

## **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 2)

**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 two 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, 2018 to March 31, 2020. 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:  $\leq 20$  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:  $\leq 30$  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:  $\leq 20$  mg per day,  $>20 - 40$  mg per day,  $>40 - 60$  mg per day,  $>60 - 200$  mg per day, and  $>200$  mg per day.

## Overview for Request: cder\_mpl1p\_wp087 (Report 2)

**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@sentinel-system.org](mailto:info@sentinel-system.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.sentinel-system.org/projects/SETINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

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**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 requests.

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										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	Minimu m	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5+ Years)</i>	277,807	187,220	67.4%	72,577	26.1%	16,661	6.0%	*****	*****	*****	*****	0.5	225.0	21.2	13.4
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)</i>	211,633	137,564	65.0%	55,480	26.2%	17,075	8.1%	1,512	0.7%	*****	*****	0.5	300.0	22.6	15.3
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 5+ Years)</i>	168,658	118,183	70.1%	44,921	26.6%	5,412	3.2%	142	0.1%	0	0.0%	0.5	150.0	19.5	10.3
<i>Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)</i>	137,867	77,738	56.4%	44,226	32.1%	15,650	11.4%	*****	*****	*****	*****	0.0	300.0	33.5	15.0

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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	Minimu m	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)</i>	171,646	102,022	59.4%	55,451	32.3%	12,093	7.0%	*****	*****	*****	*****	0.1	240.0	22.7	13.6
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)</i>	102,989	83,686	81.3%	15,170	14.7%	3,750	3.6%	*****	*****	*****	*****	0.7	240.0	16.6	13.0
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)</i>	111,379	49,891	44.8%	48,050	43.1%	11,157	10.0%	*****	*****	*****	*****	0.1	236.4	27.1	13.3
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5- 17 Years)</i>	54,850	48,612	88.6%	5,780	10.5%	439	0.8%	19	0.0%	0	0.0%	0.5	120.0	13.4	8.1



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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	Minimu m	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)</i>	28,218	25,679	91.0%	2,191	7.8%	329	1.2%	*****	*****	*****	*****	0.8	300.0	12.2	9.4
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)</i>	43,416	37,666	86.8%	5,457	12.6%	*****	*****	*****	*****	0	0.0%	0.5	100.0	14.1	7.7
<i>Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)</i>	46,442	35,306	76.0%	9,371	20.2%	1,747	3.8%	18	0.0%	0	0.0%	0.0	165.0	26.2	12.5
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5- 17 Years)</i>	73,292	43,491	59.3%	25,418	34.7%	3,777	5.2%	606	0.8%	0	0.0%	0.1	120.0	21.8	11.6

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<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)</i>	30,888	29,020	94.0%	1,626	5.3%	217	0.7%	25	0.1%	0	0.0%	0.7	180.0	11.1	8.1
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)</i>	66,062	34,093	51.6%	26,830	40.6%	4,406	6.7%	733	1.1%	0	0.0%	0.1	120.0	24.4	11.5
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 18-25 Years)</i>	52,954	36,664	69.2%	14,124	26.7%	2,053	3.9%	113	0.2%	0	0.0%	0.5	150.0	20.7	11.4
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)</i>	40,294	27,873	69.2%	10,228	25.4%	2,057	5.1%	136	0.3%	0	0.0%	0.5	150.0	21.1	13.3

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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	Minimu m	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)</i>	32,554	23,061	70.8%	8,867	27.2%	*****	*****	*****	*****	0	0.0%	2.1	90.0	19.7	8.7
<i>Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)</i>	27,096	14,434	53.3%	9,960	36.8%	2,660	9.8%	42	0.2%	0	0.0%	3.0	187.5	34.8	13.6
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)</i>	19,514	9,103	46.6%	8,079	41.4%	1,962	10.1%	370	1.9%	0	0.0%	1.7	120.0	26.7	14.0
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)</i>	10,396	8,078	77.7%	1,946	18.7%	335	3.2%	37	0.4%	0	0.0%	0.8	120.0	18.6	12.4

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<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)</i>	14,202	4,727	33.3%	7,075	49.8%	1,990	14.0%	410	2.9%	0	0.0%	5.6	120.0	30.6	13.9
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 26-44 Years)</i>	96,000	56,418	58.8%	31,158	32.5%	7,795	8.1%	629	0.7%	0	0.0%	1.0	180.0	24.1	13.9
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)</i>	79,161	45,841	57.9%	24,717	31.2%	7,913	10.0%	690	0.9%	0	0.0%	0.7	180.0	25.1	15.5
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)</i>	56,237	35,043	62.3%	18,653	33.2%	2,483	4.4%	58	0.1%	0	0.0%	0.7	122.1	21.8	10.5

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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	Minimu m	Maximum	Mean	Standard Deviation
<i>Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)</i>	40,073	17,470	43.6%	15,905	39.7%	6,591	16.4%	107	0.3%	0	0.0%	4.0	181.2	38.1	14.9
<i>Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)</i>	27,577	13,092	47.5%	10,816	39.2%	3,134	11.4%	*****	*****	*****	*****	1.7	239.2	27.1	14.9
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)</i>	17,084	11,404	66.8%	4,366	25.6%	1,221	7.1%	*****	*****	*****	*****	1.7	239.2	22.4	14.6
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)</i>	16,890	5,561	32.9%	8,130	48.1%	2,603	15.4%	596	3.5%	0	0.0%	4.3	160.0	31.3	14.6

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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	Minimu m	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 45-64 Years)</i>	53,117	31,115	58.6%	16,665	31.4%	4,894	9.2%	443	0.8%	0	0.0%	0.7	180.0	24.6	14.9
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)</i>	45,082	25,629	56.8%	13,790	30.6%	5,146	11.4%	517	1.1%	0	0.0%	0.7	180.0	26.0	16.4
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)</i>	28,260	16,901	59.8%	9,664	34.2%	1,641	5.8%	54	0.2%	0	0.0%	1.5	150.0	22.6	11.7
<i>Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)</i>	21,333	9,061	42.5%	8,088	37.9%	4,121	19.3%	63	0.3%	0	0.0%	2.0	140.0	38.9	15.7

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	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										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	Minimu m	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)</i>	23,747	13,303	56.0%	7,678	32.3%	2,346	9.9%	*****	*****	*****	*****	1.0	240.0	25.0	15.5
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)</i>	18,043	12,399	68.7%	4,255	23.6%	1,244	6.9%	*****	*****	*****	*****	1.0	240.0	21.7	15.1
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)</i>	10,624	3,704	34.9%	4,796	45.1%	1,709	16.1%	415	3.9%	0	0.0%	3.6	144.0	31.7	15.3
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 65+ Years)</i>	21,029	14,513	69.0%	4,882	23.2%	1,489	7.1%	*****	*****	*****	*****	1.3	225.0	21.4	14.9

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										Distribution of Average Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4		Dose Group 5		Minimu m	Maximum	Mean	Standard Deviation
		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/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)</i>	19,007	12,634	66.5%	4,582	24.1%	1,639	8.6%	*****	*****	*****	*****	1.3	225.0	22.7	16.0
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 65+ Years)</i>	8,251	5,556	67.3%	2,295	27.8%	379	4.6%	21	0.3%	0	0.0%	1.4	120.0	20.5	12.0
<i>Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)</i>	2,969	1,492	50.3%	919	31.0%	535	18.0%	*****	*****	*****	*****	5.0	300.0	36.9	18.4
<i>Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)</i>	27,572	23,064	83.7%	3,479	12.6%	878	3.2%	*****	*****	*****	*****	1.3	240.0	15.7	12.8



**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										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	Minimu m	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)</i>	26,630	22,827	85.7%	2,983	11.2%	737	2.8%	*****	*****	*****	*****	1.3	240.0	15.0	12.2
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)</i>	3,629	1,818	50.1%	1,229	33.9%	454	12.5%	*****	*****	*****	*****	8.6	236.4	28.9	16.8
<i>Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 18+ Years)</i>	223,018	138,658	62.2%	66,808	30.0%	16,222	7.3%	*****	*****	*****	*****	0.5	225.0	23.2	13.8
<i>Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)</i>	183,468	111,931	61.0%	53,296	29.0%	16,746	9.1%	*****	*****	*****	*****	0.5	225.0	24.2	15.5

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										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	Minimu m	Maximum	Mean	Standard Deviation
<i>Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 18+ Years)</i>	125,267	80,539	64.3%	39,467	31.5%	5,123	4.1%	138	0.1%	0	0.0%	0.7	150.0	21.4	10.5
<i>Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)</i>	91,449	42,446	46.4%	34,864	38.1%	13,904	15.2%	*****	*****	*****	*****	2.0	300.0	37.2	15.0
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)</i>	98,384	58,549	59.5%	30,042	30.5%	8,317	8.5%	*****	*****	*****	*****	1.0	240.0	23.3	14.7
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)</i>	72,129	54,690	75.8%	13,547	18.8%	3,534	4.9%	*****	*****	*****	*****	0.8	240.0	18.9	13.9

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Average Filled Daily Dose in First Treatment Episode <sup>1</sup>										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	Minimu m	Maximum	Mean	Standard Deviation
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18+ Years)</i>	45,337	15,807	34.9%	21,226	46.8%	6,755	14.9%	*****	*****	*****	*****	3.6	236.4	31.0	14.8

<sup>1</sup>Categories 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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	277,807	173,849	62.60%	82,610	29.70%	19,525	7.00%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)</i>	211,633	132,211	62.5%	58,939	27.8%	18,621	8.8%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5+ Years)</i>	168,658	114,201	67.7%	48,287	28.6%	5,980	3.5%	190	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)</i>	137,867	73,816	53.5%	46,207	33.5%	17,178	12.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)</i>	171,646	95,098	55.4%	59,031	34.4%	14,634	8.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)</i>	102,989	82,142	79.8%	16,246	15.8%	4,128	4.0%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)</i>	111,379	46,010	41.3%	50,006	44.9%	12,613	11.3%	*****	*****	*****	*****

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	54,850	46,813	85.3%	7,404	13.5%	602	1.1%	31	0.1%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)</i>	28,218	25,310	89.7%	2,511	8.9%	370	1.3%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)</i>	43,416	36,821	84.8%	6,227	14.3%	*****	*****	*****	*****	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)</i>	46,442	33,857	72.9%	10,459	22.5%	2,046	4.4%	80	0.2%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 5-17 Years)</i>	73,292	39,395	53.8%	28,109	38.4%	4,934	6.7%	854	1.2%	0	0.0%
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)</i>	30,888	28,661	92.8%	1,918	6.2%	274	0.9%	35	0.1%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)</i>	66,062	31,146	47.1%	28,743	43.5%	5,259	8.0%	914	1.4%	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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	52,954	33,215	62.7%	16,968	32.0%	2,579	4.9%	192	0.4%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)</i>	40,294	26,665	66.2%	11,146	27.7%	2,299	5.7%	184	0.5%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)</i>	32,554	22,151	68.0%	9,676	29.7%	709	2.2%	18	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)</i>	27,096	13,551	50.0%	10,454	38.6%	2,967	10.9%	124	0.5%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)</i>	19,514	8,344	42.8%	8,229	42.2%	2,400	12.3%	541	2.8%	0	0.0%
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)</i>	10,396	7,879	75.8%	2,102	20.2%	362	3.5%	53	0.5%	0	0.0%
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)</i>	14,202	4,411	31.1%	7,090	49.9%	2,207	15.5%	494	3.5%	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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	96,000	51,228	53.4%	34,758	36.2%	9,179	9.6%	835	0.9%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)</i>	79,161	43,749	55.3%	25,921	32.7%	8,651	10.9%	840	1.1%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)</i>	56,237	33,677	59.9%	19,744	35.1%	2,740	4.9%	76	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)</i>	40,073	16,506	41.2%	16,143	40.3%	7,151	17.8%	273	0.7%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)</i>	27,577	12,133	44.0%	11,066	40.1%	3,630	13.2%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)</i>	17,084	11,073	64.8%	4,572	26.8%	1,320	7.7%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)</i>	16,890	5,237	31.0%	8,106	48.0%	2,836	16.8%	711	4.2%	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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	53,117	28,892	54.4%	18,096	34.1%	5,541	10.4%	588	1.1%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)</i>	45,082	24,453	54.2%	14,437	32.0%	5,557	12.3%	635	1.4%	0	0.0%
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)</i>	28,260	16,267	57.6%	10,169	36.0%	1,760	6.2%	64	0.2%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)</i>	21,333	8,571	40.2%	8,184	38.4%	4,424	20.7%	154	0.7%	0	0.0%
<i>Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)</i>	23,747	12,669	53.3%	7,849	33.1%	2,672	11.3%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)</i>	18,043	12,076	66.9%	4,427	24.5%	1,371	7.6%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)</i>	10,624	3,524	33.2%	4,782	45.0%	1,830	17.2%	488	4.6%	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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	21,029	14,028	66.7%	5,221	24.8%	1,606	7.6%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)</i>	19,007	12,270	64.6%	4,840	25.5%	1,724	9.1%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 65+ Years)</i>	8,251	5,430	65.8%	2,391	29.0%	408	4.9%	22	0.3%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)</i>	2,969	1,449	48.8%	918	30.9%	566	19.1%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)</i>	27,572	22,668	82.2%	3,748	13.6%	972	3.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)</i>	26,630	22,523	84.6%	3,213	12.1%	797	3.0%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)</i>	3,629	1,755	48.4%	1,267	34.9%	469	12.9%	*****	*****	*****	*****

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	223,018	127,178	57.0%	75,129	33.7%	18,921	8.5%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)</i>	183,468	106,999	58.3%	56,388	30.7%	18,248	9.9%	*****	*****	*****	*****
<i>Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18+ Years)</i>	125,267	77,442	61.8%	42,024	33.5%	5,621	4.5%	180	0.1%	0	0.0%
<i>Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)</i>	91,449	40,033	43.8%	35,711	39.1%	15,118	16.5%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)</i>	98,384	55,775	56.7%	30,891	31.4%	9,689	9.8%	*****	*****	*****	*****
<i>Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)</i>	72,129	53,517	74.2%	14,320	19.9%	3,854	5.3%	*****	*****	*****	*****

**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, 2018 to March 31, 2020**

	Total Number of Patients	Number of Patients by Filled Daily Dose <sup>1</sup>									
		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>	45,337	14,911	32.9%	21,250	46.9%	7,344	16.2%	*****	*****	*****	*****

<sup>1</sup>Categories 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 <sup>1</sup>
DP01	01/01/2000	03/31/2020
DP02	01/01/2007	03/31/2020
DP03	01/01/2000	03/31/2020
DP04	01/01/2006	03/31/2020
DP05	01/01/2000	03/31/2020
DP06	01/01/2008	03/31/2020
DP07	01/01/2004	03/31/2020
DP08	01/01/2008	03/31/2020

<sup>1</sup>End 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
<b>Amphetamine/Dextroamphetamine Combination Products Immediate Release</b>	
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	dextroamphetamine-amphetamine
<b>Amphetamine/Dextroamphetamine Combination Products Extended Release</b>	
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall XR
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Mydayis
dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	dextroamphetamine-amphetamine
<b>Lisdexamfetamine Extended Release</b>	
lisdexamfetamine dimesylate	Vyvanse
lisdexamfetamine dimesylate	lisdexamfetamine
<b>Methylphenidate Single-entity Products Immediate Release</b>	
methylphenidate HCl	Methylin
methylphenidate HCl	Ritalin
methylphenidate HCl	methylphenidate HCl
<b>Methylphenidate Single-entity Products Extended Release</b>	
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:**

**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 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

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
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 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 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
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	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
18-25 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	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
18-25 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 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	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 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	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 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	
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 Exposure 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 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	
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	Current Filled
					Washout Period	Washout Includes Dispensings	Gap	Extension				Attach to Dispensings	Episode at 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+

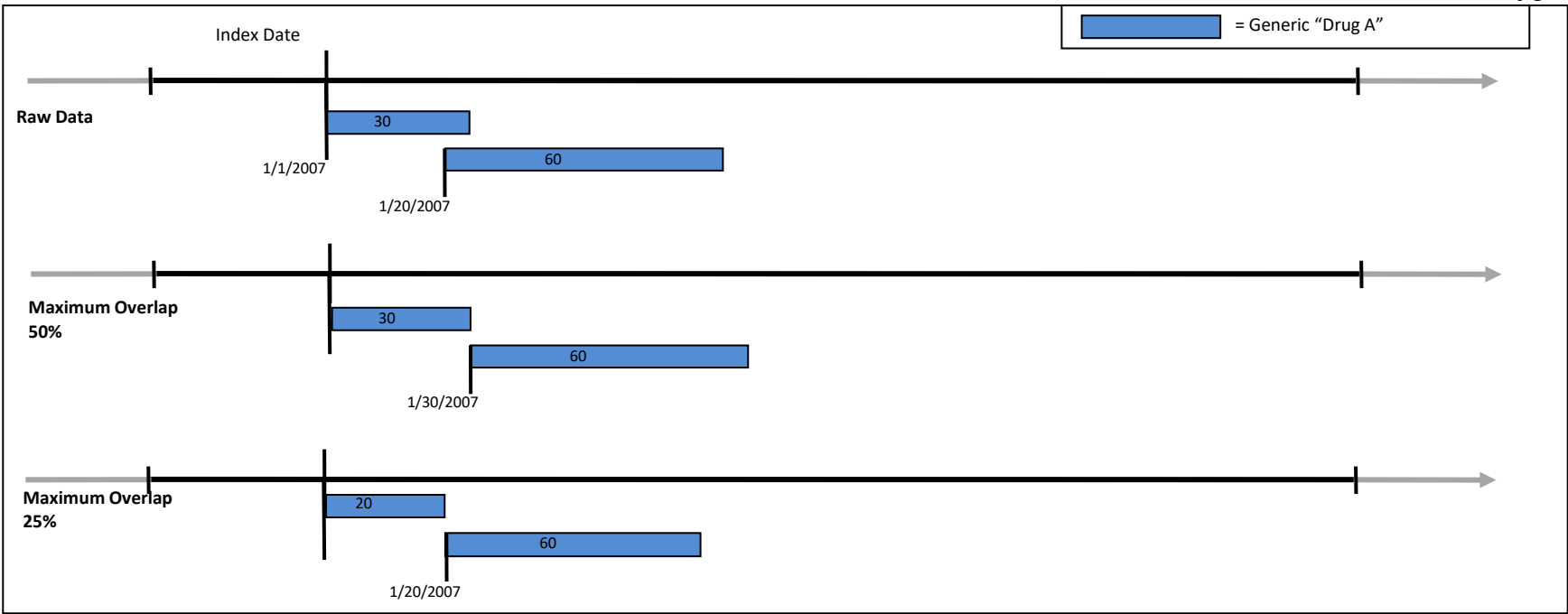
Appendix C. Specifications Defining Parameters for this Request

	Exposure													
				Incident Exposure Washout Period	Exclude Evidence of Days Supply if Exposure 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	
	Scenario	Age Restriction	Index Exposure	Cohort Definition										
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

\*See below figure





# Appendix E. Design Diagram for this Request

