Budget Impact of LYBALVI® for the Treatment of Schizophrenia and Bipolar I Disorder

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BACKGROUND

- Schizophrenia and bipolar I disorder are associated with substantial economic burden on the US health care system[1,2]
- Antipsychotics are effective treatments for schizophrenia[1] and bipolar I disorder[2] and may help reduce the risk of relapse and hospitalizations, which are primary drivers of medical costs for these conditions[3,4,5]
  - Olanzapine, a second-generation antipsychotic (SGA), is one of the most effective medications to treat these conditions,[6,7] but its clinical utility is limited by the propensity to cause weight gain and cardiometabolic sequelae[8]
  - Weight gain and associated cardiometabolic sequelae lead to higher health care resource utilization and medical costs for patients with serious mental illness[9]
- A combination of olanzapine and samidorphan (OLZ/SAM [LYBALVI®]) was approved by the US Food and Drug Administration in 2021 for the treatment of adults diagnosed with schizophrenia or bipolar I disorder
  - OLZ/SAM provides the clinical efficacy of olanzapine but with less weight gain[10]
  - It is important to understand the potential economic impacts, if any, associated with the formulary adoption of OLZ/SAM to inform health care decision-making
- We describe a budget impact model (BIM) and provide estimates of the economic outcome of adding OLZ/SAM to the formularies of hypothetical commercial, Medicaid, and Medicare plans in the United States

METHODS

- A BIM with a 3-year time horizon for hypothetical commercial, Medicaid, and Medicare plans, each with 1 million adult covered lives, was developed
- The proportions of individuals aged 18 to 64 years and those aged ≥65 years insured by each payer were estimated (**Table 1**)
- The prevalence of schizophrenia and bipolar I disorder among adults, stratified by age group and payer type, were estimated (**Table 2**)
  - Totals of 60% of patients with schizophrenia[11] and 49% of patients with bipolar I disorder[12] were estimated to be treated with an SGA within a 12-month time frame
- Other model inputs included the following:
  - Projected market share for SGAs without and with the adoption of OLZ/SAM to formulary (**Table 3** and **Table 4**)
  - For schizophrenia, the estimated market shares of OLZ/SAM (0.1%, 0.4%, and 0.7% in years 1, 2, and 3, respectively)
  - For bipolar I disorder, the estimated market shares of OLZ/SAM (0.1%, 0.8%, and 1.8% in years 1, 2, and 3, respectively)
  - Estimated average number of months on treatment and wholesale acquisition costs for each SGA (**Table 5**)
- OLZ/SAM was assumed to displace market share from other branded oral SGAs, and the displacement was proportional to the size of current market share
- The projected budgetary impact of OLZ/SAM was estimated by comparing the scenario without OLZ/SAM as a treatment option vs the scenario with OLZ/SAM as an option on formulary
- Results are presented as per-member per-month (PMPM) costs in each scenario

RESULTS

- After applying prevalence-based assumptions, the estimated numbers of patients treated with SGAs per 1 million covered lives were 4324, 39,770, and 12,178 patients each year for the hypothetical commercial, Medicaid, and Medicare plans, respectively
  - The prevalence-based estimates amount to 1009, 19,411, and 4980 patients with schizophrenia and 3315, 20,359, and 7198 patients with bipolar I disorder covered each year by the hypothetical commercial, Medicaid, and Medicare plans, respectively
- OLZ/SAM had a net neutral budget impact, with no changes in PMPM costs for the hypothetical commercial, Medicaid, and Medicare plans within the 3 years analyzed (**Figure 1**)

LIMITATIONS

- The BIM did not include estimates of costs associated with inpatient care, other types of outpatient treatment, or cost offsets (eg, medication discounts or rebates or patients' copay or coinsurance)
- In the Medicare population, the prevalence values for schizophrenia and bipolar I disorder were estimated by averaging the prevalence values from commercial and Medicaid populations and may not represent the true proportion of patients with these diagnoses who are insured by Medicare
- The prevalence of schizophrenia for patients aged ≥65 years was calculated as the weighted average of prevalence for all men and women aged ≥65 years and may not reflect the true prevalence in this age group
- The proportion of patients actively treated with an SGA was assumed to be the same across plans
- Treatment switches from generic oral SGAs to OLZ/SAM were not considered
- The BIM was developed based on assumptions of hypothetical commercial, Medicaid, and Medicare plans; results may not apply to specific health care plans that do not align with these assumptions
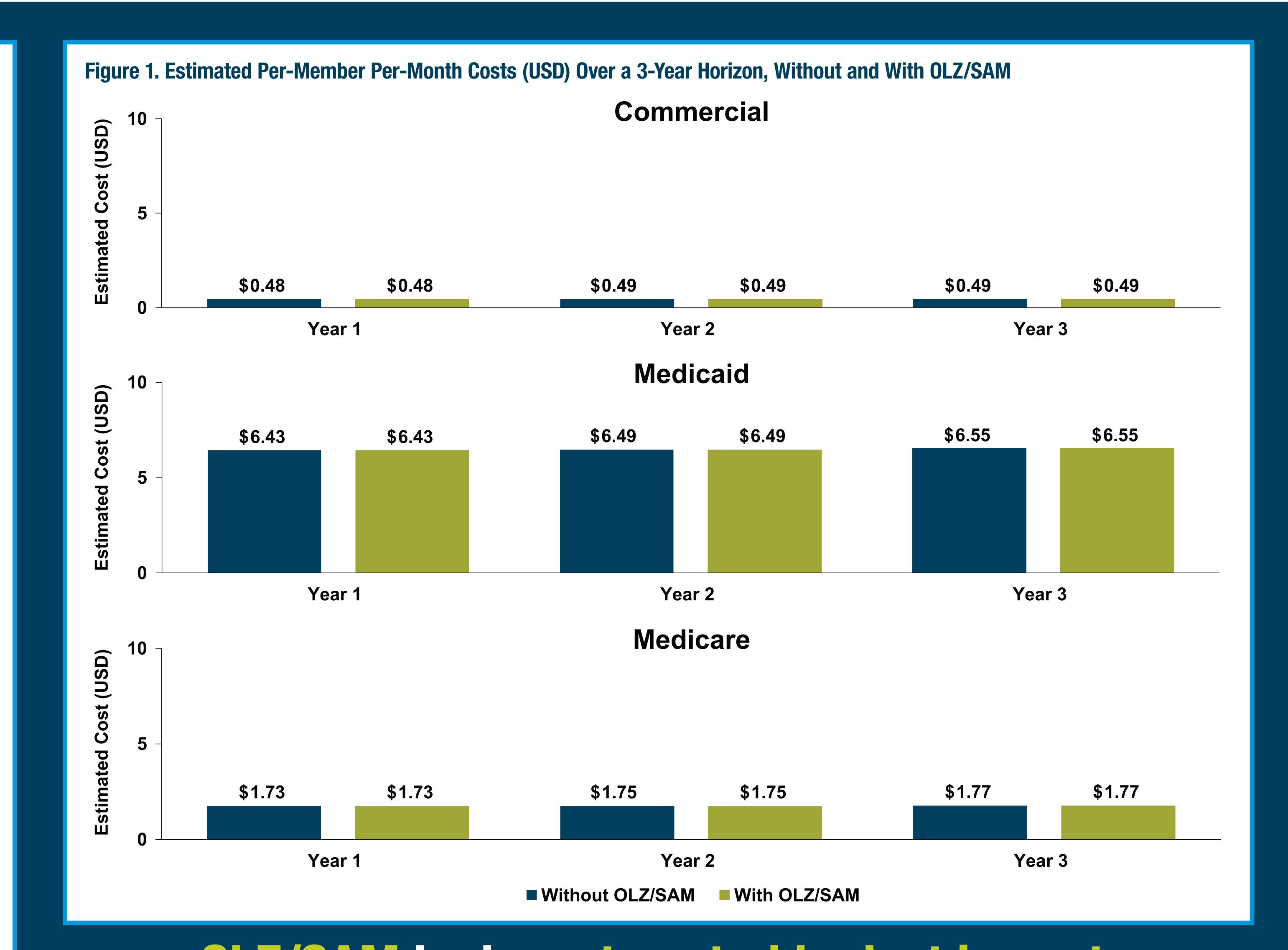
CONCLUSIONS

- Given that weight gain and associated cardiometabolic sequelae lead to higher health care resource utilization and medical costs for patients with serious mental illness, OLZ/SAM offers a new treatment option for patients living with schizophrenia or bipolar I disorder
- Results of the BIM indicate that the addition of OLZ/SAM to hypothetical commercial, Medicaid, and Medicare plans in the United States results in no additional costs

DISCLOSURES

M.J. Doane and A.K. O'Sullivan are or were employees of Alkermes, Inc., at the time of this research and may own stocks/options in the company. K. Ottino and C. Eichten are employed by Policy Analysis Inc., which received payment from Alkermes, Inc., for participation in this research.

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Figure 1. Estimated Per-Member Per-Month Costs (USD) Over a 3-Year Horizon, Without and With OLZ/SAM

Commercial

	Year 1	Year 2	Year 3
Without OLZ/SAM	$0.48	$0.49	$0.49
With OLZ/SAM	$0.48	$0.49	$0.49

Medicaid

	Year 1	Year 2	Year 3
Without OLZ/SAM	$6.43	$6.49	$6.55
With OLZ/SAM	$6.43	$6.49	$6.55

Medicare

	Year 1	Year 2	Year 3
Without OLZ/SAM	$1.73	$1.75	$1.77
With OLZ/SAM	$1.73	$1.75	$1.77

■ Without OLZ/SAM ■ With OLZ/SAM

OLZ/SAM had a net neutral budget impact, with no differences in PMPM costs when adding OLZ/SAM to the formularies of hypothetical commercial, Medicaid, and Medicare plans

Table 1. Age Distribution by Payer Type

	Payer Type		
Age Group	Commercial[a]	Medicaid[b]	Medicare[b]
18–64 years, %	98.6	85.9	14.5
≥65 years, %	1.5	14.1	85.5

[a]Commercial distribution was estimated from the IBM® MarketScan® Commercial Database.
[b]Medicaid and Medicare distributions were estimated from the US Census Bureau.[13]

Table 2. Prevalence of Schizophrenia and Bipolar I Disorder per 1 Million Covered Lives per Payer, by Age Group and Payer Type

Diagnosis	Age Group	Payer Type		
		Commercial	Medicaid	Medicare
Schizophrenia,[a] %	18–64 years	0.16	3.65	0.83
	≥65 years	0.72	0.72	0.83
Bipolar I disorder,[b] %	18–64 years	0.68	4.49	2.59
	≥65 years	0.44	2.12	1.28

[a]Prevalence for the 18- to 64-year age group based on data from the National Health Interview Survey[14] and the US Census Bureau.[15] Prevalence for the ≥65-year age group for commercial and Medicaid payers was calculated as the weighted average of prevalence for all males and females aged ≥65 years.[16] The prevalence estimate for Medicare covers both age groups.[16]
[b]Commercial and Medicaid prevalence was estimated using the IBM® MarketScan® Research Databases; the Medicare prevalence was estimated as the average of commercial and Medicaid payers.

Table 3. Projected Market Share for Patients With Schizophrenia

	Schizophrenia								
	Commercial			Medicaid			Medicare		
Medication,[a] %	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Branded oral SGAs[b]	9.3	9.3	9.3	8.5	8.5	8.5	7.6	7.6	7.6
Generic oral SGAs	85.8	85.8	85.8	78.5	78.5	78.5	79.8	79.8	79.8
LAI antipsychotics	4.9	4.9	4.9	13.0	13.0	13.0	12.7	12.7	12.7

[a]Estimates for branded oral SGAs, generic oral SGAs, and LAI antipsychotics derived from IQVIA Source of Business Data, except for Caplyta (estimated by Alkermes, Inc.).
[b]Includes Caplyta (lumateperone), Fanapt (iloperidone), Latuda (lurasidone), Rexulti (brexpiprazole), and Vraylar (cariprazine).
LAI, long-acting injectable; SGA, second-generation antipsychotic.

Table 4. Projected Market Share for Patients With Bipolar I Disorder

	Bipolar I Disorder								
	Commercial			Medicaid			Medicare		
Medication,[a] %	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Branded oral SGAs[b]	17.8	17.8	17.8	17.5	17.5	17.5	14.2	14.2	14.2
Generic oral SGAs	81.3	81.3	81.3	80.0	80.0	80.0	83.4	83.4	83.4
LAI antipsychotics	0.9	0.9	0.9	2.6	2.6	2.6	2.5	2.5	2.5

[a]Estimates for branded oral SGAs, generic oral SGAs, and LAI antipsychotics derived from IQVIA Source of Business Data.
[b]Includes Latuda (lurasidone) and Vraylar (cariprazine).
LAI, long-acting injectable; SGA, second-generation antipsychotic.

Table 5. Estimated Number of Treatment Months and Wholesale Acquisition Costs (USD)

Medication[a]	Schizophrenia No. of Treatment Months per Patient	Bipolar I Disorder No. of Treatment Months per Patient	Monthly Cost Based on WAC,[b] $
Branded oral SGAs			
Lybalvi (olanzapine and samidorphan)	4.3	4.1	1390
Caplyta[c] (lumateperone)	4.3	—	1399
Fanapt[d] (iloperidone)	4.2	—	2067
Latuda (lurasidone)	4.4	4.4	1409
Rexulti[c] (brexpiprazole)	4.6	—	1246
Vraylar (cariprazine)	4.7	4.3	1268
Generic oral SGAs	4.3	4.1	48
LAI antipsychotics	5.7	5.3	2311

[a]Estimates for Rexulti, Vraylar, generic oral SGAs, and LAI antipsychotics derived from IQVIA Days on Therapy; estimates for Latuda and Fanapt derived from IMS Health's Longitudinal Access and Adjudication Data; OLZ/SAM and Caplyta were assumed to equal the estimate for generic oral SGAs.
[b]Estimates derived from ProspectoRX and IQVIA National Sales Perspectives.
[c]Not approved for the treatment of bipolar I disorder.
[d]Not approved for the treatment of bipolar I disorder.
LAI, long-acting injectable; SGA, second-generation antipsychotic; WAC, wholesale acquisition cost.

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