

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request: cder_mpl1p_wp087 (Report 3)

Request ID: cder_mpl1p_wp087

Request Description: In this report we examined dosage of stimulant medications approved for treatment of attention-deficit/hyperactivity disorder (ADHD) in the Sentinel Distributed Database (SDD). This is part three of a four-part report series examining dosage during the pre-COVID (coronavirus disease 2019) pandemic through post-COVID pandemic period. Time periods include: overall (report one; January 1, 2017 to March 31, 2023), pre-pandemic (report two; April 1, 2018 to March 31, 2020), pandemic (report three; April 1, 2020 to March 31, 2022), and post-pandemic (report four; April 1, 2022 to March 31, 2023).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) tool, QRP version 13.1.1

Data Source: We distributed this request to eight Sentinel Data Partners (DPs) on May 23, 2024. The study period for this report included data from April 1, 2020 to March 31, 2022. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: Using the SDD, we separately identified the following cohorts of individuals who initiated each specific ADHD stimulant medication with a minimum of seven days' supply, based on age on the index date: 1) 5 years and older; 2) 18 years and older; 3) 5-17 years; 4) 18-25 years; 5) 26-44 years; 6) 45-64 years; and 7) 65 years and older. The earliest date of dispensing of the exposure drug, with no dispensing of the drug in the 365 days prior, served as the index date.

Exposures of Interest: The exposures of interest were ADHD stimulant medications prescribed in an outpatient setting with a minimum of seven days' supply, identified using National Drug Codes (NDCs). The specific ADHD stimulant medications of interest were: amphetamine/dextroamphetamine combination products, amphetamine/dextroamphetamine immediate release combination products, amphetamine/dextroamphetamine extended release combination products, lisdexamfetamine extended release, methylphenidate, methylphenidate immediate release, and methylphenidate extended release. Please see Appendix B for a list brand names of medical products used to define exposures in this request.

Cohort Eligibility Criteria: We required patients be five years of age and older and to be enrolled in health plans with both medical and drug coverage for at least 365 days prior to the index exposure, during which gaps in coverage of up to 45 days were allowed and treated as continuous enrollment. The 365 days before the index exposure was an exposure washout period (i.e., no dispensed prescription of the exposure of interest).

Episode Creation: We created exposure episodes based on the number of days of product supplied per dispensing in the outpatient pharmacy dispensing data. We bridged together episodes less than 30 days apart. Episodes were censored at the earliest occurrence of disenrollment, death, end of the data provided by each Data Partner, the end of the query period, or end of days' supply of the exposure drug.

Dose Metrics: The following dose metrics were reported: average filled daily dose (AFDD) in each patient's first treatment episode and mean current filled daily dose (CFDD) across all dispensings in all treatment episodes.

During each patient's first treatment episode, AFDD was calculated as the product of medication strength and amount supplied divided by the days' supply for each dispensing, averaged across all dispensings. For each patient, CFDD was calculated as the product of medication strength and amount supplied divided by the days' supply for each dispensing, averaged across all dispensings in all treatment episodes. Dispensings with greater than 100 days of supply or greater than 500 units of supply were excluded from all dose calculations.

Patients were grouped into five categories based on their AFDD and CFDD values. The AFDD and CFDD categories for each exposure of interest were: 1) amphetamine/dextroamphetamine combination products: ≤ 20 mg per day, $>20 - 40$ mg per day, $>40 - 60$ mg per day, $>60 - 200$ mg per day, and >200 mg per day; 2) lisdexamfetamine: ≤ 30 mg per day, $>30 - 50$ mg per day, $>50 - 70$ mg per day, $>70 - 200$ mg per day, and >200 mg per day; and 3) methylphenidate: ≤ 20 mg per day, $>20 - 40$ mg per day, $>40 - 60$ mg per day, $>60 - 200$ mg per day, and >200 mg per day.

Please refer to Appendices C through E for the specifications of parameters used in this request and the design diagram.

Overview for Request: cder_mpl1p_wp087 (Report 3)

Disclaimer: Due to the large number of analyses, and to improve efficiency and reduce runtime at the Data Partners, we first created a frozen dataset. The frozen data included the complete claims history of individuals who had a qualifying dispensing of any stimulant, non-stimulant, or C-II opioid drug classes during the study period. As a result, the total counts in the frozen dataset represent only individuals with a qualifying dispensing of drugs of interest and **do not** reflect the entire population of individuals enrolled in the datasets. Because the attrition tables would not accurately represent the full volume of enrollees in the datasets, we did not include attrition tables in this report.

Limitations: Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SETINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

Table of Contents

<u>Glossary (CIDA)</u>	List of Terms to Define the Cohort Identification and Descriptive Analysis (CIDA) Found in this Report
<u>Table 1</u>	Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022
<u>Table 2</u>	Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022
<u>Appendix A</u>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (May 23, 2024)
<u>Appendix B</u>	List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request
<u>Appendix C</u>	Specifications Defining Parameters for this Request
<u>Appendix D</u>	Specifications Defining Stockpiling Parameters Used for this Request
<u>Appendix E</u>	Design Diagram for this Request

**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module***

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module***

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1. Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode ¹										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5+ Years)</i>	329,648	240,433	72.9%	74,721	22.7%	13,516	4.1%	*****	*****	*****	*****	0.1	480.0	19.4	12.2
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)</i>	236,287	166,549	70.5%	54,670	23.1%	14,014	5.9%	*****	*****	*****	*****	0.1	480.0	20.6	14.2
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 5+ Years)</i>	209,736	158,798	75.7%	47,215	22.5%	3,627	1.7%	96	0.0%	0	0.0%	0.1	135.0	17.9	9.1
<i>Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)</i>	131,442	77,662	59.1%	40,651	30.9%	13,013	9.9%	*****	*****	*****	*****	1.0	210.0	32.4	14.6

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		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)</i>	184,068	109,112	59.3%	60,521	32.9%	12,404	6.7%	*****	*****	*****	*****	0.0	300.0	22.5	13.3
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)</i>	101,788	84,660	83.2%	13,836	13.6%	2,983	2.9%	*****	*****	*****	*****	0.2	300.0	15.9	12.3
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)</i>	126,348	57,413	45.4%	54,548	43.2%	12,109	9.6%	*****	*****	*****	*****	0.0	300.0	26.7	13.0
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5-17 Years)</i>	55,838	50,590	90.6%	4,991	8.9%	*****	*****	*****	*****	0	0.0%	0.1	90.0	12.8	7.4

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		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)</i>	27,554	25,263	91.7%	2,087	7.6%	*****	*****	*****	*****	0	0.0%	0.5	90.0	11.9	8.6
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)</i>	44,816	40,112	89.5%	4,551	10.2%	153	0.3%	0	0.0%	0	0.0%	0.1	60.0	13.3	7.0
<i>Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)</i>	37,333	29,159	78.1%	6,931	18.6%	*****	*****	*****	*****	0	0.0%	1.0	100.0	25.3	12.3
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5- 17 Years)</i>	75,087	46,055	61.3%	24,931	33.2%	3,505	4.7%	596	0.8%	0	0.0%	0.0	160.0	21.4	11.6

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		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)</i>	31,165	29,372	94.2%	1,624	5.2%	155	0.5%	14	0.0%	0	0.0%	0.5	114.7	11.0	7.7
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)</i>	66,777	35,473	53.1%	26,490	39.7%	4,098	6.1%	716	1.1%	0	0.0%	0.0	160.0	24.0	11.4
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 18-25 Years)</i>	68,912	52,971	76.9%	14,545	21.1%	1,339	1.9%	57	0.1%	0	0.0%	0.8	120.0	18.3	9.8
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)</i>	47,516	36,104	76.0%	9,958	21.0%	1,395	2.9%	59	0.1%	0	0.0%	0.5	120.0	18.7	11.6

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		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)</i>	45,112	35,575	78.9%	9,193	20.4%	*****	*****	*****	*****	0	0.0%	0.9	120.0	17.6	7.7
<i>Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)</i>	28,073	16,661	59.3%	9,340	33.3%	2,059	7.3%	13	0.0%	0	0.0%	1.5	100.0	32.5	13.0
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)</i>	27,326	13,657	50.0%	11,125	40.7%	2,191	8.0%	353	1.3%	0	0.0%	0.0	180.2	25.1	13.0
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)</i>	13,255	10,772	81.3%	2,152	16.2%	303	2.3%	28	0.2%	0	0.0%	0.2	120.0	17.3	11.2

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		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)</i>	20,526	7,667	37.4%	10,139	49.4%	2,305	11.2%	415	2.0%	0	0.0%	0.0	180.2	28.6	12.9
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 26-44 Years)</i>	127,165	86,424	68.0%	33,932	26.7%	6,379	5.0%	430	0.3%	0	0.0%	0.1	180.0	21.1	12.4
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)</i>	97,460	64,579	66.3%	25,690	26.4%	6,719	6.9%	472	0.5%	0	0.0%	0.1	180.0	22.0	14.3
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)</i>	79,823	56,896	71.3%	21,282	26.7%	1,609	2.0%	36	0.0%	0	0.0%	0.5	135.0	19.3	9.1

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		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)</i>	43,773	21,256	48.6%	16,466	37.6%	6,000	13.7%	*****	*****	*****	*****	1.0	210.0	36.0	14.6
<i>Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)</i>	35,670	17,422	48.8%	14,099	39.5%	3,612	10.1%	*****	*****	*****	*****	0.4	300.0	25.9	13.9
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)</i>	19,481	14,171	72.7%	4,296	22.1%	938	4.8%	76	0.4%	0	0.0%	0.4	160.0	20.0	13.2
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)</i>	24,082	8,452	35.1%	11,576	48.1%	3,433	14.3%	*****	*****	*****	*****	1.8	300.0	29.8	13.8

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		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 45-64 Years)</i>	55,599	34,962	62.9%	16,183	29.1%	4,129	7.4%	325	0.6%	0	0.0%	0.8	193.6	23.0	14.1
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)</i>	44,582	27,417	61.5%	12,595	28.3%	4,221	9.5%	*****	*****	*****	*****	0.8	240.0	24.2	15.8
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)</i>	30,764	19,948	64.8%	9,639	31.3%	1,147	3.7%	30	0.1%	0	0.0%	1.0	120.0	20.9	10.5
<i>Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)</i>	19,378	9,092	46.9%	7,040	36.3%	3,216	16.6%	30	0.2%	0	0.0%	1.0	140.0	37.1	15.4

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		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)</i>	21,815	12,013	55.1%	7,201	33.0%	2,209	10.1%	*****	*****	*****	*****	0.5	216.0	25.1	15.6
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)</i>	15,106	10,808	71.5%	3,259	21.6%	936	6.2%	103	0.7%	0	0.0%	0.5	180.8	20.7	14.9
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)</i>	11,046	3,866	35.0%	4,997	45.2%	1,780	16.1%	*****	*****	*****	*****	2.7	216.0	31.2	15.4
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 65+ Years)</i>	22,272	15,587	70.0%	5,101	22.9%	1,422	6.4%	*****	*****	*****	*****	0.7	480.0	21.0	15.3

Table 1. Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode ¹										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)</i>	19,295	13,275	68.8%	4,366	22.6%	1,486	7.7%	*****	*****	*****	*****	0.7	480.0	22.0	16.5
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 65+ Years)</i>	9,300	6,322	68.0%	2,572	27.7%	381	4.1%	25	0.3%	0	0.0%	2.5	120.0	20.3	12.0
<i>Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)</i>	2,922	1,520	52.0%	885	30.3%	500	17.1%	17	0.6%	0	0.0%	10.0	176.8	36.4	17.6
<i>Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)</i>	24,225	19,997	82.5%	3,182	13.1%	892	3.7%	*****	*****	*****	*****	1.0	300.0	16.0	13.3

Table 1. Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode ¹										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)</i>	22,829	19,576	85.8%	2,511	11.0%	653	2.9%	*****	*****	*****	*****	1.0	300.0	15.0	12.6
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)</i>	3,949	1,967	49.8%	1,360	34.4%	498	12.6%	124	3.1%	0	0.0%	5.0	120.0	28.4	16.0
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 18+ Years)</i>	273,877	189,898	69.3%	69,741	25.5%	13,265	4.8%	*****	*****	*****	*****	0.1	480.0	20.8	12.5
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)</i>	208,781	141,326	67.7%	52,590	25.2%	13,818	6.6%	*****	*****	*****	*****	0.1	480.0	21.7	14.4

Table 1. Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode ¹										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 18+ Years)</i>	164,960	118,720	72.0%	42,670	25.9%	3,474	2.1%	96	0.1%	0	0.0%	0.5	135.0	19.2	9.3
<i>Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)</i>	94,130	48,519	51.5%	33,725	35.8%	11,775	12.5%	*****	*****	*****	*****	1.0	210.0	35.2	14.5
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)</i>	109,010	63,073	57.9%	35,601	32.7%	8,901	8.2%	*****	*****	*****	*****	0.0	300.0	23.3	14.1
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)</i>	70,648	55,310	78.3%	12,215	17.3%	2,828	4.0%	*****	*****	*****	*****	0.2	300.0	18.0	13.2

Table 1. Summary of Average Filled Daily Dose (AFDD) in Each Initiator's First Valid Episode for Exposures of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode ¹										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5					
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Minimum	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18+ Years)</i>	59,591	21,948	36.8%	28,068	47.1%	8,013	13.4%	*****	*****	*****	*****	0.0	300.0	29.6	14.0

¹Categories of Amphetamine/Dextroamphetamine Combination Products: <=20 mg per day, >20 - 40 mg per day, >40 -60 mg per day, >60-200 mg per day, and >200 mg per day; Categories of Lisdexamfetamine Products: <=30 mg per day, >30 - 50 mg per day, >50 -70 mg per day, >70-200 mg per day, and >200 mg per day; Categories of Methylphenidate Products: <=20 mg per day, >20 - 40 mg per day, >40 -60 mg per day, >60-200 mg per day, and >200 mg per day

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 5+ Years)</i>	329,648	224,629	68.1%	87,536	26.6%	16,161	4.9%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)</i>	236,287	161,047	68.2%	58,536	24.8%	15,373	6.5%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5+ Years)</i>	209,736	154,165	73.5%	51,382	24.5%	4,063	1.9%	126	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)</i>	131,442	74,318	56.5%	42,628	32.4%	14,154	10.8%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)</i>	184,068	101,799	55.3%	64,642	35.1%	14,900	8.1%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)</i>	101,788	83,180	81.7%	14,974	14.7%	3,286	3.2%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)</i>	126,348	53,097	42.0%	56,881	45.0%	13,642	10.8%	*****	*****	*****	*****

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 5- 17 Years)</i>	55,838	48,911	87.6%	6,561	11.8%	353	0.6%	13	0.0%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)</i>	27,554	24,924	90.5%	2,391	8.7%	*****	*****	*****	*****	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)</i>	44,816	39,313	87.7%	5,308	11.8%	*****	*****	*****	*****	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)</i>	37,333	28,123	75.3%	7,767	20.8%	1,415	3.8%	28	0.1%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5-17 Years)</i>	75,087	42,076	56.0%	27,667	36.8%	4,532	6.0%	812	1.1%	0	0.0%
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)</i>	31,165	29,024	93.1%	1,934	6.2%	188	0.6%	19	0.1%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)</i>	66,777	32,503	48.7%	28,463	42.6%	4,917	7.4%	894	1.3%	0	0.0%

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18- 25 Years)</i>	68,912	48,877	70.9%	18,126	26.3%	1,813	2.6%	96	0.1%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)</i>	47,516	34,822	73.3%	10,967	23.1%	1,634	3.4%	93	0.2%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)</i>	45,112	34,448	76.4%	10,257	22.7%	*****	*****	*****	*****	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)</i>	28,073	15,895	56.6%	9,825	35.0%	2,290	8.2%	63	0.2%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)</i>	27,326	12,534	45.9%	11,599	42.4%	2,678	9.8%	515	1.9%	0	0.0%
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)</i>	13,255	10,506	79.3%	2,392	18.0%	327	2.5%	30	0.2%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)</i>	20,526	7,147	34.8%	10,302	50.2%	2,573	12.5%	504	2.5%	0	0.0%

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 26- 44 Years)</i>	127,165	79,386	62.4%	39,507	31.1%	7,663	6.0%	609	0.5%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)</i>	97,460	62,177	63.8%	27,290	28.0%	7,373	7.6%	620	0.6%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)</i>	79,823	55,147	69.1%	22,816	28.6%	1,813	2.3%	47	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)</i>	43,773	20,301	46.4%	16,884	38.6%	6,437	14.7%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)</i>	35,670	16,188	45.4%	14,536	40.8%	4,218	11.8%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)</i>	19,481	13,806	70.9%	4,538	23.3%	1,053	5.4%	84	0.4%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)</i>	24,082	7,952	33.0%	11,673	48.5%	3,720	15.4%	*****	*****	*****	*****

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 45- 64 Years)</i>	55,599	32,642	58.7%	17,771	32.0%	4,767	8.6%	419	0.8%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)</i>	44,582	26,360	59.1%	13,249	29.7%	4,554	10.2%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)</i>	30,764	19,228	62.5%	10,246	33.3%	1,250	4.1%	40	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)</i>	19,378	8,648	44.6%	7,202	37.2%	3,447	17.8%	81	0.4%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)</i>	21,815	11,442	52.5%	7,381	33.8%	2,490	11.4%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)</i>	15,106	10,569	70.0%	3,404	22.5%	1,012	6.7%	121	0.8%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)</i>	11,046	3,668	33.2%	5,017	45.4%	1,897	17.2%	*****	*****	*****	*****

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 65+ Years)</i>	22,272	15,108	67.8%	5,437	24.4%	1,545	6.9%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)</i>	19,295	12,977	67.3%	4,573	23.7%	1,557	8.1%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 65+ Years)</i>	9,300	6,181	66.5%	2,686	28.9%	407	4.4%	26	0.3%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)</i>	2,922	1,470	50.3%	895	30.6%	537	18.4%	20	0.7%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)</i>	24,225	19,680	81.2%	3,408	14.1%	966	4.0%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)</i>	22,829	19,342	84.7%	2,690	11.8%	703	3.1%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)</i>	3,949	1,911	48.4%	1,393	35.3%	514	13.0%	131	3.3%	0	0.0%

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18+ Years)</i>	273,877	175,861	64.2%	80,904	29.5%	15,803	5.8%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)</i>	208,781	136,205	65.2%	56,118	26.9%	15,135	7.2%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18+ Years)</i>	164,960	114,934	69.7%	46,033	27.9%	3,869	2.3%	124	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)</i>	94,130	46,263	49.1%	34,825	37.0%	12,727	13.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)</i>	109,010	59,795	54.9%	36,943	33.9%	10,357	9.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)</i>	70,648	54,191	76.7%	13,032	18.4%	3,096	4.4%	*****	*****	*****	*****

Table 2. Distribution of Mean Current Filled Daily Dose (CFDD) Categories for Active Pharmaceutical Ingredients (APIs) across All Dispensings in All API Treatment Episodes of Interest in the Sentinel Distributed Database from April 1, 2020 to March 31, 2022

	Total Number of Patients	Number of Patients by Filled Daily Dose ¹									
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18+ Years)</i>	59,591	20,655	34.7%	28,395	47.6%	8,708	14.6%	****	****	****	****

¹Categories of Amphetamine/Dextroamphetamine Combination Products: <=20 mg per day, >20 - 40 mg per day, >40 -60 mg per day, >60-200 mg per day, and >200 mg per day; Categories of Lisdexamfetamine Products: <=30 mg per day, >30 - 50 mg per day, >50 -70 mg per day, >70-200 mg per day, and >200 mg per day; Categories of Methylphenidate Products: <=20 mg per day, >20 - 40 mg per day, >40 -60 mg per day, >60-200 mg per day, and >200 mg per day

****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (May 23, 2024)

Masked DP ID	DP Start Date	DP End Date ¹
DP01	01/01/2000	03/31/2022
DP02	01/01/2007	03/31/2022
DP03	01/01/2000	03/31/2022
DP04	01/01/2006	03/31/2022
DP05	01/01/2000	03/31/2022
DP06	01/01/2008	03/31/2022
DP07	01/01/2004	03/31/2022
DP08	01/01/2008	03/31/2022

¹End Date represents the earliest of: (1) query end date, or (2) last day of the most recent month for which all of a Data Partner's data tables (enrollment, dispensing, etc.) have at least 80% of the record count relative to the prior month.

Appendix B. List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Amphetamine/Dextroamphetamine Combination Products Immediate Release	
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	dextroamphetamine-amphetamine
Amphetamine/Dextroamphetamine Combination Products Extended Release	
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall XR
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Mydayis
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	dextroamphetamine-amphetamine
Lisdexamfetamine Extended Release	
lisdexamfetamine dimesylate	Vyvanse
lisdexamfetamine dimesylate	lisdexamfetamine
Methylphenidate Single-entity Products Immediate Release	
methylphenidate HCl	Methylin
methylphenidate HCl	Ritalin
methylphenidate HCl	methylphenidate HCl
Methylphenidate Single-entity Products Extended Release	
methylphenidate	Cotempla XR-ODT
methylphenidate	Daytrana
methylphenidate	methylphenidate
methylphenidate HCl	Adhansia XR
methylphenidate HCl	Aptensio XR
methylphenidate HCl	Concerta
methylphenidate HCl	Jornay PM
methylphenidate HCl	Metadate CD
methylphenidate HCl	Metadate ER
methylphenidate HCl	QuilliChew ER
methylphenidate HCl	Quillivant XR
methylphenidate HCl	Relexxii
methylphenidate HCl	Ritalin LA
methylphenidate HCl	methylphenidate HCl

Appendix C. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool v13.1.1 to investigate the use of Attention-Deficit/Hyperactivity Disorder Medications within pre- and post-pandemic time periods among prespecified age groups in the Sentinel Distributed Database (SDD).

1. R01: Type 5 (Overall study period)
2. R02: Type 5 (Pre-pandemic study period)
3. R03: Type 5 (Pandemic study period)
4. R04: Type 5 (Post-pandemic study period)

Query period: January 1, 2017 - March 31, 2023 (overall)
 April 1, 2018 - March 31, 2020 (pre-pandemic)
 April 1, 2020 - March 31, 2022 (pandemic)
 April 1, 2022 - March 31, 2023 (latest available)

Coverage requirement: Medical & Drug Coverage

Pre-index enrollment requirement: 365 days

Post-index requirement: N/A

Enrollment gap: 45 days

Age groups: See below in the Age Group column

Stratifications: Age groups
 Census bureau (CB) region

Censor output categorization: -

Restrictions: None

Distribution of index-defining codes: No

*Reclassify outpatient (AV), emergency department (ED), and other ambulatory (OA) encounters that occur during an inpatient stay as inpatient (IP) encounters. Do not reclassify if an encounter occurs on the day of admission (ADate).

Envelope macro: an inpatient stay as inpatient (IP) encounters. Do not reclassify if an encounter occurs on the day of admission (ADate).

Freeze data: No

Stockpiling See stockpiling tab

Features: Run type 2 cohort off of Type 5 cohort of corresponding query period to ensure identical patients captured
 Carry forward other reporting features from cder_mpl1p_wp085
 Output the number of patients who had a mean/median current filled daily dose across all their dispensings within a user defined range
 Most frequent utilization (MFU) output and reporting
 Compute t-statistic and Z-statistic for comparisons between proportions between pre-pandemic and pandemic query periods, and report p-value

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Exposure Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
Overall	22	5+ years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	23	5+ years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	24	5+ years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure	Exclude Evidence of Days Supply if	Treatment Episode	Treatment Episode	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension						Daily Dose Summary (Mean) Category
Overall	25	5+ years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+
	26	5+ years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	27	5+ years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Exposure Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
Overall	28	5+ years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
5-17 Years	29	5-17 years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	30	5-17 years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
5-17 Years	31	5-17 years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	32	5-17 Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+
	33	5-17 years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
5-17 Years	34	5-17 years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	35	5-17 years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
18-25 Years	36	18-25 Years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure														
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if		Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
						Washout Includes Dispensings	Treatment								
18-25 Years	37	18-25 Years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+	
	38	18-25 Years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+	
	39	18-25 Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+	

Appendix C. Specifications Defining Parameters for this Request

Exposure														
Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category	
18-25 Years	40	18-25 Years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	41	18-25 Years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	42	18-25 Years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure	Exclude Evidence of Days Supply if	Treatment Episode	Treatment Episode	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to	Censor Treatment Episode at	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension				Attach to Dispensings	Evidence of:	Daily Dose Summary (Mean) Category
26-44 Years	43	26-44 Years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	44	26-44 Years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	45	26-44 Years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure	Exclude Evidence of Days Supply if	Treatment Episode	Treatment Episode	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to	Censor Treatment Episode at	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension				Attach to Dispensings	Evidence of:	Daily Dose Summary (Mean) Category
26-44 Years	46	26-44 Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+
	47	26-44 Years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	48	26-44 Years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
26-44 Years	49	26-44 Years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
45-64 Years	50	45-64 Years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	51	45-64 Years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

Exposure														
Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category	
45-64 Years	52	45-64 Years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	53	45-64 Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+
	54	45-64 Years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure	Exclude Evidence of Days Supply if	Treatment Episode	Treatment Episode	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to	Censor Treatment	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension				Attach to Dispensings	Episode at Evidence of:	Daily Dose Summary (Mean) Category
45-64 Years	55	45-64 Years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	56	45-64 Years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
65+ Years	57	65+ Years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

Exposure														
Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category	
65+ Years	58	65+ Years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	59	65+ Years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	60	65+ Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+

Appendix C. Specifications Defining Parameters for this Request

	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category
65+ Years	61	65+ Years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	62	65+ Years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	63	65+ Years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

Exposure														
Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category	
18+ Years	64	18+ Years	Amphetamine/Dextroamphetamine Combination Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	65	18+ Years	Amphetamine/Dextroamphetamine Combination Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	66	18+ Years	Amphetamine/Dextroamphetamine Combination Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

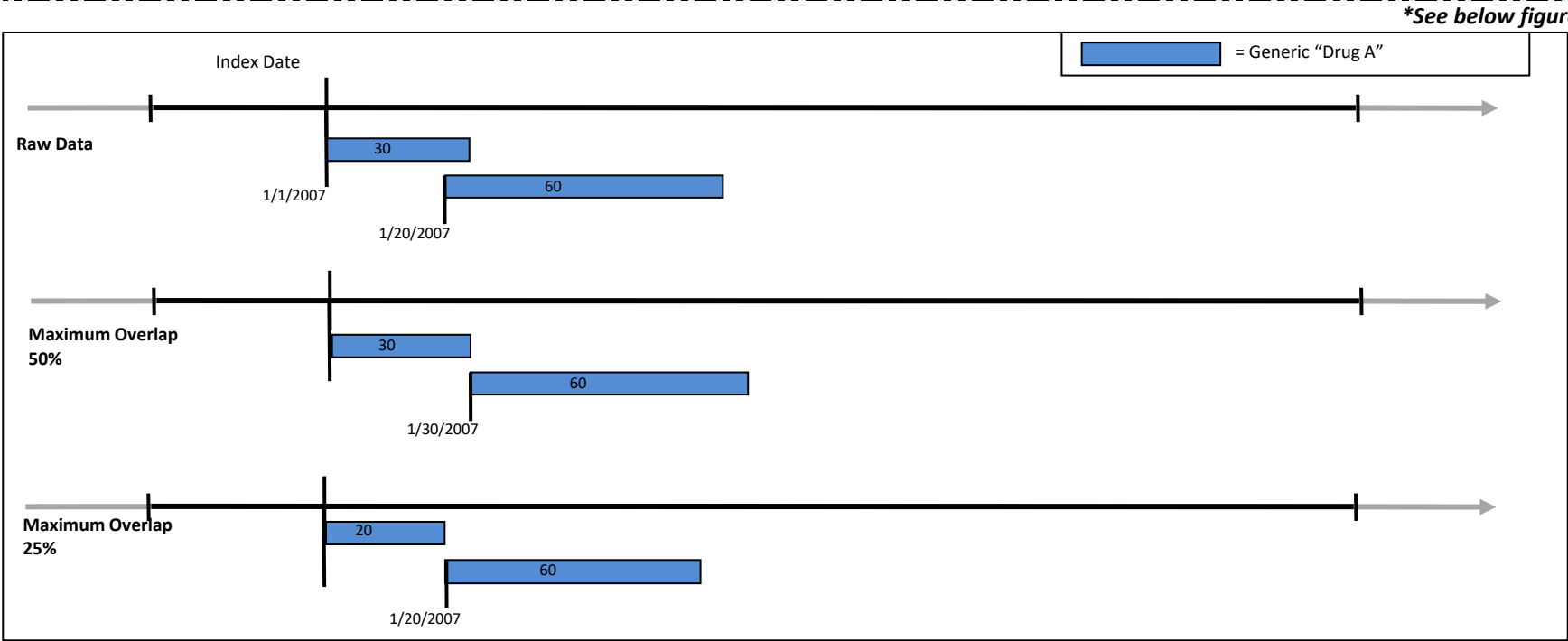
	Exposure													
	Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure	Exclude Evidence of Days Supply if	Treatment Episode	Treatment Episode	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to	Censor Treatment Episode at	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension				Attach to Dispensings	Evidence of:	Daily Dose Summary (Mean) Category
18+ Years	67	18+ Years	Lisdexamfetamine, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-30 31-50 51-70 71+
	68	18+ Years	Methylphenidate Single-entity Products, Any	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	69	18+ Years	Methylphenidate Single-entity Products, Immediate Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+

Appendix C. Specifications Defining Parameters for this Request

Appendix C: Specifications: Dosing Parameters for this Request														
Exposure														
Scenario	Age Restriction	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Exclude Evidence of Days Supply if Washout Includes Dispensings	Treatment Episode Gap	Treatment Episode Extension	Care Setting	Principal Diagnosis Position	Create Baseline Table?	Forced Supply to Attach to Dispensings	Censor Treatment Episode at Evidence of:	Current Filled Daily Dose Summary (Mean) Category	
18+ Years	70	18+ Years	Methylphenidate Single-entity Products, Extended Release	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	365 days	*Washout lookback period should search for evidence of days supply;	30 days	None	Outpatient dispensing	N/A	No	N/A	*Death; *DP end date; *Query end date; *Enrollment end date; *Episode end date	1-20 21-40 41-60 61+
	National Drug Codes (NDCs) are checked against First Data Bank's FDB MedKnowledge®.													
	N/A: Not applicable													

Appendix D. Specifications Defining Stockpiling Parameters Used for this Request

Stockpiling					
Stockpiling Group	Same Day Dispensing Processing for Days Supplied	Same Day Dispensing Processing for	Range of Allowable Days Supplied Values	Range of Allowable Amount Supplied Values	Overlap Percentage*
Use drug class for the stockpiling except when calculating average daily dose by active ingredient. For calculating average daily dose by active ingredient, use generic name for stockpiling	*Maximum for both exposure cohorts and active pharmaceutical ingredients (API) cohorts (to allow for cumulative filled daily dose (CFDD) calculations)	*Adds all	Exposure cohorts: 7 days - HIGH API cohorts: 7-100	Exposure cohorts: Does not consider amount supplied values of 0 or less API cohorts: 0<-500	Default: No truncation will occur and any overlap of supply between dispensing will be corrected by pushing overlapping days supplied forward



Appendix E. Design Diagram for this Request

