# National Real-World Study of the Patient Journey of Dually Eligible Medicare Enrollees With Schizophrenia: A Call to Action for Improving Care Quality

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## Introduction

- Schizophrenia is a chronic mental illness characterized by delusions, hallucinations, and other disabling psychiatric symptoms
- Continuous treatment with antipsychotic (AP) medications is crucial in the management of schizophrenia to reduce the risk of relapse and possible psychiatric hospitalization[1]
  - Oral antipsychotics (OAPs) have been the mainstay of schizophrenia treatment, though their effectiveness has been hindered by poor adherence[1]
  - Long-acting injectable antipsychotics (LAIs) provide a valuable alternative to daily OAPs since they require less frequent administration (e.g., every month, every 3 months)[2] and have been associated with a lower risk of antipsychotic discontinuation, hospitalization, and mortality[3]
- Although half of US patients with schizophrenia receive coverage through the Medicare program and the vast majority of these patients are also eligible for Medicaid (i.e., dual eligible), there is limited understanding of their journey in terms of treatment, clinical outcomes, and health resource utilization patterns over time in this population[4]

## Objective

- To describe AP treatment, clinical outcomes, and healthcare resource utilization (HRU) patterns for dually eligible beneficiaries with schizophrenia

## Methods

### Data source

- Data were taken from 2006-2021 national Medicare and Medicaid claims available from the Centers for Medicare and Medicaid Services

### Study sample

- The sample included all Medicare beneficiaries with ≥1 medical claim with diagnosis of schizophrenia followed by ≥1 AP prescription claim between 2009 and 2018
- Patients were required to meet the following additional criteria:
  - Evidence of a Chronic Conditions Warehouse (CCW) schizophrenia diagnosis indicator between 2009 and 2018
  - First eligible for Medicare between 2009 and 2018
  - The reason for Medicare eligibility was disability rather than age ≥65 (given these patients are more likely to be earlier in their patient journey since initial schizophrenia diagnosis)
  - Dually eligible (i.e., also eligible for Medicaid) in the first year of Medicare eligibility
  - Continuous full Medicaid (FFS or HMO) coverage prior to Medicare eligibility and continuous fee-for-service Medicare Parts A, B, and D coverage thereafter
  - First AP fill date occurred on or after the date of the first observed schizophrenia diagnosis date in Medicare or Medicaid claims AND before the end of follow-up

### Study design

- This was a descriptive longitudinal study that followed patients from their first observed AP in the Medicaid or Medicare claims until end of follow-up (i.e., death, transition to Medicare managed care, or Dec 31, 2021, whichever occurred earliest)

### Outcomes

- **Treatment utilization** (assessed from schizophrenia diagnosis until end of follow-up) included the type and number of OAP and LAI agents. We also assessed the number of OAPs tried before LAI initiation, time to LAI initiation, age at first LAI initiation, and type of LAI used
- **Evidence of a continuous gap of 60 days or more** in any AP use was assessed from AP initiation date until end of follow-up
- **Relapse** was defined as the occurrence of an inpatient admission or ER visit with a diagnosis of schizophrenia in the primary or secondary position on the claim. We report both the rate and number of relapses. Relapse was measured from AP initiation date until end of follow-up
- **Health resource utilization** measures included the rate and number of all-cause, mental health–related, and schizophrenia-related inpatient hospitalizations and ER visits. HRU measures were examined from the AP initiation date until end of follow-up

## Results

- The final sample included 25,356 dual-eligible patients with schizophrenia who received at least one AP between 2009 and 2018 (**Table 1**)
  - Over a median follow-up of 5.6 years from AP initiation, these patients tried an average of 3.3 different AP agents; 35.9% (n = 9,107) received at least one LAI whereas 64.1% (n = 16,249) received only OAPs (**Table 1**)
  - About one-quarter of the LAI users used first-generation long-acting injectable (FGA LAI) (n = 1,862 [20.4%] haloperidol, n = 567 [6.2%] fluphenazine) while starting LAI and the remaining three-quarters used a second-generation long-acting injectable (SGA LAI) (n = 3,645 [40.0%] paliperidone, n = 1,724 [18.9%] risperidone, n = 1,165 [12.8%] aripiprazole, n = 144 [1.6%] olanzapine) as their first LAI agent (**Figure 1**)
    - 36.2% (n = 880) of those who used an FGA as their first LAI agent received an SGA LAI over follow-up while 11.9% (n = 794) of those who used an SGA as their first LAI agent received an FGA LAI over follow-up (**data not shown**)
- The mean number of OAPs tried prior to LAI initiation was 1.8 (**Figure 2**)
  - 27.9% (n = 2,543) tried none
  - 45.1% (n = 4,106) tried 1 to 2
  - 27% (n = 2,458) tried 3 or more
- The mean (SD) age at first observed LAI initiation was 32.8 (10.3) years; 21.5% (n = 1,958) of the patients who received an LAI were between the ages of 18 and 24 years (**data not shown**)
- Among those who received an LAI, about two-thirds (66.1%, n = 6,020) of patients received their first LAI within 2 years of the first coded diagnosis of schizophrenia in Medicaid or Medicare claims data (**data not shown**)
- Overall, 68.9% (n = 17,462), 62.2% (n = 15,763), 70.0% (n = 17,742), and 89.0% (n = 22,570) of the 25,356 patients had a 60-day gap in any AP use, relapse, inpatient hospitalization, and ER visit, respectively, over the 5.6 years of median follow-up (**Table 1**)
- The mean number of relapses, inpatient admissions, and ER visits over this period in the overall sample were 1.9, 1.6, and 5.6 per patient per year, respectively (**Table 1**)

**TABLE 1: Antipsychotic treatment, clinical outcomes, and health resource utilization patterns from first observed antipsychotic fill date until end of follow-up among dually eligible Medicare beneficiaries diagnosed with schizophrenia**

| | N<br>25,356 | %<br>100% |
|---|---|---|
| Length of follow-up from antipsychotic initiation date to end of observation period, %[a] years, median (IQR) | 5.6 (3.3, 8.6) | |
| Age on antipsychotic initiation date, mean (SD) | 35.4 (11.9) | |
| <18 years | 137 | 0.5% |
| 18 to 24 years | 5,125 | 20.2% |
| 25 to 34 years | 8,780 | 34.6% |
| 35 to 44 years | 4,937 | 19.5% |
| 45 to 54 years | 4,178 | 16.5% |
| 55 to 64 years | 2,081 | 8.2% |
| ≥65 years | 118 | 0.5% |
| **Antipsychotic treatment** | | |
| Antipsychotic agents ever used over follow-up | | |
| OAP Only | 16,249 | 64.1% |
| Any LAI | 9,107 | 35.9% |
| Any FGA LAI | 3,223 | 12.7% |
| LAI Haloperidol | 904 | 3.6% |
| LAI Fluphenazine | 2,575 | 10.2% |
| Any SGA LAI | 7,558 | 29.8% |
| LAI PP1M | 5,226 | 20.6% |
| LAI PP3M | 881 | 3.5% |
| LAI Aripiprazole | 2,173 | 8.6% |
| LAI Olanzapine | 234 | 0.9% |
| LAI Risperidone | 2,110 | 8.3% |
| Number of different agents tried (based on unique generic name of LAI and OAP [i.e. differentiate the same generic names by route of administration]), mean (SD) | 3.3 (2.4) | |
| Time from first schizophrenia diagnosis to first LAI, days, median (IQR) | 368.0 (81.0, 1009.0) | |
| **Evidence of a continuous gap of 60 days or more in any AP use** | | |
| Any evidence of 60-day gap in AP use (n/%) | 17,462 | 68.9% |
| Time to continuous 60-day gap, days, median (IQR) | 186.0 (54.0, 599.0) | |
| **Relapse[b]** | | |
| ≥1 relapse (n/%) | 15,763 | 62.2% |
| Relapse rate per person per year, mean (SD) | 1.9 (10.3) | |
| **HRU between antipsychotic initiation date and end of follow-up** | | |
| All-cause health resource utilization | | |
| Any inpatient admission (n/%) | 17,742 | 70.0% |
| Inpatient admission rate per person per year, mean (SD) | 1.6 (13.2) | |
| Any ER visit (n/%) | 22,570 | 89.0% |
| ER visit rate per person per year, mean (SD) | 5.6 (23.6) | |
| Mental health related health resource utilization | | |
| Any MH inpatient admission (n/%) | 15,017 | 59.2% |
| MH inpatient admission rate per person per year, mean (SD) | 1.2 (11.5) | |
| Any MH ER visit (n/%) | 17,799 | 70.2% |
| ER visit rate per person per year, mean (SD) | 2.4 (10.4) | |
| Schizophrenia-related health resource utilization | | |
| Any SCZ-related inpatient admission (n/%) | 12,471 | 49.2% |
| SCZ-related inpatient admission rate per person per year, mean (SD) | 0.7 (7.4) | |
| Any SCZ-related ER visit (n/%) | 11,795 | 46.5% |
| SCZ-related ER visit rate per person per year, mean (SD) | 1.2 (5.7) | |

[a]Patients were followed until death, transition to an MAPD plan, or the end of the study period [Dec 31, 2021], whichever occurred earlier.

[b]Relapse was defined as the occurrence of an inpatient admission or ER visit with a diagnosis of schizophrenia in the primary or secondary position on the claim.

NR = Not reported due to CMS rules prohibiting presentation of any cell size <11 or any cell that would permit calculation of a cell size <11

**FIGURE 1: Type of LAI agent used as first LAI agent among patients ever receiving an LAI (N=9,107)**

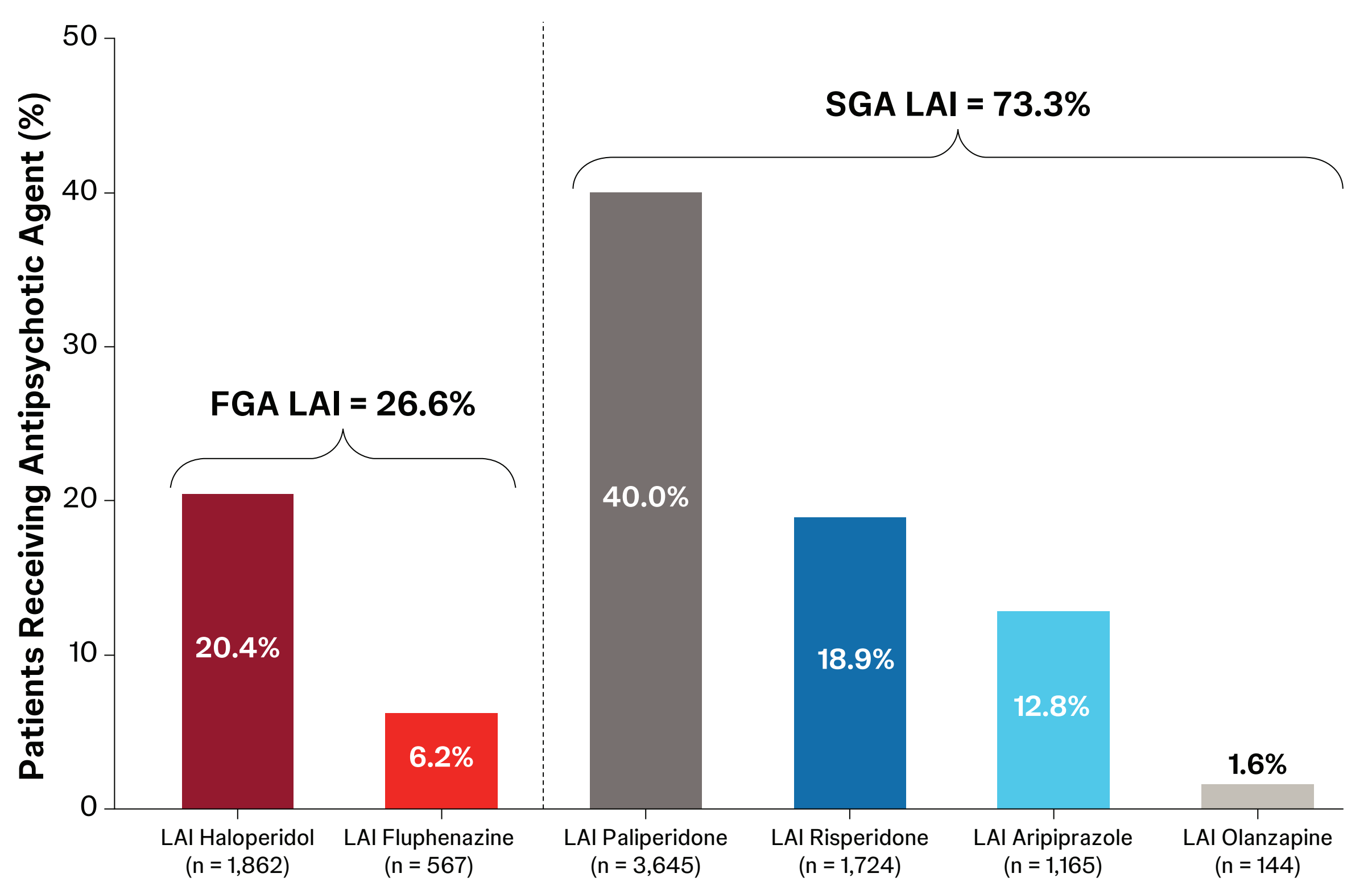
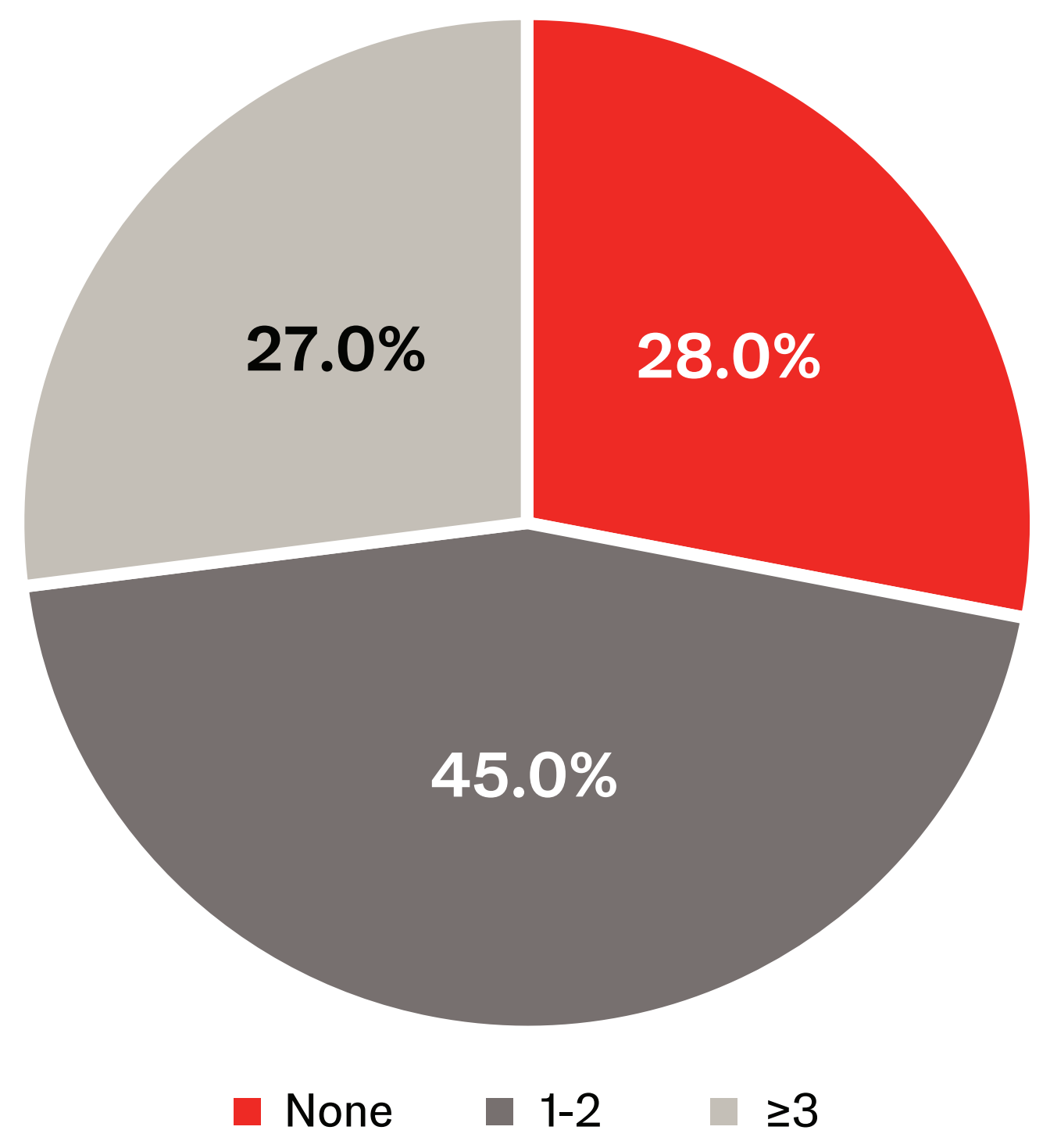


**FIGURE 2: Number of OAP agents tried before first LAI initiation among patients ever receiving an LAI (N=9,107)**



## Limitations

- Our study is only generalizable to the dually eligible population with Medicare/Medicaid coverage and not other insurance types
- Given left-censoring issues with all claims-based studies, we are only able to identify the first observed schizophrenia diagnosis or AP received in the claims data but do not know the true date of first diagnosis or AP prescription
- LAIs received in an inpatient setting are not recorded in the claims and hence were not captured in this analysis

## Conclusions

- ✓ This national longitudinal study is the first to assess the patient journey of dually eligible patients with schizophrenia
- ✓ Despite the benefits of LAIs, only about one-third of patients received them over nearly 6 years of follow-up. The vast majority of LAI initiators started an SGA LAI
- ✓ High rates of relapse, inpatient hospitalization, and ER visits were observed despite AP treatment
- ✓ The unmet need highlighted by our findings should serve as a call to action for mental health practitioners and policymakers to increase efforts to improve quality of care and outcomes in this vulnerable population

**Disclosures**

Dr Li received personal fees from Cobbs Creek Healthcare and SKB Consulting Inc, unrelated to the submitted work. Ms Benson and Ms Patel are employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, and are stockholders of Johnson and Johnson. Dr Doshi received grants from Janssen Scientific Affairs, LLC during the conduct of the study; personal fees from AbbVie, Acadia, Janssen, Merck, Otsuka, and Takeda; and grants from Merck and Spark Therapeutics unrelated to the submitted work. No other authors reported disclosures.

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