RWD103

# 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]

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## 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 injection of the AL NanoCrystal Dispersion initiation formulation ($AL_{NCD}$) and 30 mg of oral aripiprazole[2,3]; the first AL dose is given on the same day or up to 10 days later[4]
- In a previous retrospective database study, AL treatment initiation using 21 days of oral aripiprazole supplementation resulted in significant reductions from baseline in all-cause and mental health–related inpatient (IP) admissions per patient and proportion of patients with at least 1 mental health–related emergency department (ED) visit during 6 months of follow-up ($P \leq 0.025$ for each)[5]
- The objective was to assess and compare treatment patterns and healthcare resource utilization (HCRU) 6 months before and after initiating AL using $AL_{NCD}$ in patients treated for schizophrenia

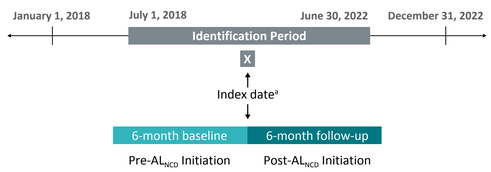
## METHODS

### *Data Source*

- Administrative claims data were obtained from the US-based Komodo Healthcare Map, a deidentified database containing IP, outpatient (OP), and pharmacy claims data from 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 **Table 1**

### *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 the first AL injection)
- HCRU outcomes: all-cause IP admissions, 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
- Treatment pattern outcomes were summarized using descriptive statistics
- Changes in IP admissions, ED visits, and OP visits between baseline and follow-up were assessed using unadjusted pairwise comparisons

## RESULTS

**Table 1**. Patient Identification

| Criteria | Number of patients |
|---|---|
| Patients with ≥1 medical claim with an ICD-10-CM diagnosis code for schizophrenia during the study period | **1,345,866** |
| Patients with ≥1 medical or pharmacy claim for $AL_{NCD}$ during the identification period | **4128** |
| Patients aged ≥18 years in the index year | **4090** |
| Patients with continuous enrollment ≥6 months before (baseline) and ≥6 months after (follow-up) index date | **2453** |
| Patients with ≥1 IP or ≥2 OP medical claims with an ICD-10-CM diagnosis code for schizophrenia during baseline or follow-up | **1492** |
| Patients with no other LAI antipsychotic or unknown dose of AL within 10 days of index date (initiation) | **1426** |
| Patients with claim for AL within 10 days of index date[a] | **1152** |

[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 2**. Patient Demographics, Baseline Clinical Characteristics, and Recent Use of Antipsychotic Medications

| Characteristic | $AL_{NCD}$ + AL (N=1152) |
|---|---|
| Age, mean (SD), years | **38.4 (13.0)** |
| Sex, male, n (%) | **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)** |
| Quan-Charlson Comorbidity score,[c] mean (SD) | **0.6 (1.2)** |
| Behavioral health–related comorbid conditions of interest, n (%) | |
| Any substance use disorder[c] | **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)** |
| Recent[d] 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[e] | **354 (30.7)** |
| Paliperidone palmitate | **201 (17.4)** |
| Aripiprazole monohydrate | **151 (13.1)** |
| Risperidone microspheres | **14 (1.2)** |

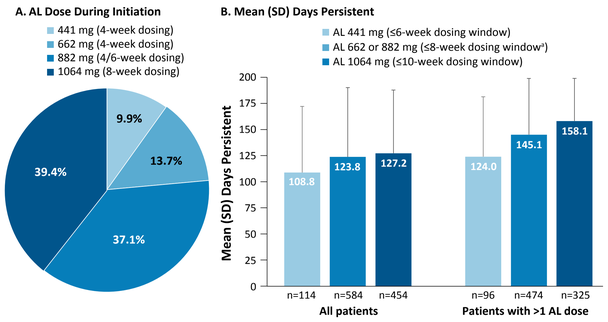
[a]Included Armed Forces, American Samoa, Federated State of Micronesia, Guam, Marshall Islands, Commonwealth of the Northern Mariana Islands, Puerto Rico, Palau, and Virgin Islands.
[b]A small proportion of patients (<1%) had insurance type listed as none/unknown.
[c]Excludes tobacco.
[d]Within the 6 months before the index date.
[e]LAI second-generation antipsychotics reported for >1% of patients.
AL, aripiprazole lauroxil; $AL_{NCD}$, AL NanoCrystal Dispersion; LAI, long-acting injectable.

**Table 3**. Treatment Patterns

| Characteristic | $AL_{NCD}$ + AL (N=1152) |
|---|---|
| **Initiation** | |
| First dose of AL administered on same day as $AL_{NCD}$, 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)** |

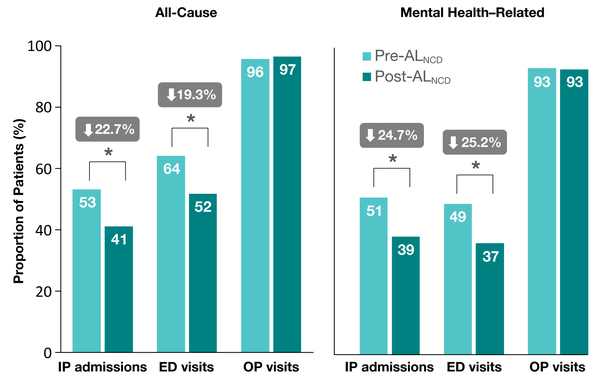
[a]Defined as number of days from index date to discontinuation date, or from index date to end of follow-up for patients who did not discontinue.
[b]Defined as having a continuous 60-day gap without a subsequent AL claim after expiration of the dosing window (441 mg, ≤6 weeks; 662 or 882 mg, ≤8 weeks; 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 2**. 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.

**Figure 3**. Healthcare Resource Utilization[a]




*$P$<0.001.
[a]Gray boxes represent percent change from baseline.
AL, aripiprazole lauroxil; $AL_{NCD}$, AL NanoCrystal Dispersion; ED, emergency department; HCRU, healthcare resource utilization; IP, inpatient; OP, outpatient.

## LIMITATIONS

- Results 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 all-cause and mental health–related IP admissions and ED visits during the 6 months after initiating AL using $AL_{NCD}$ compared with the 6-month baseline
- 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

## REFERENCES

**1.** Aristada [package insert]. Waltham, MA: Alkermes, Inc.; 2023. **2.** Jain R, et al. *CNS Spectr.* 2020;25(3): 323-30. DOI: 10.1017/S1092852919000816. **3.** Hard ML, et al. *J Clin Psychopharmacol.* 2018;38(5):435-41. DOI: 10.1097/jcp.0000000000000921. **4.** Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; 2023. **5.** Lauriello J, et al. *CNS Drugs.* 2021;35(10):1123-35. DOI: 10.1007/s40263-021-00849-2. **6.** Quan H, et al. *Am J Epidemiol.* 2011;173(6):676-82. DOI: 10.1093/aje/kwq433.

## AUTHOR DISCLOSURES

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**JL** has served as a consultant for Alkermes, Inc.

## ACKNOWLEDGMENTS

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## 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[a]
- 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[1]
- Objective: to examine treatment patterns and healthcare resource utilization (HCRU) among patients with schizophrenia before and after initiating AL using $AL_{NCD}$

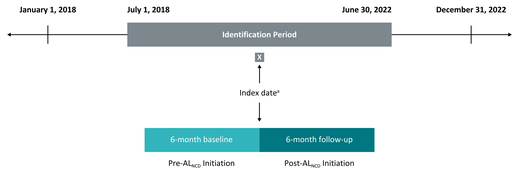
## METHODS

### 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

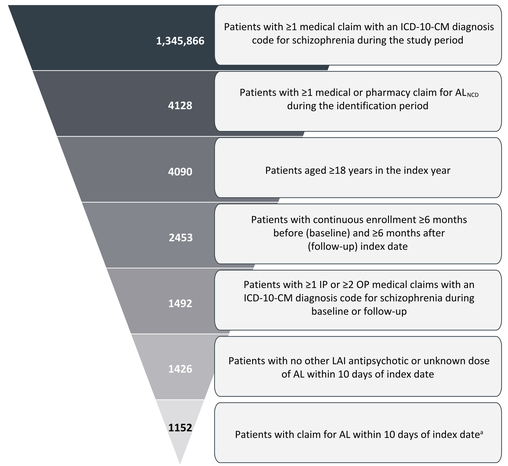
### Statistical Analysis

- 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.
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**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) |
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| 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 | 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) |
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[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) |
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| – *Switch,[c,e] n/N (%)* | 231/303 (76.2) |

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[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.
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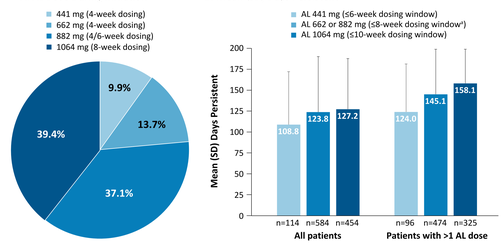
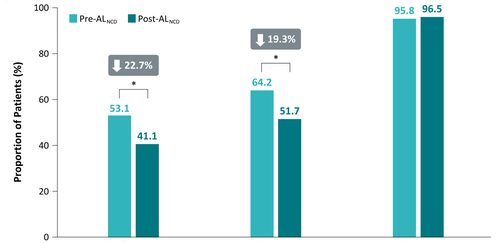



[a]AL 662 and 882 mg both have a dosing window of ≤8 weeks and were combined for the days-persistent analysis.
AL, aripiprazole lauroxil.

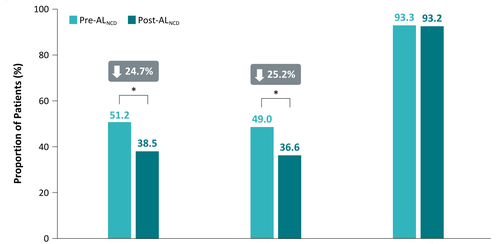
### Healthcare Resource Utilization

**Figure 4**. All-Cause HCRU[a]




[a]*P*<0.001.
[b]Gray boxes represent percent change from baseline.
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]

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## 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

## REFERENCES

**1.** Aristada [package insert]. Waltham, MA: Alkermes, Inc.; 2023. **2.** Jain R, et al. *CNS Spectr.* 2020;25(3):323-30. DOI: 10.1017/S1092852919000816. **3.** Hard ML, et al. *J Clin Psychopharmacol.* 2018;38(5):435-41. DOI: 10.1097/jcp.0000000000000921. **4.** Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; 2023. **5.** Lauriello J, et al. *CNS Drugs.* 2021;35(10):1123-35. DOI: 10.1007/s40263-021-00849-2. **6.** Quan H, et al. *Am J Epidemiol.* 2011;173(6):676-82. DOI: 10.1093/aje/kwq433.

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