AL using AL_{NCD}

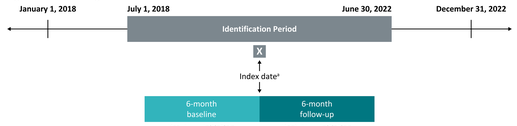
METHODS

Data Source

- Administrative claims data from January 1, 2018, to December 31, 2022 (study period) were obtained from the US-based Komodo Healthcare Map, a fully deidentified database containing detailed inpatient (IP), outpatient (OP), and pharmacy claims data from ~150 million patients covered by a commercial, Medicaid, or Medicare Advantage insurance plan

Study Design and Patient Selection

Figure 1. Study Design



[a]Date of first observed pharmacy or medical claim for AL_{NCD} during the identification period. Neither 2018 nor 2022 included a full year of data; most patients had an index date during 2021.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion.

- Criteria for patient identification for this analysis are listed in **Figure 2**

Outcomes

- Demographics, clinical characteristics, and medication use during the 6-month baseline
- Treatment patterns: AL timing and dosage during initiation (index date of AL_{NCD} administration through the first administration of AL); persistence, discontinuation, and time to discontinuation during maintenance (starting the day after AL initiation)
  - Discontinuation of AL: a continuous 60-day gap without a subsequent AL claim after expiration of the dosing window (441 mg, ≤6 weeks; 662 or 882 mg, ≤8 weeks; 1064 mg, ≤10 weeks)
  - Persistence with AL: number of days from index date to discontinuation date or to the end of follow-up for patients who did not discontinue
- HCRU outcomes: all-cause IP admissions, emergency department (ED) visits, and OP visits and these same outcomes for the mental health–related subset of resource use

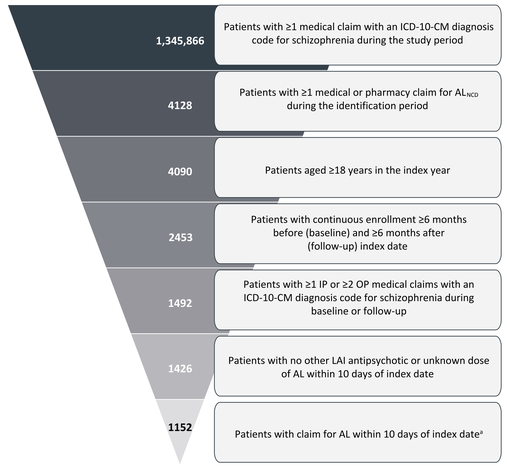
Statistical Analysis

- Data from patients who had their first AL dose within 10 days of AL_{NCD} (consistent with prescribing information) were analyzed
  - Per AL_{NCD} prescribing information, a single 30-mg dose of oral aripiprazole is administered together with AL_{NCD} on day 1; however, administration of the oral dose of aripiprazole was not captured in this analysis
- Patient demographics, baseline clinical characteristics, recent medication use, and treatment pattern outcomes were summarized using descriptive statistics
- For IP admissions, ED visits, and OP visits, unadjusted pairwise comparisons were made between baseline and follow-up; because each patient served as their own control, no adjustments for additional covariates were made

RESULTS

Patients

Figure 2. Patient Identification



[a]As defined in AL$_{NCD}$ prescribing information.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion; ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*; IP, inpatient; LAI, long-acting injectable; OP, outpatient.

Table 1. Patient Demographics

Characteristic	AL_{NCD} + AL (N=1152)
Age, mean (SD), years	38.4 (13.0)
Sex, n (%)	
Male	739 (64.1)
Region, n (%)	
West	382 (33.2)
South	328 (28.5)
Midwest	241 (20.9)
Northeast	123 (10.7)
Other[a]	78 (6.8)
Insurance type, n (%)[b]	
Medicaid	822 (71.4)
Multiple	147 (12.8)
Medicare Advantage	122 (10.6)
Commercial	52 (4.5)

[a]Included Armed Forces, American Samoa, Federated State of Micronesia, Guam, Marshall Islands, Commonwealth of the Northern Mariana Islands, Puerto Rico, Palau, Virgin Islands.
[b]A small proportion of patients (<1%) had insurance type listed as none/unknown.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion.

Table 2. Baseline Clinical Characteristics and Recent Antipsychotic Use

Characteristic	AL_{NCD} + AL (N=1152)
Quan-Charlson Comorbidity score,[6] mean (SD)	0.6 (1.2)
Behavioral health–related comorbidity, n (%)	
Any substance use disorder[a]	605 (52.5)
Alcohol use disorder	233 (20.2)
Opioid use disorder	154 (13.4)
Cannabis use disorder	102 (8.9)
Anxiety disorder	497 (43.1)
Major depressive disorder	444 (38.5)
Posttraumatic stress disorder	203 (17.6)
Intentional self-inflicted injury	162 (14.1)
Suicide attempt	0
Other comorbidities of interest, n (%)	
Hypertension	409 (35.5)
Obesity	359 (31.2)
Hyperlipidemia	271 (23.5)
Metabolic syndrome	5 (0.4)
Recent[b] use of antipsychotics, n (%)	1004 (87.2)
Any oral antipsychotic	903 (78.4)
Aripiprazole	550 (47.7)
Olanzapine	236 (20.5)
Risperidone	195 (16.9)
Quetiapine	177 (15.4)
Any LAI first-generation antipsychotic	95 (8.2)
Any LAI second-generation antipsychotic[c]	354 (30.7)
Paliperidone palmitate	201 (17.4)
Aripiprazole monohydrate	151 (13.1)
Risperidone microspheres	14 (1.2)

[a]Excludes tobacco.
[b]Within the 6 months before the index date.
[c]LAI second-generation antipsychotics reported for >1% of patients.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion; LAI, long-acting injectable.

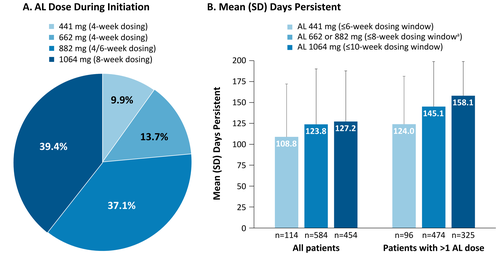
Treatment Patterns

Table 3. Treatment Patterns

Characteristic	AL_{NCD} + AL (N=1152)
Initiation	
First dose of AL administered on index date, n (%)	1040 (90.3)
Maintenance	
Persistence[a] over 6 months, mean (SD), days	123.7 (64.0)
Discontinuation,[b] proportion of patients, n (%)	558 (48.4)
– Time to discontinuation,[c] mean (SD), days	61.6 (31.1)
– AL injections before discontinuation,[c,d] mean (SD)	1.9 (1.2)
– Switch,[c,e] n/N (%)	428/558 (76.7)
Subgroup of patients who had >1 AL dose, n/N (%)	898 (78.0)
Persistence[a] over 6 months, mean (SD), days	148 (50.9)
Discontinuation,[b] proportion of patients, n/N (%)	303/895 (33.9)
– Time to discontinuation,[c] mean (SD), days	80 (28.3)
– AL injections before discontinuation,[c,d] mean (SD)	2.6 (1.1)
– Switch,[c,e] n/N (%)	231/303 (76.2)

[a]Defined as number of days from index date to discontinuation date, or from index date to end of follow-up for patients who did not discontinue.
[b]Defined as having a continuous 60-day gap without a subsequent AL claim after expiration of the dosing window (441 mg, ≤6 weeks; 662 or 882 mg, ≤8 weeks; 1064 mg, ≤10 weeks) in which follow-up AL use was associated with the previous AL claim. The discontinuation date was defined as the last day of the supply of the last prescription filled before the first observed gap in therapy without subsequent fills for AL.
[c]Among the subset of patients who discontinued; does not include patients who remained on index medication through follow-up.
[d]AL_{NCD} injection and initial AL injection not included in count.
[e]Defined as claims for a non-AL antipsychotic after discontinuation of AL. The most common switch was to oral aripiprazole (40%).
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion; n/N, number of patients/number of patients in analysis of parameter.

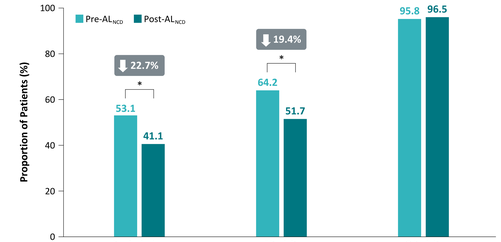
Figure 3. Treatment Patterns by Dose



[a]AL 662 and 882 mg both have a dosing window of ≤8 weeks and were combined for the days-persistent analysis.
AL, aripiprazole lauroxil.

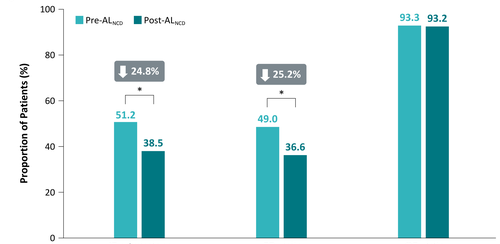
Healthcare Resource Utilization

Figure 4. All-Cause HCRU[a]



[a]*P<0.001.
[b]Gray boxes represent percent change from baseline. Numbers are rounded for clarity and may not represent exact values.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion; ED, emergency department; HCRU, healthcare resource utilization; IP, inpatient; OP, outpatient.

Figure 5. Mental Health–Related HCRU[a]



[a]*P<0.001.
[b]Gray boxes represent percent change from baseline. Numbers are rounded for clarity and may not represent exact values.
AL, aripiprazole lauroxil; AL_{NCD}, AL NanoCrystal Dispersion; ED, emergency department; HCRU, healthcare resource utilization; IP, inpatient; OP, outpatient.

LIMITATIONS

- Results from the insured population studied may not be generalizable to uninsured populations, to the general population of those who receive aripiprazole, or to those who initiate AL using an oral aripiprazole starting regimen
- Claims data do not capture disease severity and may be subject to data omissions or coding inaccuracies
- Because of the limited follow-up time, HCRU reported may not fully capture long-term effects of initiating AL with AL_{NCD}
- This analysis did not assess whether patients received the single 30-mg oral aripiprazole dose,[4] which may or may not have affected treatment outcome

CONCLUSIONS

- In this first real-world study focusing on AL_{NCD}, almost all patients initiated AL using AL_{NCD} in a single day, and most continued AL treatment through the 6-month follow-up
- Initiation of AL using AL_{NCD} was associated with reductions in IP and ED visits during the 6 months after initiating AL using AL_{NCD} compared with the 6 months before initiation
- Results were consistent across all-cause and mental health–related resource use
- These findings suggest that initiating AL with AL_{NCD} may result in clinically meaningful reductions in patient burden and healthcare costs, as evidenced by significant declines in HCRU

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DISCLOSURES

LNS, MJD, and **JAM** are or were employees of Alkermes, Inc., and may own stock/options in the company.

AGH is an employee of Optum, Inc., a health services innovation company that received funding from Alkermes, Inc.

JL has served as a consultant for Alkermes, Inc.

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