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Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020

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Why OIG Did This Review

The ACA requires OIG to conduct a study of the extent to which formularies used by Medicare Part D plans include drugs commonly used by full-benefit dual eligible individuals (i.e., individuals who are eligible for both Medicare and full Medicaid benefits). These individuals generally get drug coverage through Medicare Part D. Pursuant to the ACA, OIG must annually issue a report with recommendations as appropriate. This is the tenth report OIG has produced to meet this mandate.

How OIG Did This Review

For this report, we determined whether the 448 unique formularies used by the 4,610 Part D plans operating in 2020 cover the 200 drugs most commonly used by dual eligibles. We also determined the extent to which plan formularies applied utilization management tools to those commonly used drugs. To create the list of the 200 drugs most commonly used by dual eligibles, we used data from the 2017 Medicare Current Beneficiary Survey—the most recent data available at the time of our study. Of the top 200 drugs, 195 are eligible for Part D prescription drug coverage, 2 are excluded from coverage, 1 is no longer offered as a prescription, and 1 is a medical supply item covered by Part D. One additional drug is eligible for Part D prescription drug coverage. However, we did not include it in our analysis because we could not confidently project the use of this drug to the entire dual eligible population.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020

Key Takeaway

Overall, we found that the rate of Part D plan formularies' inclusion of the drugs commonly used by dual eligibles is high, with some variation. Because some variation exists in formularies' inclusion and utilization management of these drugs, some dual eligibles may need to make additional efforts (e.g., appeal coverage decisions) to access the drugs they take.

What OIG Found

Overall, we found that the rate of Part D plan formularies' inclusion of the 195 drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. On average, Part D plan formularies include 97 percent of the 195 commonly used drugs. In addition, 75 percent of the commonly used drugs are included by all Part D plan formularies. These results are largely unchanged from the Office of Inspector General's (OIG's) findings for formularies reported in the mandated annual report from 2019, as well as from the findings in our reports from 2011 through 2018.

We also found that the percentage of drugs to which plan formularies applied utilization management tools increased slightly between 2019 and 2020. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2020, an increase of 1 percentage point from 2019.

What OIG Concludes

Inclusion rates for the 195 drugs commonly used by dual eligibles are largely unchanged from the inclusion rates listed in our previous reports. Part D formularies include roughly the same high percentage of these commonly used drugs in 2020 as they did in 2019.

As mandated by the Patient Protection and Affordable Care Act (ACA), OIG will continue to monitor and produce annual reports on the extent to which Part D plan formularies cover drugs that dual eligibles commonly use. In addition, OIG will continue to monitor Part D plan formularies' application of utilization management tools to these drugs. OIG has no recommendations at this time.

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BACKGROUND

Objectives

1. To determine the extent to which Part D plan formularies cover the drugs commonly used by dual eligibles.
 2. To determine the extent to which Part D plan formularies applied utilization management tools to the drugs commonly used by dual eligibles.
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Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), comprehensive prescription drug coverage under Medicare Part D is available to all Medicare beneficiaries through prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs), hereinafter referred to collectively as Part D plans.¹

For beneficiaries who are eligible for both Medicare and Medicaid (hereinafter referred to as dual eligibles), Medicare subsidizes Part D plan premiums, deductibles, and other cost sharing up to a determined premium benchmark that varies by region. If dual eligibles enroll in Part D plans with premiums higher than the regional benchmark, the dual eligibles are responsible for paying the premium amounts above that benchmark.

To control costs and ensure the safe use of drugs, Part D plans are allowed to establish formularies from which they may omit certain drugs from prescription coverage and are allowed to control drug utilization through utilization management tools.² These tools include prior authorization, quantity limits, and step therapy.³ In addition, Centers for Medicare & Medicaid Services (CMS) authorized Part D plans to

¹ MMA, P.L. No. 108-173 (enacted Dec. 8, 2003), § 101, Social Security Act § 1860D-1(a).

² A formulary is a list of drugs covered by a Part D plan. Part D plans can exclude certain drugs from their formularies and can control utilization for formulary-included drugs within certain parameters. Social Security Act § 1860D-4(b) and (c).

³ Prior authorization—often required for very expensive drugs—requires that physicians obtain approval from Part D plans to prescribe a specific drug. Quantity limits are intended to ensure that beneficiaries receive the proper dose and recommended duration of drug therapy. Step therapy is the practice of beginning drug therapy for a medical condition with the drug therapy that is the most cost-effective or safest and progressing if necessary to more costly or riskier drug therapy.

use indication-based formulary design beginning in contract year 2020 to further control drug utilization.⁴

CMS annually reviews Part D plan formularies to ensure that they include a range of drugs in a broad distribution of therapeutic categories or classes. CMS also assesses the utilization management tools present in each formulary.

The Medicare Prescription Drug Benefit

Beginning in 2006, the MMA made comprehensive prescription drug coverage under Medicare Part D available to all Medicare beneficiaries.⁵ Medicare beneficiaries generally have the option to enroll in a PDP and receive all other Medicare benefits on a fee-for-service basis, or to enroll in an MA-PD and receive all of their Medicare benefits, including prescription drug coverage, through managed care.⁶ As of January 2020, approximately 47 million of the 62.2 million Medicare beneficiaries were enrolled in a Part D plan.

Part D plans are administered by private companies—known as “plan sponsors”—that contract with CMS to offer prescription drug coverage in one or more PDP or MA-PD regions. CMS has designated 34 PDP regions and 26 MA-PD regions. In 2020, plan sponsors offer 4,610 unique Part D plans, with many plan sponsors offering multiple Part D plans.

Dual Eligibles Under Medicare Part D

Approximately 12.2 million Medicare beneficiaries are dual eligibles. For about 8.7 million dual eligibles, referred to as “full-benefit dual eligibles,” Medicaid provides full Medicaid benefits, including Medicaid-covered services, and may also assist beneficiaries with premiums and cost sharing for Medicare fee-for-service or Medicare managed care. For other dual eligibles, Medicaid does not provide Medicaid-covered services, but provides assistance with beneficiaries’ Medicare premiums or cost sharing, depending on their level of income and assets.⁷

Dual eligibles are a particularly vulnerable population. Overall, most dual eligibles have very low incomes—86 percent have annual incomes below 150 percent of the

⁴ Indication-based formulary design allows Part D plans to limit certain drugs to specific indications. However, if a plan limits coverage of a drug to a specific indication, the plan must ensure that there is a therapeutically similar drug for other indications.

⁵ MMA, P.L. No. 108-173 (enacted Dec. 8, 2003), § 101, Social Security Act § 1860D-1(a).

⁶ CMS, *Prescription Drug Benefit Manual (PDBM)*, ch. 1, § 10.1.

⁷ Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission, *Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid—January 2018*. Accessed at <https://www.macpac.gov/wp-content/uploads/2017/01/January-2018-Beneficiaries-Dually-Eligible-for-Medicare-and-Medicaid-Data-Book.pdf> on April 9, 2019.

Federal poverty level, compared with 22 percent of all other Medicare beneficiaries. Additionally, dual eligibles are in worse health than the average Medicare beneficiary—half are in fair or poor health, more than twice the rate of others in Medicare.⁸ Because of their self-reported health needs, dual eligibles may use more prescription drugs and health care services in general than other Medicare beneficiaries.

Until December 31, 2005, dual eligibles received outpatient prescription drug benefits through Medicaid. In January 2006, Medicare began covering outpatient prescription drugs for dual eligibles through Part D plans.⁹

Medicare covers Part D plan premiums for dual eligibles up to a set benchmark. The benchmark is a statutorily defined amount that is based on the average premium amounts for Part D plans for each region.^{10, 11} If dual eligibles enroll in Part D plans with premiums higher than the regional benchmark, the dual eligibles are responsible for paying the premium amounts above that benchmark.¹²

Dual eligibles' assignment to Part D plans

When individuals become eligible for both Medicare and Medicaid, CMS randomly assigns those individuals to PDPs unless they have elected a specific Part D plan or have opted out of Part D prescription drug coverage.¹³ The PDPs to which CMS assigns dual eligibles must meet certain requirements, such as having a premium at or below the regional benchmark amount and offering basic prescription drug coverage (or equivalent).¹⁴ Basic prescription drug coverage is defined in terms of benefit structure (initial coverage, coverage gap, and catastrophic coverage) and costs (initial deductible and coinsurance).

Given that assignment is done on a random basis, dual eligibles may be enrolled in PDPs that do not cover the specific drugs the dual eligibles use, or that only cover the

⁸ Kaiser Family Foundation, *Medicare's Role for Dual Eligible Beneficiaries*. Accessed at <http://www.kff.org/medicare/upload/8138-02.pdf> on March 19, 2019.

⁹ MMA, P.L. No. 108-173 (enacted Dec. 8, 2003), § 101, Social Security Act § 1860D-1(a).

¹⁰ Social Security Act § 1860D-14(b); 42 CFR § 423.780(b)(2)(i).

¹¹ Dual eligibles residing in territories are not eligible to receive cost sharing assistance from Medicare. Consequently, there are no benchmarks for Part D plans offered in the territories. Social Security Act § 1860D-14(a)(3)(F).

¹² The ACA established a "de minimus" premium policy whereby a Part D plan may elect to charge dual eligibles the benchmark premium amount if the Part D plan's basic premium exceeds the regional benchmark by a de minimus amount. ACA, P.L. No. 111-148 (enacted Mar. 23, 2010), § 3303, Social Security Act § 1860D 14(a)(5). For 2019, CMS set the de minimis amount at \$2 above the regional benchmark.

¹³ CMS, *PDBM*, ch. 3, § 40.1.4.

¹⁴ *Ibid.*

specific drugs the dual eligibles use for a limited set of indications. However, unlike the general Medicare population, dual eligibles have up to three special election periods during the first 9 months of the year to find plans that cover the prescription drugs the dual eligibles require and switch plans if needed.¹⁵ When they use a special election period to change plans, dual eligibles' prescription drug coverage under the new Part D plan becomes effective at the beginning of the following month.

CMS annually reassigns some dual eligibles to new PDPs if the dual eligibles' current PDPs will have premiums above the regional benchmark premium for the following year.¹⁶ For dual eligibles who were randomly assigned to their current PDPs, CMS chooses new PDPs that will have premiums at or below the regional benchmark premium.¹⁷ For 2020, CMS reported reassigning approximately 433,473 Medicare beneficiaries—including, but not exclusively, dual eligibles—because of premium increases.

Part D Prescription Drug Coverage

Under Part D, plans can establish formularies from which they may exclude drugs and control drug utilization within certain parameters. These parameters are intended to balance Medicare beneficiaries' needs for adequate prescription drug coverage with Part D plan sponsors' needs to contain costs. Generally, a formulary must include at least two drugs in each therapeutic category or class.^{18, 19} In addition, Part D plans must include drugs covered by Part D in certain categories and classes.²⁰

Starting in 2020, Part D plans are permitted to use indication-based formulary design. Plans that use this type of design limit formulary coverage of drugs to certain indications, or uses approved by the Food and Drug Administration (FDA). However, for each drug limited to certain indications, these plans must ensure that their

¹⁵ 83 Fed. Reg. 16440, 16514–19 (Apr. 16, 2018). In general, Medicare beneficiaries can switch Part D plans only once a year during a defined enrollment period. In previous years, dual eligibles could switch Part D plans monthly to find plans that covered the drugs they required.

¹⁶ CMS, *PDBM*, ch. 3, § 40.1.5. CMS also reassigns beneficiaries who were assigned to plans that were terminated and will not be offered in the following year. For 2020, no beneficiaries were reassigned because of terminated plans.

¹⁷ *Ibid.*

¹⁸ CMS, *PDBM*, ch. 6, § 30.2.1.

¹⁹ Therapeutic categories or classes classify drugs according to their most common intended uses. For example, cardiovascular agents compose a therapeutic class intended to affect the rate or intensity of cardiac contraction, blood vessel diameter, or blood volume.

²⁰ Social Security Act § 1860D-4(b)(3)(G). Current Part D policy requires sponsors to include in their formularies all drugs in six categories or classes, except in limited circumstances: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. CMS, *PDBM*, ch. 6, § 30.2.5.

formularies also cover at least one therapeutically similar drug for the nonformulary indications.²¹

Part D plans may also control drug utilization by applying utilization management tools. These tools include the following: requiring prior authorization to obtain drugs that are on plan formularies; establishing quantity limits; and requiring step therapy. Utilization management tools can help Part D plans and the Part D program limit the cost of prescription drug coverage by placing restrictions on the use of certain drugs.

In addition to these drug coverage decisions that Part D plans make regarding individual formularies, certain categories of drugs are excluded from Medicare Part D prescription drug coverage as mandated by the MMA.²² For example, prescription vitamins, prescription mineral products, and nonprescription drugs are excluded from Part D prescription drug coverage.²³

Until 2013, barbiturates and benzodiazepines were excluded from Part D prescription drug coverage. However, the Patient Protection and Affordable Care Act (ACA) reversed this exclusion, removing these two drug types from the list of drug classes ineligible for such coverage.^{24, 25}

CMS Efforts To Ensure Prescription Drug Coverage

Formulary review

CMS annually reviews Part D plan formularies to ensure that they include a range of drugs in a broad distribution of therapeutic categories or classes, as well as all drugs in specified therapeutic categories or classes.²⁶ During this review, CMS analyzes formularies' coverage of the drug classes most commonly prescribed for the Medicare population. CMS intends for Part D plans to cover the most widely used medications, or therapeutically alternative medications (i.e., drugs from the same therapeutic

²¹ CMS, *Indication-Based Formulary Design Beginning in Contract Year (CY) 2020*. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf> on March 22, 2019.

²² MMA, P.L. No. 108-173 (enacted Dec. 8, 2003), § 101, Social Security Act § 1860D-2(e).

²³ Social Security Act § 1860D-2(e)(2), 1927(d)(2).

²⁴ ACA, P.L. No. 111-148 (enacted Mar. 23, 2010), § 2502, Social Security Act § 1927(d).

²⁵ CMS, *Transition to Part D Coverage of Benzodiazepines and Barbiturates Beginning in 2013*. Accessed at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/BenzoandBarbituratesin2013.pdf> on March 20, 2019.

²⁶ CMS, *PDBM*, ch. 6, § 30.2.7.

category or class), for the most common conditions. CMS uses Part D prescription drug data to identify the most commonly prescribed classes of drugs.²⁷

CMS also assesses each formulary's utilization management tools to ensure consistency with current industry standards and with standards that are widely used with drugs for the elderly and people with disabilities.^{28, 29}

Exceptions and appeals process

CMS has implemented an exceptions and appeals process whereby beneficiaries can request coverage of nonformulary drugs or exceptions to utilization management tools that apply to formulary drugs. When a Part D plan receives a prescriber's statement supporting an exception request, the plan must notify the beneficiary of its determination within 72 hours or, for expedited requests, within 24 hours.³⁰ If the beneficiary's plan makes an adverse determination, the beneficiary has the right to appeal.³¹ If the plan continues to deny the beneficiary's request, the beneficiary has additional appeal rights and may continue to appeal until those rights are exhausted. Alternatively, the beneficiary can work with his or her prescriber to determine whether there is an appropriate, therapeutically equivalent alternative drug on the plan's formulary.

Transitioning new enrollees to Part D

CMS requires that Part D plans establish a transition process for new enrollees (including dual eligibles) who are transitioning to their respective Part D plans either from different Part D plans or from other prescription drug coverage. During Medicare beneficiaries' first 90 days under a new Part D plan, the new plan must provide one temporary fill of a prescription when the beneficiary requests either a drug that is not in the plan's formulary or a drug that requires prior authorization or step therapy under the formulary's utilization management tools.³² The temporary fill accommodates beneficiaries' immediate drug needs the first time the beneficiary attempts to fill a prescription. The transition period also allows the beneficiary time to work with his or her prescribing physician(s) to obtain prescriptions for therapeutically alternative drugs or to request a formulary exception from the Part D plan.

²⁷ Ibid.

²⁸ CMS, *PDBM*, ch. 6, § 30.2.2.

²⁹ CMS, *PDBM*, ch. 6, § 30.2.7.

³⁰ CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, § 40.5.3.

³¹ CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, § 50.

³² CMS, *PDBM*, ch. 6, § 30.4.4.

Related OIG Work

In 2006, the Office of Inspector General (OIG) published a report assessing the extent to which PDP formularies included drugs commonly used by dual eligibles under Medicaid. The study found that PDP formularies included between 76 and 100 percent of the 178 drugs commonly used by dual eligibles under Medicaid prior to the implementation of Part D. Approximately half of the 178 commonly used drugs were covered by all formularies.³³

In 2011, OIG issued the first annual mandated report examining dual eligibles' access to drugs under Medicare Part D. (See Appendix A for the statutory mandate.) We have released an annual mandated report each year since then. (See Appendix B for a list of these reports.) The current report is the tenth report released.

Methodology

As mandated in the ACA, this study assessed the extent to which drugs commonly used by dual eligibles are included by Part D plan formularies. To make this assessment, we evaluated formularies for Part D plans operating in 2020. As part of our assessment, we included dual eligibles' enrollment data from January 2020, the most recent enrollment data available from CMS at the time of our study. We also compared the results of our 2020 study with those of our 2019 study.³⁴

The ACA did not define which drugs commonly used by dual eligibles we should review. We defined drugs commonly used by dual eligibles as the 200 drugs with the highest utilization by dual eligibles as reported in the Medicare Current Beneficiary Survey (MCBS)—i.e., the 2017 MCBS. We used the MCBS because it contains drugs that dual eligibles received through multiple sources (e.g., Part D, Medicaid, and the Department of Veterans Affairs), and, as such, it provides a comprehensive picture of drug utilization. Of the 200 highest-utilization drugs that we identified using the MCBS, 195 are eligible for coverage under Part D. In this report, we refer to these 195 Part D-eligible, high-utilization drugs as “commonly used drugs.”

For each study, OIG went beyond the ACA's mandate by reviewing drug coverage for all dual eligibles under Medicare Part D, rather than only for full-benefit dual eligibles. With the data available for this study, we could not confidently identify and segregate full-benefit dual eligibles—and, thus, the drugs they used—from the total population of dual eligibles.

In the current (2020) report and the previous seven reports, we have also gone beyond the ACA's mandate by examining the utilization management tools that Part D plan formularies apply to the drugs commonly used by dual eligibles. These tools

³³ OIG, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090, January 2006.

³⁴ OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2019*, OEI-05-19-00220, June 2019.

may affect dual eligibles' access, even in cases in which formularies include the commonly used drugs. Analyzing the extent to which Part D plan formularies apply these tools to drugs commonly used by dual eligibles allows us to provide a comprehensive picture of Part D plan formularies' coverage of, and dual eligibles' access to, those drugs.

Data sources

MCBS. We used the 2017 MCBS Cost and Use data to create a list of the 200 drugs with the highest utilization by dual eligibles. The MCBS Cost and Use data contain information on hospitals, physicians, prescription drug costs, and prescription drug utilization. The 2017 MCBS Cost and Use data were the most recent data available at the time of our study. Historically, the list of the 200 drugs with the highest utilization by dual eligibles has remained largely unchanged from year to year. The list for 2020 overlapped by 91 percent with the list for 2019, which in turn overlapped by 88 percent with the list for 2018.³⁵

The MCBS is a continuous, multipurpose survey that CMS conducts of a representative national sample of the Medicare population, including dual eligibles. Sampled Medicare beneficiaries were interviewed three times per year and asked what drugs they were taking and whether they had started taking any new drugs since the previous interview. The MCBS also includes Part D prescription drug events for surveyed Medicare beneficiaries. In 2016, the MCBS surveyed 15,207 Medicare beneficiaries, of whom 2,224 were dual eligibles who had used prescription drugs during the year (out of 3,790 dual eligible survey respondents).

First DataBank National Drug Data File. We used the February 2020 First DataBank National Drug Data File to identify the drug product information for the 200 drugs with the highest utilization by dual eligibles. The National Drug Data File is a database that contains information—such as drug name, therapeutic category or class, and the unique combination of active ingredients—for each drug as defined by a National Drug Code (NDC).³⁶

Part D plan data. In January 2020, we collected from CMS the formulary data and the plan data for Part D plans operating in 2020. The formulary data includes Part D plans' formularies and utilization management tools for plans operating in 2020. In 2020, there are 448 unique formularies offered by 4,610 Part D plans. The plan data provides information such as the State in which a Part D plan is offered, whether the Part D plan is a PDP or an MA-PD, and whether the Part D plan premium is below the regional benchmark.

We also collected 2020 enrollment data for Part D plans. These data provide the number of dual eligibles enrolled in each Part D plan as of January 2020.

³⁵ In 2019, we used 2016 data. In 2018, we used 2013 data. In 2017, we used 2012 data.

³⁶ An NDC is a three-part universal identifier that specifies the drug manufacturer's name, the drug form and strength, and the package size.

Determining the most commonly used drugs

To determine the drugs most commonly used by dual eligibles, we took the following steps:

1. We created a list of all drugs reported by dual eligibles surveyed in the 2017 MCBS. We excluded respondents from territories because they are not eligible to receive cost sharing assistance under Part D. The MCBS listed 150,560 drug events for 2,224 dual eligibles who did not reside in territories.³⁷
2. We collapsed this list to a list of drugs based on their active ingredients using the Ingredient List Identifier located in First DataBank's National Drug Data File. For example, a multiple source drug such as fluoxetine hydrochloride (the active ingredient for the brand-name drug Prozac) has only one entry on our list, covering all strengths of both the brand-name drug Prozac and the available generic versions of fluoxetine hydrochloride. From this point forward, unless otherwise stated, we will use the term "drug" to refer to any drug in the same Ingredient List Identifier category, and the term "unique drug" to refer to an NDC corresponding to a drug, as a given drug can have multiple NDCs. This process left 150,560 drug events associated with 858 drugs.
3. We ranked the 858 drugs by frequency of utilization, weighting the drug-event information from MCBS by sample weight.
4. We selected the 200 drugs with the highest utilization by dual eligibles. For a full list of the top 200 drugs, see Appendix C.
5. We removed all drugs not covered under Part D. Of the 200 drugs with the highest utilization, 195 are eligible under Part D. Two fall into a drug category excluded under Part D. (For details on the two drugs excluded under Part D, see Appendix D.) One drug is no longer offered as a prescription. An additional drug is eligible for Part D prescription drug coverage. However, we did not include it in our analysis because—although it is eligible under Part D—Medicare considers it to be a medical supply item. We did not include another drug in our analysis because we could not confidently project the use of this drug to the entire dual eligible population.

Formulary analysis

We analyzed the 448 unique Part D plan formularies to determine their rates of inclusion of the 195 drugs commonly used by dual eligibles. We counted a drug as included in a Part D plan's formulary if the formulary included the active ingredient.

³⁷ For the purposes of this report, a drug event is an MCBS survey response indicating that the responding beneficiary took a specific drug at least once in 2017. For example, one MCBS survey respondent reported taking alprazolam 11 times in 2017. We counted this beneficiary/drug combination as 11 drug events.

Low rates of inclusion by formularies. We determined which of the 195 commonly used drugs had low rates of inclusion by formularies by counting how many of the 448 formularies covered each drug. We considered a drug to have a low rate of inclusion if it was included by 75 percent or less of formularies. For such drugs, we counted the number of drugs (if any) that each formulary covered in the same therapeutic category or class.

We conducted this analysis to ensure that dual eligibles have access to therapeutically similar drugs. We also conducted additional research to identify potential reasons why some of the 195 commonly used drugs were included by 75 percent or less of formularies.

Utilization management tools. We determined the extent to which Part D plans apply utilization management tools to the 195 drugs that we reviewed. The tools that we reviewed are prior authorization, quantity limits, and step therapy.

To determine the extent to which Part D plan formularies applied utilization management tools to the 195 commonly used drugs, we conducted an analysis of the NDCs that correspond to the commonly used drugs. Part D plan formularies do not apply utilization management tools at the active ingredient level. Rather, Part D plan formularies apply utilization management tools at a more specific level that identifies whether a drug is brand-name or generic and its dosage form, strength, and route of administration, irrespective of package size. To conduct this analysis, we determined the NDCs (unique drugs) associated with each of the 195 commonly used drugs that are on each Part D formulary. We then calculated the percentage of unique drugs to which each Part D plan formulary applies utilization management tools.

Enrollment analysis

We weighted the formulary analysis by dual eligible enrollment and weighted the analysis of utilization management tools by both dual eligible enrollment and Medicare enrollment. To do this, we applied enrollment data from January 2020 to Part D plans available in 2020.

Data limitations

We did not assess individual dual eligibles' prescription drug use or whether individual dual eligibles are enrolled in Part D plans that include the specific drugs that each individual uses. Because we developed our list of commonly used drugs by using a sample of dual eligibles who responded to the MCBS, a particular dual eligible might not use any of the drugs on our list. However, the drugs most commonly used by dual eligible participants in the 2017 MCBS survey account for 89 percent of all prescriptions dispensed to the dual eligible respondents in the 2017 MCBS.

We also did not assess the impact of indication-based formulary design on dual eligibles' access to prescription drugs. The formulary data we used for this analysis does not include sufficient details for us to determine which drugs were covered for

only a limited number of indications. As a result, some beneficiaries included in our analysis may not be able to access all commonly used drugs covered by their Part D plans because certain drugs are not available for all indications.

Standards

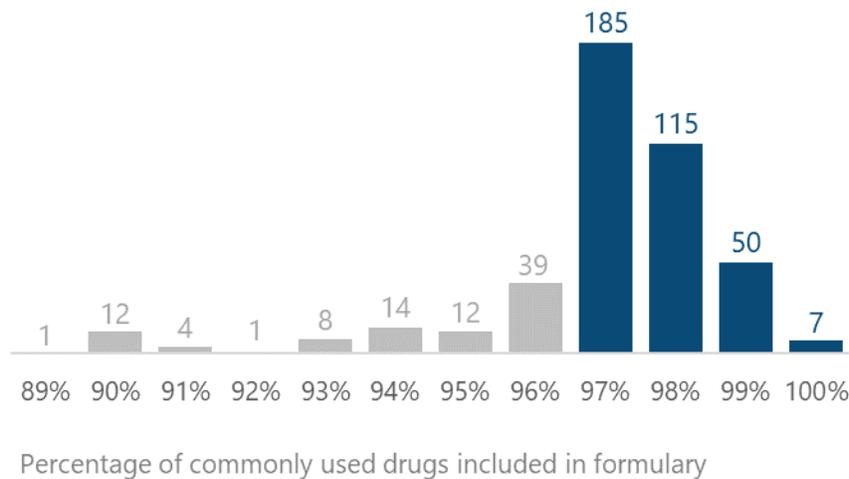
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Part D plan formularies include between 89 and 100 percent of the drugs commonly used by dual eligibles

On average, Part D plan formularies include 97 percent of the drugs commonly used by dual eligibles. Of the 448 unique formularies used by Part D plans in 2020, 7 formularies include 100 percent of the commonly used drugs. At the other end of the inclusion range, one formulary includes 89 percent of the commonly used drugs. Exhibit 1 provides a breakdown of the formularies' inclusion rates for the drugs most commonly used by dual eligibles. CMS generally requires Part D plan formularies to include at least two drugs—rather than all drugs—in each therapeutic category or class. Therefore, Part D plan formularies may still meet CMS's formulary requirements, even if the formularies do not include all of the drugs we identified as commonly used by dual eligibles.

Exhibit 1: About 80 percent of the 448 Part D plan formularies cover at least 97 percent of the drugs commonly used by dual eligibles.



Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2020.

Part D plan formularies' rates of inclusion of the drugs commonly used by dual eligibles in 2020 did not change from the rates in 2019. The average rate of inclusion remained at 97 percent between 2019 and 2020. The range of inclusion rates also remained the same between 2019 and 2020; rate of inclusion ranged from 89 to 100 percent in both 2019 and 2020.

Nationally, PDP and MA-PD formularies have similar rates of inclusion of the drugs commonly used by dual eligibles, averaging 96 percent and 97 percent, respectively. For PDP formularies, the rates of inclusion range from 89 to 100 percent. For MA-PD formularies, the rates of inclusion range from 90 to 100 percent. Eight formularies—

2 percent of the 448 unique formularies used by Part D plans in 2020—are offered by both PDPs and MA-PDs.

Regionally, all dual eligibles have the choice of a Part D plan that includes at least 98 percent of the commonly used drugs. Every PDP region has a plan that includes at least 99 percent of the commonly used drugs, while every MA-PD region has a plan that includes at least 98 percent of the commonly used drugs. Appendix E provides a breakdown of formularies' rates of inclusion of the drugs by PDP and MA-PD region.

On average, formularies for Part D plans with premiums below the regional benchmark include 97 percent of the drugs commonly used by dual eligibles

The percentage of drugs included by Part D plans with premiums below the regional benchmark is important because dual eligibles are automatically enrolled in, or annually reassigned to, such plans. For drugs commonly used by dual eligibles, formularies for such plans have rates of inclusion that range from 89 percent to 100 percent. Approximately 82 percent of dual eligibles are enrolled in Part D plans with premiums below the regional benchmark.

Most dual eligibles are enrolled in Part D plans that include at least 90 percent of the drugs commonly used by dual eligibles

Of the approximately 11 million dual eligibles enrolled in Part D plans, approximately 95 percent are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. Five percent of dual eligibles are enrolled in Part D plans that use formularies that include less than 90 percent of these drugs. Exhibit 2 provides a breakdown of dual eligibles' enrollment in Part D plans by the rates at which the plans' formularies include the commonly used drugs.

Exhibit 2: Most dual eligibles are enrolled in Part D plans that include at least 90 percent of the drugs commonly used by dual eligibles.

Part D Plans With Formularies That Include:	Number of Dual Eligibles Enrolled	Percentage of Dual Eligibles Enrolled
100% of commonly used drugs	8,850	0.1%
95% to 99% of commonly used drugs	9,493,260	86.7%
90% to 94% of commonly used drugs	883,689	8.1%
86% to 89% of commonly used drugs	568,034	5.2%
Total	10,953,833	100%*

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles and dual eligibles' enrollment, 2020.

*Percentages do not add up to 100 percent due to rounding.

The percentage of dual eligibles enrolled in Part D plans that include at least 90 percent of the drugs commonly used by dual eligibles increased slightly from 94 percent in 2019 to 95 percent in 2020.

Seventy-five percent of the drugs commonly used by dual eligibles are included in all Part D plan formularies

Because most of the commonly used drugs are included in a large percentage of formularies, dual eligibles can be confident that regardless of the Part D plan in which they are enrolled, the plan’s formulary will include many of these drugs. By drug, inclusion in formularies ranges from 46 percent to 100 percent. At one end of the range, there is a drug that is included in 46 percent of Part D plan formularies, and, at the other end, 146 drugs are included in all plan formularies. The average rate of inclusion in formularies is 97 percent. Exhibit 3 shows the rates at which formularies include the 195 drugs. Appendix C lists the 195 drugs and the rates at which formularies include them.

Exhibit 3: Nearly three quarters of the drugs most commonly used by dual eligibles are included in all Part D plan formularies.

Percentage of the 448 Formularies	Percentage of the 195 Commonly Used Drugs Included in Formularies
100%	75% (146 drugs)
85% to 99%	17% (34 drugs)
76% to 84%	4% (7 drugs)
46% to 75%	4% (8 drugs)
Total	100% (195 drugs)

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2020.

The rates at which formularies include the drugs commonly used by dual eligibles increased in 2020. Formularies included 75 percent of the commonly used drugs in 2020, compared to 72 percent in 2019.

Part D plan formularies include certain drugs less frequently than others

Of the commonly used drugs, 4 percent (eight drugs) are included by less than 75 percent of Part D plan formularies. Exhibit 4 provides the percentage of formularies covering each of these eight drugs.

The drugs that make up this group include both brand-name and generic drugs and are used to treat a variety of primary indications. Seven of the eight drugs are brand-name drugs, which are typically more costly than generic drugs. As for the primary indications, four of the eight drugs are used for diabetes therapy, and the remaining four drugs treat a variety of conditions, including asthma and chronic obstructive pulmonary disorder.

Exhibit 4: Drugs included by less than 75 percent of Part D plan formularies were most frequently used for diabetes therapy.

Generic Name of Drug	Primary Indication(s)	Rate of Inclusion by Formularies
Insulin detemir	Diabetes	74%
Tiotropium bromide*	Chronic obstructive pulmonary disease	72%
Insulin aspart*	Diabetes	71%
Budesonide/formoterol fumarate	Asthma	70%
Canagliflozin*	Diabetes	58%
Solifenacin succinate*	Overactive bladder, incontinence	54%
Dexlansoprazole*	Gastroesophageal reflux disease	53%
Insulin lispro*	Diabetes	46%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2020.

* These drugs also had low rates of formulary inclusion in 2019.

Although Part D formularies frequently omit these eight drugs, they all cover other drugs in the same respective therapeutic classes. For each of these 8 drugs, 100 percent of formularies cover at least 1 drug in the same therapeutic class that is also on the list of 195 drugs commonly used by dual eligibles.

The number of drugs included by less than 75 percent of formularies remained the same in 2019 and 2020—with eight drugs both years. There are six drugs with low inclusion rates in 2020 that were also on the list of commonly used drugs with low inclusion rates in our 2019 report; we note these six drugs with asterisks in Exhibit 4 (above). Five of these six drugs were also on the list of drugs with low inclusion rates in our 2018 report.

There are multiple potential reasons why a commonly used drug might be included by less than 75 percent of formularies:

- In the case of two of the eight drugs—insulin lispro and insulin aspart—FDA has issued MedWatch Safety Alerts because of the drugs’ delivery systems, which can vary and sometimes result in situations in which patients do not get the insulin they think they injected.^{38, 39}
- The American Geriatrics Society cautions against certain uses of proton pump inhibitor drugs and drugs with strong anticholinergic properties. Dexamprazole is a proton pump inhibitor drug, and solifenacin succinate has strong anticholinergic properties.⁴⁰

If a formulary does not include a particular drug, a dual eligible has three options, all of which require taking additional action:

- Obtaining a therapeutically equivalent alternative drug that is included by the plan’s formulary. (This option necessitates getting a new prescription from the dual eligible’s doctor.)
- Going through an appeals process to obtain coverage of a nonformulary drug by submitting a statement of medical necessity from the dual eligible’s physician.⁴¹
- Switching to a Part D plan with a formulary that does include the drug. Dual eligibles can make such a switch once per calendar quarter during the first 9 months of the year, with the new coverage becoming effective the following month.⁴²

The percentage of commonly used drugs to which plan formularies applied utilization management tools increased slightly between 2019 and 2020

For the unique drugs that compose the list of commonly used drugs, the percentage to which Part D plan formularies applied utilization management tools increased slightly from 28 percent in 2019 to 29 percent in 2020. Plans with premiums below the regional benchmarks used utilization management tools less frequently than all plans; formularies of these plans used utilization management tools for 24 percent of their drugs. See Exhibit 5 for a breakdown of the 2019 percentage of unique drugs to

³⁸ FDA, *Caution When Using Pen Needles To Inject Medicines: FDA Safety Communication*. Accessed at <https://www.drugs.com/fda-alerts/1341-0.html> on April 2, 2019.

³⁹ Ibid.

⁴⁰ American Geriatrics Society, *American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*.

⁴¹ CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, ch. 18, § 40.5.

⁴² 83 Fed. Reg. 16440, 16519 (Apr. 16, 2018).

which Part D plan formularies applied utilization management tools as well as the 2020 percentage.

Exhibit 5: Part D plan formularies’ application of utilization management tools increased slightly between 2019 and 2020 for commonly used drugs.

Percentage of Unique Drugs to Which Plan Formularies Applied Utilization Management Tools	Number of 2019 Part D Plan Formularies	Percentage of 2019 Part D Plan Formularies	Number of 2020 Part D Plan Formularies	Percentage of 2020 Part D Plan Formularies
Greater than 40%	68	17%	72	16%
30% to 39%	94	23%	118	26%
20% to 29%	137	34%	151	34%
10% to 19%	82	21%	100	22%
Less than 10%	20	5%	7	2%
Totals	401	100%	448	100%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2020.

Although utilization management tools can restrict beneficiaries’ access to drugs, they are important tools for managing costs in Medicare and ensuring the appropriate utilization of drugs. For example, in 2013, CMS set forth expectations for reviews of opioid overutilization to help ensure that opioids are appropriately prescribed and used.⁴³

The percentage of unique drugs for which formularies applied the utilization management tools of quantity limits, prior authorization, or step therapy⁴⁴ changed slightly between 2019 and 2020. Formularies applied quantity limits to 26 percent of drugs in 2020, an increase of 1 percentage point from 2019; require prior authorization for 4 percent of drugs; and require step therapy for 1 percent of unique drugs.

The rate at which plan formularies applied specific utilization management tools varies widely. In 2020, some formularies applied utilization management tools to very few of the unique drugs, whereas at the other end of the range, some formularies applied tools to 48 percent of the unique drugs. More specifically, formularies applied quantity limits to between 0 and 44 percent of unique drugs; require prior authorization for between less than 1 percent and 10 percent of unique drugs; and require step therapy for between 0 and 7 percent of unique drugs.

⁴³ CMS, *Improving Drug Utilization Review Controls in Part D (Excerpt from Final 2013 Call Letter 04-02-2012)*. Accessed at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/improving-dur-controls-in-part-d.pdf> on April 8, 2019.

⁴⁴ See footnote 3 for explanations of quantity limits, prior authorization, and step therapy.

Looking at enrollment across plans provides a slightly different picture than looking only at plans themselves. On average, plan formularies in 2020 applied utilization management tools to 29 percent of unique drugs. However, dual eligibles tend to be enrolled in plans with formularies that applied these tools at a slightly higher rate. In 2020, the median plan weighted by dual eligible enrollment applied such tools to 31 percent of unique drugs; in 2019, the figure was 32 percent. Similarly, the median plan weighted by overall Medicare enrollment applied these tools to 32 percent of unique drugs in 2020; in 2019, the figure was also 32 percent.

Both dual eligibles and Medicare beneficiaries overall tend to be enrolled in plans with formularies that applied utilization management tools to between 20 and 39 percent of unique drugs. In 2020, 77 percent of dual eligibles and 71 percent of Medicare beneficiaries overall were enrolled in plans with formularies in this range.

In 2020, there was an increase in the percentage of Medicare beneficiaries who were enrolled in plans that applied utilization management tools to more than 40 percent of unique drugs. In 2019, 11 percent of dual eligibles and 14 percent of Medicare beneficiaries overall were enrolled in plans that applied utilization management tools to more than 40 percent of unique drugs. These figures increased to 17 percent and 22 percent, respectively, in 2020. Exhibit 6 shows enrollment in Part D plans by dual eligibles and Medicare beneficiaries, as broken down by the percentages at which the plans' formularies applied utilization management tools.

Exhibit 6: The number of beneficiaries who were enrolled in plans that applied utilization management tools to more than 40 percent of unique drugs increased from 2019 to 2020.

Percentage of Unique Drugs to Which Plan Formularies Applied Utilization Management Tools	Percentage of Dual Eligibles Enrolled, 2019	Percentage of Medicare Beneficiaries Enrolled, 2019	Percentage of Dual Eligibles Enrolled, 2020	Percentage of Medicare Beneficiaries Enrolled, 2020
Greater than 40%	11%	14%	17%	22%
30% to 39%	49%	51%	40%	44%
20% to 29%	34%	28%	37%	27%
10% to 19%	4%	4%	4%	4%
Less than 10%	2%	3%	2%	3%
Totals	100%	100%	100%	100%

Source: OIG analysis of formulary inclusion of drugs commonly used by Medicare beneficiaries and dual eligibles, 2020.

CONCLUSION

When establishing formularies and applying utilization management tools, Part D plans need to balance Medicare beneficiaries' needs for adequate prescription drug coverage with the need to contain costs for plan sponsors and for the Part D program. By law and under CMS policy, Part D plan formularies do not generally have to include every available drug. Rather, to meet CMS's formulary requirements, they must include at least two drugs in each therapeutic category or class. For example, for each of the eight drugs that this report identifies as being included by less than 75 percent of Part D plan formularies, all Part D plan formularies cover at least one therapeutically equivalent alternative drug. Additionally, starting in 2020, Part D plans are authorized to limit access to some drugs to only certain indications, provided that they also include a therapeutically similar drug that covers nonformulary indications as well. Part D plan formularies may also institute utilization management tools to ensure appropriate utilization, as well as to control costs.

For the drugs commonly used by dual eligibles, we found that the rate of formulary inclusion is high, with some variation. On average, Part D plan formularies include 97 percent of the commonly used drugs. Part D plan formularies' inclusion of the commonly used drugs ranges from 89 percent to 100 percent. Formulary inclusion rates are similar for PDPs and MA-PDs. Further, formularies for Part D plans with premiums below the regional benchmark include the commonly used drugs at a rate similar to that of Part D plan formularies overall. However, some dual eligibles may be unable to access all drugs covered by their plans' formularies to the extent that Part D sponsors implement indication-based formulary designs, beginning this year.

Inclusion rates for the 195 drugs commonly used by dual eligibles are largely unchanged from those listed in OIG's 2019 report. Part D plan formularies include roughly the same percentage of these commonly used drugs in 2020 as they did in 2019. Enrollment in plans that cover at least 90 percent of unique drugs increased slightly, with 95 percent of dual eligibles enrolled in such plans in 2020, compared to 94 percent of dual eligibles in 2019.

Because some variation exists in the inclusion by Part D plan formularies of the commonly used drugs and in Part D plan formularies' application of utilization management tools to these drugs, some dual eligibles may need to make additional efforts to access the drugs they take. These dual eligibles could appeal prescription drug coverage decisions, switch prescription drugs, or switch Part D plans. Because these scenarios require additional effort by dual eligibles, they may result in administrative barriers to accessing certain prescription drugs.

As mandated by the ACA, OIG will continue to monitor and produce annual reports on the extent to which Part D plan formularies cover drugs that dual eligibles commonly use. In addition, OIG will continue to monitor Part D plan formularies'

application of utilization management tools to these drugs. OIG has no recommendations at this time.

APPENDIX A

Section 3313 of the Patient Protection and Affordable Care Act of 2010

SEC. 3313. OFFICE OF THE INSPECTOR GENERAL STUDIES AND REPORTS.

(a) STUDY AND ANNUAL REPORT ON PART D FORMULARIES' INCLUSION OF DRUGS COMMONLY USED BY DUAL ELIGIBLES.—

(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA-PD plans under Part D include drugs commonly used by full-benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act (42 U.S.C. 1396u–5(c)(6))).

(2) ANNUAL REPORTS.—Not later than July 1 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

APPENDIX B

List of mandated OIG reports examining dual eligibles' access to drugs under Part D

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2011, OEI 05-10-00390, April 2011

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2012, OEI 05-12-00060, June 2012

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2013, OEI 15-13-00090, June 2013

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2014, OEI 05-14-00170, June 2014

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2015, OEI 05-15-00120, June 2015

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2016, OEI 05-16-00090, June 2016

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2017, OEI-05-17-00016, June 2017

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2018, OEI-05-18-00240, June 2018

OIG, Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2019, OEI-05-19-00220, June 2019

APPENDIX C

Commonly used drugs and rates of inclusion by formularies

The 200 drugs with the highest utilization by dual eligibles.

*Sample is from the 2017 MCBS. Projections and confidence intervals are derived from its survey methodology.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Atorvastatin Calcium	3,506	26,514,761	23,033,296	29,996,226	448	100%
Lisinopril	3,399	24,917,840	21,021,953	28,813,726	448	100%
Amlodipine Besylate	3,292	23,984,655	20,528,125	27,441,185	448	100%
Levothyroxine Sodium	4,649	23,948,599	20,854,803	27,042,395	448	100%
Omeprazole	3,406	22,249,989	19,516,288	24,983,689	448	100%
Metformin Hcl	2,567	21,366,050	18,296,220	24,435,879	448	100%
Furosemide	4,107	18,523,601	16,142,689	20,904,514	448	100%
Gabapentin	3,293	18,267,640	15,450,285	21,084,994	448	100%
Metoprolol Tartrate	2,082	14,241,702	12,095,195	16,388,208	448	100%
Simvastatin	1,828	14,228,468	11,645,305	16,811,630	448	100%
Hydrocodone/Acetaminophen	2,647	14,094,248	11,761,058	16,427,438	448	100%
Losartan Potassium	1,732	12,764,473	10,547,181	14,981,766	448	100%
Potassium Chloride	2,628	12,023,377	9,989,348	14,057,406	448	100%
Nystatin	2,768	11,830,879	7,823,249	15,838,510	448	100%
Albuterol Sulfate	1,741	11,626,113	9,587,105	13,665,121	448	100%
Hydrochlorothiazide	1,417	9,884,529	7,988,837	11,780,220	448	100%
Metoprolol Succinate	1,600	9,533,225	7,982,869	11,083,581	448	100%
Clopidogrel Bisulfate	1,329	9,147,802	7,443,727	10,851,878	448	100%
Sertraline Hcl	1,621	8,472,094	6,834,658	10,109,530	448	100%
Pravastatin Sodium	931	8,431,469	6,603,696	10,259,242	448	100%
Insulin Glargine,hum.Rec.Anlog	1,034	8,167,922	6,313,173	10,022,671	447	100%
Carvedilol	1,261	8,147,860	6,778,897	9,516,822	448	100%
Pantoprazole Sodium	1,308	7,997,279	6,548,332	9,446,227	448	100%
Alprazolam	1,431	7,873,074	5,711,557	10,034,591	429	96%
Ranitidine Hcl	1,349	7,869,357	6,150,384	9,588,329	448	100%
Tramadol Hcl	1,589	7,374,208	6,063,505	8,684,912	448	100%
Glipizide	821	7,143,261	5,481,593	8,804,929	448	100%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Fluticasone Propionate	1,174	7,069,289	5,674,640	8,463,938	448	100%
Warfarin Sodium	1,475	6,974,147	4,675,838	9,272,456	448	100%
Tamsulosin Hcl	1,196	6,882,707	5,628,311	8,137,103	448	100%
Trazodone Hcl	1,392	6,858,709	5,584,708	8,132,711	448	100%
Quetiapine Fumarate	1,527	6,296,582	5,124,931	7,468,232	448	100%
Citalopram Hydrobromide	1,187	5,942,838	4,468,612	7,417,065	448	100%
Montelukast Sodium	1,008	5,914,073	4,551,247	7,276,899	448	100%
Prednisone	999	5,727,417	4,639,144	6,815,690	448	100%
Oxycodone Hcl/Acetaminophen	879	5,707,652	4,647,439	6,767,866	448	100%
Escitalopram Oxalate	1,131	5,563,743	3,730,479	7,397,007	448	100%
Atenolol	659	5,446,245	4,126,705	6,765,785	448	100%
Sitagliptin Phosphate	806	5,377,234	4,208,739	6,545,729	429	96%
Mirtazapine	1,320	5,366,122	4,161,516	6,570,727	448	100%
Bupropion Hcl	755	5,155,729	3,469,359	6,842,098	448	100%
Allopurinol	763	5,082,766	4,079,784	6,085,748	448	100%
Divalproex Sodium	1,355	5,054,977	3,793,666	6,316,288	448	100%
Duloxetine Hcl	1,035	5,029,421	3,971,712	6,087,130	448	100%
Rosuvastatin Calcium	610	5,027,684	3,784,042	6,271,326	448	100%
Donepezil Hcl	1,361	4,806,567	3,608,052	6,005,083	448	100%
Ibuprofen	749	4,772,743	3,851,505	5,693,980	448	100%
Clonazepam	915	4,521,679	3,110,574	5,932,783	448	100%
Meloxicam	761	4,419,667	3,415,543	5,423,791	448	100%
Esomeprazole Magnesium	664	4,317,203	3,218,639	5,415,766	345	77%
Venlafaxine Hcl	706	4,219,899	3,292,550	5,147,249	448	100%
Oxybutynin Chloride	722	4,205,538	2,896,338	5,514,739	448	100%
Latanoprost	770	4,187,300	3,121,852	5,252,748	448	100%
Insulin Aspart	630	4,083,231	3,001,193	5,165,270	316	71%
Diltiazem Hcl	580	4,041,979	3,123,707	4,960,251	448	100%
Isosorbide Mononitrate	675	4,016,792	2,974,421	5,059,162	448	100%
Alendronate Sodium	533	3,974,224	3,079,871	4,868,578	448	100%
Lisinopril/Hydrochlorothiazide	341	3,971,405	2,701,519	5,241,291	448	100%
Hydralazine Hcl	585	3,927,628	3,023,269	4,831,987	448	100%
Fluoxetine Hcl	678	3,898,533	2,839,966	4,957,101	448	100%
Oxycodone Hcl	736	3,776,828	2,784,364	4,769,291	447	100%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Lorazepam	1,042	3,745,369	2,952,179	4,538,560	448	100%
Pregabalin	658	3,693,834	2,845,309	4,542,358	448	100%
Cyclobenzaprine Hcl	545	3,662,123	2,652,038	4,672,208	447	100%
Memantine Hcl	1,088	3,624,505	2,716,486	4,532,523	448	100%
Zolpidem Tartrate	490	3,513,758	2,208,838	4,818,679	440	98%
Levetiracetam	770	3,496,607	2,450,170	4,543,044	448	100%
Famotidine	839	3,428,420	2,569,603	4,287,236	445	99%
Diclofenac Sodium	599	3,411,890	2,682,805	4,140,976	448	100%
Baclofen	644	3,348,267	2,607,072	4,089,462	448	100%
Aripiprazole	741	3,287,230	2,464,984	4,109,475	448	100%
Insulin Detemir	608	3,263,891	2,259,060	4,268,722	330	74%
Risperidone	912	3,261,673	2,142,436	4,380,909	448	100%
Lovastatin	407	3,252,884	2,438,753	4,067,016	447	100%
Tizanidine Hcl	551	3,251,194	2,461,005	4,041,382	448	100%
Buspirone Hcl	642	3,238,310	2,342,026	4,134,594	448	100%
Losartan/Hydrochlorothiazide	335	3,163,313	2,330,813	3,995,813	448	100%
Naproxen	493	3,146,415	2,403,633	3,889,197	448	100%
Finasteride	480	2,960,782	1,827,731	4,093,833	448	100%
Budesonide/Formoterol Fumarate	448	2,954,173	2,211,854	3,696,491	315	70%
Alcohol Antiseptic Pads**	274	2,905,342	1,837,210	3,973,474	Supply Item	Supply Item
Polyethylene Glycol 3350**	908	2,828,333	2,170,778	3,485,888	Excluded	Excluded
Amitriptyline Hcl	389	2,804,769	1,839,361	3,770,177	448	100%
Rivaroxaban	444	2,771,551	2,280,525	3,262,578	442	99%
Azithromycin	530	2,771,301	2,333,713	3,208,888	448	100%
Spironolactone	470	2,753,760	1,943,293	3,564,227	448	100%
Tiotropium Bromide	374	2,750,249	2,096,743	3,403,755	322	72%
Valsartan	394	2,711,004	1,873,134	3,548,874	446	100%
Paroxetine Hcl	411	2,695,821	1,881,253	3,510,389	448	100%
Clonidine Hcl	513	2,572,597	1,901,774	3,243,419	448	100%
Lamotrigine	601	2,565,889	1,611,136	3,520,643	448	100%
Triamcinolone Acetonide	450	2,424,745	1,787,234	3,062,256	448	100%
Glimepiride	332	2,319,173	1,483,930	3,154,417	448	100%
Diazepam	370	2,237,272	1,399,880	3,074,664	448	100%
Apixaban	522	2,190,255	1,291,509	3,089,002	445	99%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Benzotropine Mesylate	585	2,181,952	1,524,443	2,839,461	448	100%
Cephalexin	462	2,168,923	1,808,636	2,529,210	448	100%
Valsartan/Hydrochlorothiazide	208	2,083,648	1,273,641	2,893,655	445	99%
Ezetimibe	283	2,080,407	1,434,528	2,726,286	448	100%
Topiramate	329	2,060,546	1,203,140	2,917,953	448	100%
Carbamazepine	436	2,042,858	1,335,518	2,750,198	448	100%
Ciprofloxacin Hcl	440	2,015,783	1,664,815	2,366,751	448	100%
Lactulose	411	1,992,207	1,187,329	2,797,084	448	100%
Acetaminophen With Codeine	362	1,981,127	1,254,226	2,708,028	448	100%
Insulin Lispro	329	1,896,051	1,279,278	2,512,824	205	46%
Triamterene/Hydrochlorothiazid	185	1,824,876	1,074,026	2,575,725	448	100%
Propranolol Hcl	323	1,791,767	1,097,354	2,486,179	448	100%
Fenofibrate	217	1,782,991	1,082,751	2,483,231	447	100%
Enalapril Maleate	179	1,769,779	905,593	2,633,964	448	100%
Gemfibrozil	113	1,763,947	1,143,080	2,384,814	448	100%
Ketoconazole	463	1,760,991	1,353,705	2,168,277	448	100%
Lidocaine	294	1,694,796	1,212,579	2,177,014	448	100%
Amoxicillin	354	1,668,610	1,403,958	1,933,263	448	100%
Pioglitazone Hcl	208	1,667,963	1,269,416	2,066,511	448	100%
Brimonidine Tartrate	319	1,639,611	1,127,120	2,152,101	448	100%
Ropinirole Hcl	315	1,631,405	965,956	2,296,854	448	100%
Chlorthalidone	181	1,604,503	929,770	2,279,237	448	100%
Temazepam	277	1,601,283	998,072	2,204,494	420	94%
Linagliptin	322	1,592,388	974,706	2,210,070	353	79%
Olanzapine	632	1,591,348	1,110,709	2,071,988	448	100%
Solifenacin Succinate	234	1,568,041	958,484	2,177,597	242	54%
Amoxicillin/Potassium Clav	314	1,559,156	1,287,885	1,830,427	448	100%
Digoxin	372	1,557,726	1,113,667	2,001,785	448	100%
Sulfamethoxazole/Trimethoprim	376	1,556,394	1,296,981	1,815,806	448	100%
Levofloxacin	344	1,537,701	1,287,012	1,788,389	448	100%
Dorzolamide Hcl/Timolol Maleat	172	1,422,922	746,389	2,099,456	448	100%
Dexlansoprazole	253	1,421,606	1,126,083	1,717,130	235	52%
Verapamil Hcl	139	1,407,301	702,478	2,112,124	448	100%
Meclizine Hcl	266	1,385,985	1,066,354	1,705,615	448	100%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Promethazine Hcl	356	1,374,089	901,853	1,846,325	445	99%
Celecoxib	260	1,373,116	1,003,862	1,742,370	424	95%
Sucralfate	287	1,338,530	868,210	1,808,851	448	100%
Nifedipine	209	1,333,977	866,495	1,801,460	443	99%
Cyclosporine	192	1,321,576	829,261	1,813,891	448	100%
Nitroglycerin	247	1,311,819	1,007,730	1,615,907	448	100%
Olopatadine Hcl	271	1,309,908	846,997	1,772,819	429	96%
Carbidopa/Levodopa	376	1,294,425	545,138	2,043,711	448	100%
Bimatoprost	190	1,286,227	946,896	1,625,559	427	95%
Fluticasone/Vilanterol	225	1,257,029	873,110	1,640,948	420	94%
Fenofibrate Nanocrystallized	196	1,251,598	723,275	1,779,920	441	98%
Fentanyl	281	1,248,854	627,928	1,869,779	448	100%
Bumetanide	203	1,235,654	573,161	1,898,148	448	100%
Phenytoin Sodium Extended	201	1,226,893	685,081	1,768,704	448	100%
Ondansetron Hcl	297	1,226,258	906,182	1,546,334	448	100%
Benazepril Hcl	154	1,211,933	660,106	1,763,760	447	100%
Morphine Sulfate	333	1,206,063	751,687	1,660,439	448	100%
Methylprednisolone	199	1,203,903	1,018,121	1,389,686	448	100%
Doxycycline Hyclate	279	1,201,848	906,926	1,496,770	448	100%
Ergocalciferol (Vitamin D2)**	189	1,200,330	596,167	1,804,493	Excluded	Excluded
Dicyclomine Hcl	168	1,159,216	618,650	1,699,783	448	100%
Fluconazole	210	1,153,890	753,047	1,554,733	448	100%
Calcitriol	175	1,148,149	612,607	1,683,691	448	100%
Doxepin Hcl	181	1,144,832	635,462	1,654,202	448	100%
Ramipril	130	1,142,590	584,408	1,700,772	448	100%
Ziprasidone Hcl	222	1,123,534	531,199	1,715,869	448	100%
Omega-3 Acid Ethyl Esters	139	1,119,997	764,858	1,475,135	344	77%
Linaclotide	246	1,090,286	777,467	1,403,104	422	94%
Timolol Maleate	184	1,083,472	671,116	1,495,828	448	100%
Clozapine	330	1,034,103	382,927	1,685,279	448	100%
Lurasidone Hcl	261	1,024,610	570,101	1,479,119	448	100%
Ipratropium Bromide	196	1,021,067	570,571	1,471,563	448	100%
Torseamide	202	1,015,661	534,031	1,497,290	433	97%
Doxazosin Mesylate	119	1,000,405	520,599	1,480,211	448	100%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Amiodarone Hcl	212	976,206	463,364	1,489,049	448	100%
Haloperidol	205	957,307	472,576	1,442,039	448	100%
Canagliflozin	101	949,529	471,952	1,427,107	261	58%
Hydrocortisone	239	945,236	676,889	1,213,583	448	100%
Dextroamphetamine/Amphetamine	181	943,299	345,815	1,540,783	448	100%
elviteg/cob/emtri/tenof alafen**	169	929,383	-188,460	2,047,226	Excluded	Excluded
Lubiprostone	204	924,910	414,901	1,434,918	347	77%
Amlodipine Besylate/Benazepril	160	924,647	523,690	1,325,604	434	97%
Tolterodine Tartrate	168	910,574	613,074	1,208,073	433	97%
Prednisolone Acetate	136	908,681	672,083	1,145,279	448	100%
Folic Acid**	158	908,345	422,315	1,394,376	Excluded	Excluded
Ipratropium/Albuterol Sulfate	292	907,850	635,783	1,179,918	433	97%
Insulin Degludec	97	904,496	157,185	1,651,807	343	77%
Valacyclovir Hcl	127	893,860	335,040	1,452,681	448	100%
Clobetasol Propionate	216	887,582	407,481	1,367,684	345	77%
Umeclidinium Bromide	113	874,194	285,404	1,462,984	342	76%
Clindamycin Hcl	145	839,832	684,231	995,434	448	100%
Tacrolimus	73	835,964	575,871	1,096,058	448	100%
Fluvoxamine Maleate	193	834,436	203,536	1,465,336	448	100%
Adalimumab	93	830,593	442,227	1,218,960	448	100%
Valproic Acid	53	821,974	616,774	1,027,173	448	100%
Mupirocin	212	805,700	576,692	1,034,708	448	100%
Lithium Carbonate	200	801,133	247,245	1,355,021	448	100%
Brimonidine Tartrate/Timolol	185	797,031	500,453	1,093,609	411	92%
Oxcarbazepine	247	795,983	438,599	1,153,368	448	100%
Colchicine	118	770,523	369,814	1,171,232	448	100%
Metoclopramide Hcl	159	770,150	437,879	1,102,421	448	100%
Insulin Regular, Human	132	767,711	405,593	1,129,829	448	100%
Ranolazine	107	767,060	262,796	1,271,324	448	100%
Metolazone	129	761,836	316,141	1,207,530	406	91%
Sitagliptin Phos/Metformin Hcl	113	760,918	327,297	1,194,539	428	96%
Fluocinonide	153	756,816	250,866	1,262,766	442	99%
Mirabegron	105	746,707	259,499	1,233,916	447	100%
Ammonium Lactate	150	740,771	356,666	1,124,875	439	98%

The 200 drugs with the highest utilization by dual eligibles, continued.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*		Number of Formularies Including Drug	Percentage of Formularies Including Drug
			Lower Bound	Upper Bound		
Paliperidone	124	733,149	566,608	899,690	448	100%
Metronidazole	160	729,510	513,216	945,805	448	100%
Travoprost	213	727,589	435,398	1,019,780	397	89%

Source: OIG analysis of drugs commonly used by dual eligibles, 2020.

**See Appendix D.

APPENDIX D

Five drugs commonly used by dual eligibles were excluded from this analysis

In 2020, five drugs commonly used by dual eligibles were excluded from this analysis.

Generic Name	Reason Excluded From Analysis
Alcohol antiseptic pads	Supply covered by Part D
Polyethylene glycol 3350	Nonprescription drug not covered under Part D
Ergocalciferol (vitamin D2)	Vitamin or mineral product not covered under Part D
Elviteg/cob/emtri/tenof alafen	Unable to confidently project use to entire dual eligible population
Folic acid	Vitamin or mineral product not covered under Part D

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2020.

APPENDIX E

Rates at which prescription drug plan formularies associated with stand-alone or Medicare Advantage plans include commonly used drugs, by region

Inclusion of commonly used drugs by formularies associated with stand-alone plans, by PDP region

Across all 34 PDP regions, the rates of formularies' inclusion of commonly used drugs ranged from 89 percent to 100 percent. The average range of inclusion was 96 percent for all PDP regions, except for the New York region, which averaged 97 percent.

Inclusion of commonly used drugs by formularies associated with Medicare Advantage plans, by MA-PD region

Exhibit E-1: MA-PD formularies' inclusion of commonly used drugs, by MA-PD region.

MA-PD Region*	State(s)	Number of MA-PDs	Average Rate of Drug Inclusion by Formularies	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	69	98%	96%	98%
2	Connecticut, Massachusetts, Rhode Island, Vermont	125	98%	93%	99%
3	New York	218	97%	93%	98%
4	New Jersey	64	97%	90%	99%
5	Delaware, the District of Columbia, Maryland	44	98%	97%	99%
6	Pennsylvania, West Virginia	202	98%	93%	100%
7	North Carolina, Virginia	186	98%	94%	99%
8	Georgia, South Carolina	180	98%	96%	99%
9	Florida	448	98%	90%	100%
10	Alabama, Tennessee	148	98%	96%	99%
11	Michigan	94	98%	96%	99%
12	Ohio	154	98%	93%	99%
13	Indiana, Kentucky	147	98%	96%	99%

MA-PD formularies' inclusion of commonly used drugs, by MA-PD region, continued.

MA-PD Region*	State(s)	Number of MA-PDs	Average Rate of Drug Inclusion by Formularies	Minimum Rate	Maximum Rate
14	Illinois, Wisconsin	206	98%	90%	100%
15	Arkansas, Missouri	130	98%	96%	99%
16	Louisiana, Mississippi	98	98%	96%	99%
17	Texas	199	98%	93%	99%
18	Kansas, Oklahoma	86	98%	96%	99%
19	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	140	98%	90%	99%
20	Colorado, New Mexico	89	98%	93%	99%
21	Arizona	99	98%	96%	99%
22	Nevada	45	98%	93%	99%
23	Idaho, Oregon, Utah, Washington	255	98%	93%	99%
24	California	374	98%	94%	99%
25	Hawaii	23	98%	96%	99%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2020.

* Region 26, which covers Alaska, had no MA-PDs available for 2020.

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