

A Retrospective Real-World Analysis Demonstrating the Value of Azstarys for Patients With Attention-Deficit Hyperactivity Disorder

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INTRODUCTION

- Serdexmethylphenidate/dexmethylphenidate (SDX/d-MPH; Azstarys[®]) is a once-daily treatment approved by the US Food and Drug Administration in 2021 for the treatment of patients aged ≥6 years with attention-deficit hyperactivity disorder (ADHD).
- SDX/d-MPH contains 70% SDX, a novel prodrug of d-MPH hydrochloride, and 30% d-MPH.
- Efficacy and safety of SDX/d-MPH were reported in a pivotal laboratory classroom study of 6–12-year-old children with ADHD.¹
- The goal of this analysis was to determine real-world treatment patterns of SDX/d-MPH use among patients with ADHD.

OBJECTIVE

- To quantify the value of SDX/d-MPH for patients with ADHD with real-world data from the large-scale Komodo[®] Healthcare Map database.

METHODS

Study Design

- Retrospective analyses were performed on data from open and closed insurance claims datasets spanning ~15 months (January 2021 to March 2022) to evaluate treatment patterns and use in patients with ADHD.
- Patients were identified based on the diagnosis of ADHD (≥2 International Classification of Diseases-10 [ICD-10] codes for ADHD) or through a fulfilled prescription for SDX/d-MPH.
- Patients were required to be continuously enrolled in a health care plan with both medical and prescription coverage during the study period.
- Patients with at least 90 days of stability on SDX/d-MPH were analyzed for treatment patterns.
- Users of methylphenidate long-acting (MLA), amphetamine long-acting (ALA), and lisdexamfetamine products were identified via the presence of a minimum of 2 claims including 1 of the listed ADHD ICD-10 diagnoses codes; at least 1 fulfilled prescription claim for an MLA, ALA, or lisdexamfetamine product; and no fulfilled prescription claim for SDX/d-MPH.

RESULTS

Table 1. Patient characteristics.

	SDX/d-MPH users	MLA users	ALA users	Lisdexamfetamine users	All patients treated for ADHD
Sample size	3367	810,582	1,045,162	943,825	3,568,005
Age, mean (SD), y	19 (13)	17 (11)	27 (15)	25 (14)	26 (15)
Age distribution, n (%)					
0-5 y	8 (0)	3925 (0) ^a	1964 (0)	1629 (0)	16,889 (1)
6-12 y	1299 (39)	358,796 (44) ^b	179,701 (17) ^b	194,641 (21) ^b	800,014 (22)
13-17 y	970 (29)	244,819 (30)	164,060 (16) ^b	199,692 (21) ^b	650,880 (18)
18-35 y	629 (19)	142,241 (18)	410,087 (39) ^b	332,598 (35) ^b	1,166,981 (33)
36-55 y	395 (12)	46,675 (6) ^b	237,708 (23) ^b	179,306 (19) ^b	742,424 (21)
55+ y	66 (2)	14,126 (2)	51,640 (5) ^b	35,959 (4) ^b	190,812 (5)
Unknown	—	—	<5 (0)	—	<5 (0)
Sex, n (%)					
Male	2026 (60)	521,932 (64) ^b	529,997 (51) ^b	497,430 (53) ^b	1,914,806 (54)
Female	1341 (40)	288,588 (36) ^b	515,074 (49) ^b	446,297 (47) ^b	1,652,853 (46)
Unknown	0	62 (0)	91 (0)	98 (0)	346 (0)
Patient insurance, n (%)					
Commercial	1462 (43)	294,956 (36) ^b	528,790 (51) ^b	457,898 (49) ^b	1,691,643 (47)
Medicaid	568 (17)	335,926 (41) ^b	264,325 (25) ^b	281,716 (30) ^b	1,038,333 (29)
Medicare	10 (0)	3269 (0)	9395 (1) ^b	6123 (1) ^c	41,976 (1)
Dual	0	293 (0)	843 (0)	435 (0)	3141 (0)
Other	13 (0)	2164 (0)	3647 (0)	3565 (0)	11,840 (0)
Unknown	1376 (41)	192,593 (24) ^b	259,346 (25) ^b	214,020 (23) ^b	856,120 (24)
US geographical region, n (%)					
Northeast	55 (2)	121,885 (15) ^b	184,866 (18) ^b	106,202 (11) ^b	536,647 (15)
Midwest	438 (13)	187,754 (23) ^b	259,829 (25) ^b	221,675 (23) ^b	851,464 (24)
South	2347 (70)	351,430 (43) ^b	356,216 (34) ^b	431,548 (46) ^b	1,423,311 (40)
West	117 (3)	103,676 (13) ^b	159,473 (15) ^b	104,228 (11) ^b	472,435 (13)
Unknown	410 (12)	45,837 (6) ^b	84,778 (8) ^b	80,172 (8) ^b	284,148 (8)

ADHD, attention-deficit hyperactivity disorder; ALA, amphetamine long-acting; MLA, methylphenidate long-acting; SD, standard deviation; SDX/d-MPH, serdexmethylphenidate/dexmethylphenidate.

^ap < .05.

^bp < .001.

^cp < .01.

- Of the 3,568,005 patients with ADHD, 3367, 810,582, 1,045,162, and 943,825 were users of SDX/d-MPH, MLA, ALA, and lisdexamfetamine products, respectively (**Table 1**).
 - In the SDX/d-MPH, MLA, ALA, and lisdexamfetamine cohorts, the mean ages of patients were 19, 17, 27, and 25 years, respectively; 68%, 74%, 33%, and 42% of patients were aged <18 years.
 - In the SDX/d-MPH, MLA, ALA, and lisdexamfetamine cohorts, 60%, 64%, 51%, and 53%, respectively, were male.
 - Patients treated for ADHD in this study were predominantly covered under a commercial or Medicaid insurance plan (47% and 29%, respectively).
 - Patients using SDX/d-MPH were mostly from the southern region of the United States as compared with the overall cohort treated for ADHD (70% vs 40%). The regional difference reflects the commercial launch of SDX/d-MPH in 2021 that primarily focused on the southern region.

Table 2. Patient treatment characteristics by cumulative time-interval during the 90 days after SDX/d-MPH initiation.

Patient treatment characteristic	Patients with at least 90 d of stability on SDX/d-MPH (n = 138)		
	Days 1-30	Days 1-60	Days 1-90+
Patient size, no. of unique patients	138	138	138
Distribution by treatment class and type by patient line, n (%)			
With concomitant use of SA treatment	10 (7)	14 (10)	15 (11)
Without concomitant use of SA treatment	128 (93)	124 (90)	122 (89)
MSA treatment	8 (6)	12 (9)	14 (10)
ASA treatment	<5 (1)	<5 (1)	<5 (1)
Treatment persistence			
Mean % of days ^a covered by SA treatment	65	53	48
Median % of days ^a covered by SA treatment	72	48	37
Patients with SA treatment throughout the entire stability window, n	3	2	1

ASA, amphetamine short-acting; MSA, methylphenidate short-acting; SA, short-acting; SDX/d-MPH, serdexmethylphenidate/dexmethylphenidate.

^aPercentage of days covered is calculated based on fixed look-forward windows (1-30 d, 1-60 d, and 1-90 d) for all patients.

Statistical testing was not performed because of small sample sizes.

- Most SDX/d-MPH users (89%) received SDX/d-MPH without any supplementation with short-acting treatments during the 90-day period after SDX/d-MPH initiation (**Table 2**).
 - During the first 90 days of SDX/d-MPH use, approximately 11% of patients had concomitant use of SDX/d-MPH and a short-acting treatment.
 - Among patients with concomitant short-acting treatment, the need for persistent short-acting prescription is low.

CONCLUSION

- Most patients transitioning to SDX/d-MPH did not require persistent use of concomitant short-acting ADHD medications over the 90-day period after SDX/d-MPH initiation.

REFERENCES

1. Kollins SH, et al. *J Child Adolesc Psychopharmacol*. 2021;31(9):597-609.

DISCLOSURES

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MC and CO: employees of Corium, Inc.

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