**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 4)

**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 four 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, 2022 to March 31, 2023. 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 4)**

**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@sentinelsystem.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.sentinelsystem.org/projects/SETINEL/repos/sentinel-routine-querying-tool-documentation/browse).

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**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.

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

**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.

**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 - i**ndicator 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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5+ Years)* | 166,864 | 126,253 | 75.7% | 33,631 | 20.2% | 6,488 | 3.9% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 18.6 | 12.1 |
| *Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)* | 125,696 | 91,247 | 72.6% | 26,819 | 21.3% | 7,087 | 5.6% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 19.9 | 14.1 |
| *Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 5+ Years)* | 118,470 | 89,303 | 75.4% | 26,415 | 22.3% | 2,666 | 2.3% | 86 | 0.1% | 0 | 0.0% | 0.3 | 200.0 | 18.0 | 9.8 |
| *Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)* | 97,484 | 57,706 | 59.2% | 29,832 | 30.6% | 9,877 | 10.1% | 69 | 0.1% | 0 | 0.0% | 0.8 | 140.0 | 32.7 | 14.8 |

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)* | 121,320 | 71,811 | 59.2% | 39,570 | 32.6% | 8,547 | 7.0% | ***** | ***** | ***** | ***** | 0.1 | 300.0 | 23.1 | 13.8 |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)* | 68,568 | 53,716 | 78.3% | 11,424 | 16.7% | 3,166 | 4.6% | ***** | ***** | ***** | ***** | 0.1 | 285.7 | 17.9 | 13.9 |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)* | 80,787 | 39,205 | 48.5% | 33,246 | 41.2% | 6,919 | 8.6% | ***** | ***** | ***** | ***** | 1.0 | 300.0 | 26.1 | 13.0 |
| *Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 5-17 Years)* | 26,720 | 24,788 | 92.8% | 1,831 | 6.9% | ***** | ***** | ***** | ***** | 0 | 0.0% | 0.5 | 90.0 | 11.9 | 6.9 |

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)* | 13,479 | 12,571 | 93.3% | 832 | 6.2% | ***** | ***** | ***** | ***** | 0 | 0.0% | 0.5 | 90.0 | 11.0 | 8.1 |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)* | 22,183 | 20,311 | 91.6% | 1,794 | 8.1% | ***** | ***** | ***** | ***** | 0 | 0.0% | 0.5 | 90.0 | 12.5 | 6.8 |
| *Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)* | 22,128 | 17,799 | 80.4% | 3,752 | 17.0% | ***** | ***** | ***** | ***** | 0 | 0.0% | 1.0 | 120.0 | 24.6 | 12.0 |
| *Methylphenidate Single-entity Products, Any (Patients of Age 5-17 Years)* | 41,884 | 27,441 | 65.5% | 12,346 | 29.5% | 1,725 | 4.1% | 372 | 0.9% | 0 | 0.0% | 0.7 | 100.0 | 20.6 | 11.6 |

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| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)* | 17,277 | 16,514 | 95.6% | 669 | 3.9% | ***** | ***** | ***** | ***** | 0 | 0.0% | 0.4 | 90.0 | 10.3 | 7.3 |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)* | 37,502 | 21,847 | 58.3% | 13,230 | 35.3% | 1,966 | 5.2% | 459 | 1.2% | 0 | 0.0% | 1.0 | 108.0 | 23.2 | 11.7 |
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18-25 Years)* | 31,988 | 25,865 | 80.9% | 5,636 | 17.6% | 473 | 1.5% | 14 | 0.0% | 0 | 0.0% | 0.2 | 120.0 | 17.2 | 9.3 |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)* | 22,770 | 18,131 | 79.6% | 4,113 | 18.1% | 506 | 2.2% | 20 | 0.1% | 0 | 0.0% | 0.2 | 120.0 | 17.4 | 11.1 |

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)* | 22,567 | 18,349 | 81.3% | 4,045 | 17.9% | ***** | ***** | ***** | ***** | 0 | 0.0% | 0.3 | 60.2 | 16.9 | 7.6 |
| *Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)* | 17,612 | 10,994 | 62.4% | 5,461 | 31.0% | ***** | ***** | ***** | ***** | 0 | 0.0% | 1.0 | 136.4 | 31.8 | 13.1 |
| *Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)* | 17,291 | 9,356 | 54.1% | 6,546 | 37.9% | 1,199 | 6.9% | 190 | 1.1% | 0 | 0.0% | 1.4 | 160.0 | 24.3 | 12.7 |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)* | 8,752 | 7,129 | 81.5% | 1,405 | 16.1% | 207 | 2.4% | 11 | 0.1% | 0 | 0.0% | 1.0 | 160.0 | 17.3 | 11.4 |

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)* | 12,795 | 5,437 | 42.5% | 5,929 | 46.3% | 1,205 | 9.4% | 224 | 1.8% | 0 | 0.0% | 2.2 | 120.0 | 27.4 | 12.6 |
| *Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 26-44 Years)* | 66,558 | 47,740 | 71.7% | 15,590 | 23.4% | 3,024 | 4.5% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 20.1 | 12.2 |
| *Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)* | 53,359 | 37,285 | 69.9% | 12,589 | 23.6% | 3,255 | 6.1% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 20.8 | 14.1 |
| *Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)* | 48,384 | 34,508 | 71.3% | 12,640 | 26.1% | 1,214 | 2.5% | 22 | 0.0% | 0 | 0.0% | 0.5 | 90.0 | 19.3 | 9.7 |

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)* | 38,089 | 19,413 | 51.0% | 13,755 | 36.1% | 4,895 | 12.9% | 26 | 0.1% | 0 | 0.0% | 1.0 | 140.0 | 35.6 | 14.7 |
| *Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)* | 29,480 | 14,665 | 49.7% | 11,610 | 39.4% | 2,797 | 9.5% | 408 | 1.4% | 0 | 0.0% | 0.5 | 133.3 | 26.1 | 14.1 |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)* | 16,696 | 11,464 | 68.7% | 4,047 | 24.2% | 1,107 | 6.6% | 78 | 0.5% | 0 | 0.0% | 0.5 | 133.3 | 21.9 | 14.6 |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)* | 18,923 | 7,338 | 38.8% | 8,996 | 47.5% | 2,181 | 11.5% | 408 | 2.2% | 0 | 0.0% | 1.0 | 126.0 | 28.7 | 13.4 |

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| | | 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 | | | | | |
| | Total Number of 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 | Number of Patients | Percent of Total Patients | Minimum | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 45-64 Years)* | 29,181 | 19,219 | 65.9% | 7,803 | 26.7% | 1,982 | 6.8% | ***** | ***** | ***** | ***** | 0.5 | 210.0 | 22.1 | 14.0 |
| *Amphetamine/Dextro amphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)* | 24,529 | 15,563 | 63.4% | 6,544 | 26.7% | 2,227 | 9.1% | ***** | ***** | ***** | ***** | 0.5 | 210.0 | 23.6 | 15.8 |
| *Amphetamine/Dextro amphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)* | 19,267 | 12,251 | 63.6% | 6,130 | 31.8% | 850 | 4.4% | 36 | 0.2% | 0 | 0.0% | 0.5 | 145.4 | 21.4 | 11.3 |
| *Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)* | 16,721 | 8,048 | 48.1% | 5,938 | 35.5% | 2,707 | 16.2% | 28 | 0.2% | 0 | 0.0% | 0.8 | 140.0 | 37.1 | 15.6 |

**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)* | 17,228 | 8,794 | 51.0% | 6,206 | 36.0% | 1,948 | 11.3% | 280 | 1.6% | 0 | 0.0% | 0.8 | 120.0 | 26.8 | 15.6 |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)* | 11,628 | 7,472 | 64.3% | 3,009 | 25.9% | 1,064 | 9.2% | 83 | 0.7% | 0 | 0.0% | 0.8 | 120.0 | 23.8 | 16.0 |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)* | 8,698 | 3,189 | 36.7% | 4,045 | 46.5% | 1,221 | 14.0% | 243 | 2.8% | 0 | 0.0% | 1.8 | 108.0 | 30.2 | 14.4 |
| *Amphetamine/Dextro amphetamine Combination Products, Any (Patients of Age 65+ Years)* | 12,417 | 8,641 | 69.6% | 2,771 | 22.3% | 911 | 7.3% | 94 | 0.8% | 0 | 0.0% | 1.3 | 160.0 | 21.3 | 15.3 |

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**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)* | 11,559 | 7,697 | 66.6% | 2,741 | 23.7% | 1,027 | 8.9% | 94 | 0.8% | 0 | 0.0% | 1.3 | 160.0 | 22.7 | 16.2 |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 65+ Years)* | 6,069 | 3,884 | 64.0% | 1,806 | 29.8% | 353 | 5.8% | 26 | 0.4% | 0 | 0.0% | 4.3 | 200.0 | 21.6 | 13.4 |
| *Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)* | 2,934 | 1,452 | 49.5% | 926 | 31.6% | ***** | ***** | ***** | ***** | 0 | 0.0% | 5.0 | 140.0 | 37.2 | 17.5 |
| *Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)* | 15,437 | 11,555 | 74.9% | 2,862 | 18.5% | 878 | 5.7% | ***** | ***** | ***** | ***** | 0.1 | 300.0 | 19.0 | 15.4 |

**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)* | 14,215 | 11,137 | 78.3% | 2,294 | 16.1% | 698 | 4.9% | ***** | ***** | ***** | ***** | 0.1 | 285.7 | 17.9 | 14.8 |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)* | 2,869 | 1,394 | 48.6% | 1,046 | 36.5% | 346 | 12.1% | ***** | ***** | ***** | ***** | 3.0 | 300.0 | 28.6 | 16.5 |
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18+ Years)* | 140,144 | 101,465 | 72.4% | 31,800 | 22.7% | 6,390 | 4.6% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 19.9 | 12.4 |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)* | 112,217 | 78,676 | 70.1% | 25,987 | 23.2% | 7,015 | 6.3% | ***** | ***** | ***** | ***** | 0.2 | 300.0 | 20.9 | 14.3 |

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**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18+ Years)* | 96,287 | 68,992 | 71.7% | 24,621 | 25.6% | 2,589 | 2.7% | 85 | 0.1% | 0 | 0.0% | 0.3 | 200.0 | 19.3 | 10.0 |
| *Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)* | 75,356 | 39,907 | 53.0% | 26,080 | 34.6% | 9,305 | 12.3% | 64 | 0.1% | 0 | 0.0% | 0.8 | 140.0 | 35.1 | 14.8 |
| *Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)* | 79,436 | 44,370 | 55.9% | 27,224 | 34.3% | 6,822 | 8.6% | ***** | ***** | ***** | ***** | 0.1 | 300.0 | 24.5 | 14.6 |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)* | 51,291 | 37,202 | 72.5% | 10,755 | 21.0% | 3,076 | 6.0% | ***** | ***** | ***** | ***** | 0.1 | 285.7 | 20.4 | 14.7 |

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**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 18+ Years)* | 43,285 | 17,358 | 40.1% | 20,016 | 46.2% | 4,953 | 11.4% | ***** | ***** | ***** | ***** | 1.0 | 300.0 | 28.6 | 13.7 |

[1]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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 5+ Years)* | 166,864 | 120,722 | 72.3% | 38,192 | 22.9% | 7,293 | 4.4% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5+ Years)* | 125,696 | 89,237 | 71.0% | 28,220 | 22.5% | 7,559 | 6.0% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5+ Years)* | 118,470 | 87,693 | 74.0% | 27,822 | 23.5% | 2,843 | 2.4% | 112 | 0.1% | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 5+ Years)* | 97,484 | 56,444 | 57.9% | 30,522 | 31.3% | 10,302 | 10.6% | 216 | 0.2% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 5+ Years)* | 121,320 | 68,577 | 56.5% | 41,346 | 34.1% | 9,628 | 7.9% | ***** | ***** | ***** | ***** |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5+ Years)* | 68,568 | 53,029 | 77.3% | 11,919 | 17.4% | 3,305 | 4.8% | ***** | ***** | ***** | ***** |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 5+ Years)* | 80,787 | 37,521 | 46.4% | 34,106 | 42.2% | 7,542 | 9.3% | ***** | ***** | ***** | ***** |

**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, 2022 to March 31, 2023**

| | | Number of Patients by Filled Daily Dose[1] | | | | | | | | | |
| | | Dose Group 1 | | Dose Group 2 | | Dose Group 3 | | Dose Group 4 | | Dose Group 5 | |
| | Total Number of 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 | Number of Patients | Percent of Total Patients |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 5-17 Years)* | 26,720 | 24,322 | 91.0% | 2,262 | 8.5% | ***** | ***** | ***** | ***** | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 5-17 Years)* | 13,479 | 12,475 | 92.6% | 907 | 6.7% | ***** | ***** | ***** | ***** | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 5-17 Years)* | 22,183 | 20,094 | 90.6% | 2,006 | 9.0% | ***** | ***** | ***** | ***** | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 5-17 Years)* | 22,128 | 17,503 | 79.1% | 3,971 | 17.9% | 632 | 2.9% | 22 | 0.1% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 5-17 Years)* | 41,884 | 26,019 | 62.1% | 13,344 | 31.9% | 2,059 | 4.9% | 462 | 1.1% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 5-17 Years)* | 17,277 | 16,422 | 95.1% | 748 | 4.3% | ***** | ***** | ***** | ***** | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 5-17 Years)* | 37,502 | 20,806 | 55.5% | 13,934 | 37.2% | 2,239 | 6.0% | 523 | 1.4% | 0 | 0.0% |

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**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18-25 Years)* | 31,988 | 24,552 | 76.8% | 6,802 | 21.3% | 605 | 1.9% | 29 | 0.1% | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18-25 Years)* | 22,770 | 17,741 | 77.9% | 4,410 | 19.4% | 589 | 2.6% | 30 | 0.1% | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18-25 Years)* | 22,567 | 18,015 | 79.8% | 4,349 | 19.3% | ***** | ***** | ***** | ***** | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 18-25 Years)* | 17,612 | 10,718 | 60.9% | 5,633 | 32.0% | 1,229 | 7.0% | 32 | 0.2% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 18-25 Years)* | 17,291 | 8,851 | 51.2% | 6,761 | 39.1% | 1,431 | 8.3% | 248 | 1.4% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18-25 Years)* | 8,752 | 7,027 | 80.3% | 1,488 | 17.0% | 223 | 2.5% | 14 | 0.2% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 18-25 Years)* | 12,795 | 5,220 | 40.8% | 5,977 | 46.7% | 1,331 | 10.4% | 267 | 2.1% | 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, 2022 to March 31, 2023**

| | 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 |
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 26-44 Years)* | 66,558 | 45,095 | 67.8% | 17,739 | 26.7% | 3,438 | 5.2% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 26-44 Years)* | 53,359 | 36,331 | 68.1% | 13,242 | 24.8% | 3,483 | 6.5% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 26-44 Years)* | 48,384 | 33,796 | 69.8% | 13,253 | 27.4% | 1,298 | 2.7% | 37 | 0.1% | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 26-44 Years)* | 38,089 | 18,923 | 49.7% | 13,990 | 36.7% | 5,093 | 13.4% | 83 | 0.2% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 26-44 Years)* | 29,480 | 13,885 | 47.1% | 11,938 | 40.5% | 3,107 | 10.5% | 550 | 1.9% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 26-44 Years)* | 16,696 | 11,226 | 67.2% | 4,212 | 25.2% | 1,157 | 6.9% | 101 | 0.6% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 26-44 Years)* | 18,923 | 7,081 | 37.4% | 9,058 | 47.9% | 2,324 | 12.3% | 460 | 2.4% | 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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 45-64 Years)* | 29,181 | 18,325 | 62.8% | 8,457 | 29.0% | 2,174 | 7.5% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 45-64 Years)* | 24,529 | 15,149 | 61.8% | 6,807 | 27.8% | 2,337 | 9.5% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 45-64 Years)* | 19,267 | 11,968 | 62.1% | 6,356 | 33.0% | 902 | 4.7% | 41 | 0.2% | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 45-64 Years)* | 16,721 | 7,887 | 47.2% | 5,982 | 35.8% | 2,789 | 16.7% | 63 | 0.4% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 45-64 Years)* | 17,228 | 8,463 | 49.1% | 6,304 | 36.6% | 2,109 | 12.2% | 352 | 2.0% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 45-64 Years)* | 11,628 | 7,326 | 63.0% | 3,090 | 26.6% | 1,115 | 9.6% | 97 | 0.8% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 45-64 Years)* | 8,698 | 3,072 | 35.3% | 4,068 | 46.8% | 1,283 | 14.8% | 275 | 3.2% | 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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 65+ Years)* | 12,417 | 8,457 | 68.1% | 2,908 | 23.4% | 939 | 7.6% | 113 | 0.9% | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 65+ Years)* | 11,559 | 7,556 | 65.4% | 2,844 | 24.6% | 1,054 | 9.1% | 105 | 0.9% | 0 | 0.0% |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 65+ Years)* | 6,069 | 3,837 | 63.2% | 1,842 | 30.4% | 361 | 5.9% | 29 | 0.5% | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 65+ Years)* | 2,934 | 1,438 | 49.0% | 923 | 31.5% | 557 | 19.0% | 16 | 0.5% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 65+ Years)* | 15,437 | 11,394 | 73.8% | 2,973 | 19.3% | 912 | 5.9% | ***** | ***** | ***** | ***** |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 65+ Years)* | 14,215 | 11,031 | 77.6% | 2,377 | 16.7% | 714 | 5.0% | ***** | ***** | ***** | ***** |
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 65+ Years)* | 2,869 | 1,369 | 47.7% | 1,050 | 36.6% | 357 | 12.4% | ***** | ***** | ***** | ***** |

**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Amphetamine/Dextroamphetamine Combination Products, Any (Patients of Age 18+ Years)* | 140,144 | 96,408 | 68.8% | 35,923 | 25.6% | 7,160 | 5.1% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Immediate Release (Patients of Age 18+ Years)* | 112,217 | 76,762 | 68.4% | 27,314 | 24.3% | 7,468 | 6.7% | ***** | ***** | ***** | ***** |
| *Amphetamine/Dextroamphetamine Combination Products, Extended Release (Patients of Age 18+ Years)* | 96,287 | 67,604 | 70.2% | 25,811 | 26.8% | 2,761 | 2.9% | 111 | 0.1% | 0 | 0.0% |
| *Lisdexamfetamine, Extended Release (Patients of Age 18+ Years)* | 75,356 | 38,950 | 51.7% | 26,541 | 35.2% | 9,671 | 12.8% | 194 | 0.3% | 0 | 0.0% |
| *Methylphenidate Single-entity Products, Any (Patients of Age 18+ Years)* | 79,436 | 42,577 | 53.6% | 27,989 | 35.2% | 7,562 | 9.5% | ***** | ***** | ***** | ***** |
| *Methylphenidate Single-entity Products, Immediate Release (Patients of Age 18+ Years)* | 51,291 | 36,607 | 71.4% | 11,170 | 21.8% | 3,209 | 6.3% | ***** | ***** | ***** | ***** |

**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, 2022 to March 31, 2023**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Methylphenidate Single-entity Products, Extended Release (Patients of Age 18+ Years)* | 43,285 | 16,732 | 38.7% | 20,160 | 46.6% | 5,298 | 12.2% | ***** | ***** | ***** | ***** |

[1]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[1] |
|---|---|---|
| DP01 | 01/01/2000 | 03/31/2023 |
| DP02 | 01/01/2007 | 03/31/2023 |
| DP03 | 01/01/2000 | 03/31/2023 |
| DP04 | 01/01/2006 | 03/31/2023 |
| DP05 | 01/01/2000 | 03/31/2023 |
| DP06 | 01/01/2008 | 03/31/2023 |
| DP07 | 01/01/2004 | 03/31/2023 |
| DP08 | 01/01/2008 | 03/31/2023 |

[1]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 |
|---|---|
| **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 |
| **Envelope macro:** | *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). |
| **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**

| | 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**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Exposure** | | | | | | | | |
| 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+ |

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| | 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**

| | 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 | 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+ |

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| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Exposure | | | | | | | | | | | |
| **5-17 Years** | 34 | 5-17 years | Methylphenidate Single-entity Products, Immediate Release | *Include all valid exposure episodes during query period;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*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;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*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;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*Episode end date | 1-20 21-40 41-60 61+ |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **18-25 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**

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Exposure** | | | | | | | | |
| **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+ |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **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+ |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **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+ |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **Exposure** | | | | | | | | | | | |
| **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+ |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | **Exposure** | |
| **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**

| | Scenario | Age Restriction | Exposure 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **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+ |

| | 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**

| | 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** | 61 | 65+ Years | Methylphenidate Single-entity Products, Any | *Include all valid exposure episodes during query period;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*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;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*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;<br>--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;<br>*DP end date;<br>*Query end date;<br>*Enrollment end date;<br>*Episode end date | 1-20 21-40 41-60 61+ |

**Appendix C. Specifications Defining Parameters for this Request**

| | Scenario | Age Restriction | Exposure | | | | | | | | | | | Current Filled Daily Dose Summary (Mean) Category |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 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: | |
| 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+ |

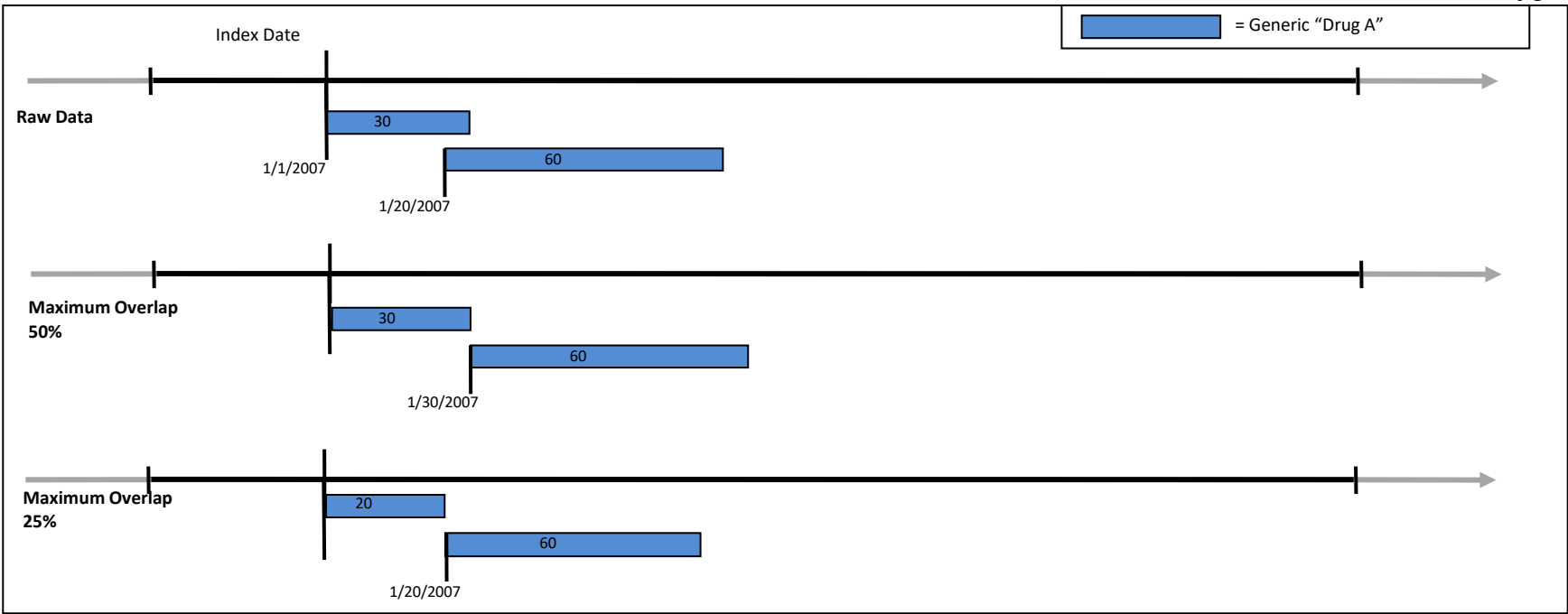| | Scenario | Age Restriction | Index Exposure | Cohort Definition | Incident Exposure Washout Period | Exclude Evidence of Days Supply if Exposure Washout Includes Dispensings | Treatment Episode Gap | Treatment Episode Extension | Care Setting | Principal Diagnosis Position | Create Baseline Table? | Forced Supply to Attach to Dispensings | Censor Treatment Episode at Evidence of: | Current Filled Daily Dose Summary (Mean) Category |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18+ Years | 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**

| | Scenario | Age Restriction | Exposure | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 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 | 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.<br><br>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<br>API cohorts: 7-100 | Exposure cohorts: Does not consider amount supplied values of 0 or less<br>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**

Type 5 design diagram