

**Abstract**

**Introduction.** Earlier onset of schizophrenia, which occurs more commonly in males, is characterized by greater illness severity, chronicity, and functional impairment with a less favorable prognosis than later-onset schizophrenia. The aim of this pooled analysis was to evaluate the long-term safety and effectiveness of lurasidone in the treatment of schizophrenia in adolescents (13–17 years) and young adults (18–25 years).

**Methods.** The 2 pooled studies used similar designs and outcome measures. Patients (13–25 years) with schizophrenia completed an initial double-blind 6-week trial of lurasidone (40 and 80 mg/d), and (80 and 160 mg/d) in the young adult trial. In the open-label long-term trials, adolescent patients were treated with 20–80 mg/d of lurasidone, and adults were treated with 40–160 mg/d of lurasidone. Efficacy was evaluated based on the Positive and Negative Syndrome Scale (PANSS) and Clinical Global Impression-Severity Scale (CGI-S).

**Results.** The safety population consisted of 306 patients (mean age, 16.2 years; 208 patients (68.0%) who completed 12 months of treatment; 8.2% discontinued by 12 months due to an adverse event. Mean (SD) change in the PANSS total score from extension Baseline to Months 6 and 12 was -11.8 (13.9) and -15.3 (15.0), respectively (OC); and mean (SD) change in the CGI-S score was -0.8 (1.0) and -1.0 (1.1), respectively (OC). The most frequent adverse events were headache (17.6%), anxiety (11.4%), schizophrenia (9.8%), and nausea (9.8). No clinically meaningful changes were observed in weight, metabolic parameters, or prolactin.

**Conclusions.** In adolescents and young adults with schizophrenia, treatment with lurasidone was generally well-tolerated and effective. Long-term treatment was associated with continued reduction in symptoms of schizophrenia. Long-term treatment was associated with minimal effects on weight, metabolic parameters, and prolactin.

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## IVIG for Treatment-Resistant Psychosis For a Child with Turner Syndrome

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**Abstract**

Psychosis is defined as the presence of false beliefs or false perceptions. In children some causes of psychosis include psychiatric diagnosis such as schizophrenia and autism. However, it may also be secondary to medical conditions like various forms of encephalitis. Studies have shown that IVIG has been efficacious in the treatment of psychosis in the setting of autoimmune encephalitis.

A 9-year-old girl with a past medical history of Turner Syndrome, developmental delay, epilepsy, growth hormone deficiency, metabolic bone disease, and autism (ASD) presented

with auditory and visual hallucinations that began June 2020. She began with her hearing voices that repeated the word “dead” and told her that she would not live. The hallucination later took the form of a man that would mock her, laugh about her parents dying, and tell her to kill them. The patient had associated symptoms of insomnia, anxiety, sadness, and increased anger. On her initial admission, CSF studies including culture and gram stain were unremarkable. NMDA, VHKC, and GAD65 antibodies were negative. At this time the hallucinations were thought to be due to ASD and she was prescribed Risperdal 0.25mg twice a day. Unfortunately, this did not improve her symptoms and from the time period of June 2020 to May 2021 she subsequently underwent trials of Risperdal, Zyprexa, Invega, Abilify, Thorazine, Haldol, and Clozaril. However, the symptoms persisted. Zoloft was prescribed, which was efficacious for anger and dysphoria. Trazodone, melatonin, and Remeron were tried for the treatment of insomnia, but did not cause enough improvement to continue the medications. Due to progression of command hallucinations with “the man” instructing her to hurt others, the patient was admitted July 2021 for administration of IVIG. Repeat CSF studies and brain MRI were unremarkable. From July 29, 2021 to August 1, 2021 she received three doses of IVIG which resulted in improvement of psychosis. Prior to administration, she was seeing “the man” throughout the day every single day, was sleeping only 3–4 hours a night, and having nightmares everyday. On evaluation 2 weeks after IVIG, she was only seeing “the man” 1–2 time a day, sleeping 6–8 hours a night, having nightmares 1–2 times a week, and her mood had improved.

This case illustrates the potential use of IVIG for the treatment of treatment-resistant psychosis. Although the cause of this patient’s symptoms remains unclear, there were clear benefits from the administration of IVIG that were not seen with trials of antipsychotics.

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## Real-World Treatment Patterns and Healthcare Resource Utilization in Patients Prescribed Benzotropine: A Claims Analysis From 2017-2020

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**Abstract**

**Introduction.** We sought to examine real-world treatment patterns and healthcare resource utilization (HCRU) for patients receiving an antipsychotic (AP) and subsequently prescribed benzotropine.

**Methods.** A retrospective analysis was conducted among patients with evidence of benzotropine initiation using claims data from

IQVIA's New Data Warehouse from January 2017–March 2020. Patients were indexed on the date of first pharmacy claim for bupropion and had continuous enrollment in the 6 months prior (pre-index) and minimum 12 months post-index date, up to 24 months. Patients also had  $\geq 1$  pharmacy claim for an AP either pre-index or on the index date.

**Results.** A total of 112,542 patients were included; 59% were female with mean age of 46 years. The most common comorbidities were bipolar disorder (BD; 28.3%), schizophrenia (SCZ; 28.3%), and depression (26.3%). Over half of the cohort (54.1%) had  $\geq 2$  comorbid conditions. Nearly 20% of patients had  $\geq 20$  medications (median 10–14) and medications with anticholinergic (AC) properties were used by 87.9%. Approximately 80% of patients had mild AC burden at baseline (using AC burden calculator). The median number of bupropion prescription fills was 5 with treatment duration  $< 3$  months in 44.3% of patients and  $< 6$  months in 61.7%. All-cause mean healthcare costs in the 12-month cohort (24-month cohort) were \$11,755 (\$23,128), mean costs for pharmacy were \$9,229 (\$18,148), and mean costs for inpatient stays were \$34,669 (\$41,280). Emergency room (ER) visits occurred in 47.3% and physician office visits in 78.9% of the cohort. In patients with available inpatient 12-month data ( $n=33,717$ ), inpatient stays occurred in 4.0% (13.3% when extrapolated to total cohort). In patients with 24-month data ( $n=73,836$ ), ER visits occurred in 61% of the cohort and inpatient stays in 6.6% (21.9% when extrapolated to the total cohort). Multivariate analyses showed baseline SCZ was associated with a significantly increased risk of ER visit of 30% and inpatient stay of 50%. Similarly, substance abuse was associated with an increased risk of ER visit of 85% and inpatient stay of about 40%. Other significant associations with ER visits included falls/accidents at baseline (148% increased risk), abnormal movement disorders (38% increased risk), and orthostatic hypotension (38% increased risk).

**Conclusions.** In this real-world analysis of patients initiating bupropion, polypharmacy and AC burden were frequently observed. BD, SCZ, and depression were the most common comorbidities. Healthcare costs and HCRU were high for the entire cohort; inpatient stays contributed to high costs. Baseline SCZ, falls/accidents (ER only), and substance abuse were significantly associated with ER and inpatient admissions. The comorbidity and medication profiles of this cohort may have influenced the high healthcare costs and HCRU observed in the study.

**Funding.** Neurocrine Biosciences, Inc.

## Economic Outcomes with Adjunctive Cariprazine and Other Atypical Antipsychotics in Patients with Major Depressive Disorder

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### Abstract

**Introduction.** Patients with major depressive disorder (MDD) who have inadequate responses to antidepressants (ADs) can benefit from augmentation with atypical antipsychotics (AAs). Cariprazine, a  $D_3/D_2$  receptor partial agonist, is approved for schizophrenia and for manic, mixed, or depressive episodes associated with bipolar I disorder. Cariprazine is also currently under investigation for the adjunctive treatment of MDD. The aim of this retrospective cohort study was to describe healthcare resource utilization (HCRU) and associated medical costs with cariprazine and other adjunctive AA therapies for MDD.

**Methods.** IBM® MarketScan Commercial Claims and Encounters, Medicare Supplemental, and Medicaid databases were searched for claims made from 01-Jan-2018 to 31-Mar-2021. The study population included adults ( $\geq 18$  years) who met the following criteria:  $\geq 1$  inpatient claim with an MDD diagnosis or  $\geq 2$  outpatient claims that were  $> 30$  days apart;  $\geq 1$  AD therapy after MDD diagnosis;  $\geq 1$  branded or generic adjunctive AA (with AD); enrollment for  $\geq 6$  and  $\geq 12$  months for baseline and follow-up analyses, respectively. Branded AAs were analyzed individually; generic AAs were grouped. MDD-related HCRU outcomes per person over the 12-month follow-up period included inpatient stays, inpatient costs, office visits, and office visit costs, with adjusted pairwise comparisons between cariprazine and other AAs. Statistical significance was defined as the 95% confidence interval (CI) for the estimated mean ratio (EMR) of comparator AA to cariprazine not including 1 (i.e., value indicating no difference).

**Results.** Analyses included 46,197 patients, with AA cohorts as follows: generics ( $n=39,410$ , including mostly aripiprazole and quetiapine); brexpiprazole ( $n=3,249$ ); lurasidone ( $n=1,795$ ); cariprazine ( $n=1,051$ ); quetiapine-XR ( $n=644$ ). A majority of patients across cohorts were women (range, 65.7% to 75.4%). Inpatient stays were statistically significantly fewer with cariprazine than all other AA therapies (EMR range [95% CI]: 1.7 [1.2–2.3] to 2.9 [2.1–3.9] for brexpiprazole and generics, respectively). Inpatient costs were lower for cariprazine than other branded AAs and statistically significantly lower compared to generics (2.4 [1.6–4.1]). Office visits were fewer with cariprazine than all other AAs and significantly lower than generics (1.1 [1.03–1.2]), lurasidone (1.3 [1.2–1.4]), and brexpiprazole (1.4 [1.2–1.5]). Office visit costs were also lower for cariprazine than all other AAs and statistically significantly lower than lurasidone (1.2 [1.03–1.5]) and brexpiprazole (1.4 [1.2–1.6]).

**Conclusions.** The results of this study suggest that in patients with MDD, adjunctive treatment with cariprazine is associated with statistically significantly lower HCRU for certain outcomes and numerically lower medical costs compared to other branded AAs, along with statistically significantly lower HCRU and medical costs versus generic AAs.

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