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Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2021

Suzanne Murrin

Deputy Inspector General for Evaluation and Inspections

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Why OIG Did This Review

The Patient Protection and Affordable Care Act (ACA) requires the Office of Inspector General (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 eleventh report OIG has produced to meet this mandate.

How OIG Did This Review

For this report, we determined whether the 453 unique formularies used by the 5,128 Part D plans operating in 2021 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 2018 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: 2021

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, 74 percent of the commonly used drugs are included by all Part D plan formularies. These results are largely unchanged from OIG's findings for formularies reported in the mandated annual report from 2020, as well as from the findings in our reports from 2011 through 2019.

We also found that the percentage of drugs to which plan formularies applied utilization management tools remained the same between 2020 and 2021. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in both 2020 and 2021.

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 2021 as they did in 2020.

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. 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, they 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, the Centers for Medicare & Medicaid Services (CMS) authorized Part D plans to use indication-based formulary design beginning in contract year 2020 to further control drug utilization.⁴

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 drug therapy that is more costly or more risky.

⁴ Indication-based formulary design allows Part D plans to limit certain drugs to specific indications. (An indication is a sign, symptom, or medical condition that leads to the recommendation of a treatment, test, or procedure.) 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.

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 2021, approximately 48.4 million of the 63.1 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 2021, plan sponsors offer 5,128 unique Part D plans, with many plan sponsors offering multiple Part D plans.

Dual Eligibles Under Medicare Part D

Approximately 12.3 million Medicare beneficiaries are dual eligibles. For about 8.8 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 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

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 [Children’s Health Insurance Program] 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, 2021.

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, 2021.

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, they 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).

Because CMS does this PDP assignment on a random basis, dual eligibles may find themselves enrolled in PDPs that do not cover the specific drugs that they use, or that cover those specific drugs for only 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 dual eligibles use

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 minimis" 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 minimis amount. ACA, P.L. No. 111-148 (enacted Mar. 23, 2010), § 3303, Social Security Act § 1860D 14(a)(5). For 2021, CMS set the de minimis amount at \$2 above the regional benchmark.

¹³ CMS, *PDBM*, ch. 3, § 40.1.4.

¹⁴ *Ibid.*

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. Prior to 2019, dual eligibles could switch Part D plans monthly to find plans that covered the drugs they required.

a special election period to change plans, their 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 those individuals' 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 2021, CMS reported reassigning approximately 1,107 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. (An indication is a sign, symptom, or medical condition that leads to the recommendation of a treatment, test, or procedure. The Food and Drug Administration (FDA) approves a drug for one or more indications.) However, for each drug limited to certain indications, these plans must ensure that their formularies also cover at least one therapeutically similar drug for the nonformulary indications.²¹

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 2021, CMS reassigned 121,685 beneficiaries 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 constitute 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—except in limited circumstances—all drugs in six categories or classes: (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.

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, 2021. For example, a plan could cover a drug for plaque psoriasis, but not for Crohn's disease, a condition for which the drug is also approved to treat. The plan must then ensure that its formulary covers another, therapeutically similar drug for Crohn's disease.

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 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}

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, 2021.

²⁶ CMS, *PDBM*, ch. 6, § 30.2.7.

²⁷ *Ibid.*

²⁸ CMS, *PDBM*, ch. 6, § 30.2.2.

²⁹ CMS, *PDBM*, ch. 6, § 30.2.7.

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 a Medicare beneficiary's 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 the beneficiary's immediate drug needs the first time the beneficiary attempts to fill a prescription. The transition period also allows the beneficiary time to work with the beneficiary's prescribing physician(s) to obtain prescriptions for therapeutically alternative drugs or to request a formulary exception from the Part D plan.

Related Office of Inspector General 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

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.

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

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.) This report is the eleventh 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 2021. As part of our assessment, we included dual eligibles' enrollment data from January 2021, the most recent enrollment data available from CMS at the time of our study. We also compared the results of our 2021 study with those of our 2020 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 2018 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 has gone 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 (2021) report and the previous 10 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 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 2018 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

³⁴ OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020*, OEI-05-20-00190, June 2020.

utilization. The 2018 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 2021 overlapped by 90 percent with the list for 2020, which in turn overlapped by 91 percent with the list for 2019.³⁵

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 are interviewed three times per year and asked which drugs they are taking and whether they have started taking any new drugs since the previous interview. The MCBS also includes Part D prescription drug events for surveyed Medicare beneficiaries. In 2018, the MCBS surveyed 15,237 Medicare beneficiaries, of whom 2,246 were dual eligibles who had used prescription drugs during the year (out of 3,896 dual-eligible survey respondents).

First DataBank National Drug Data File. We used the February 2021 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 2021, we collected from CMS the formulary data and the plan data for Part D plans operating in 2021. The formulary data includes Part D plans' formularies and utilization management tools for plans operating in 2021. In 2021, there are 453 unique formularies offered by 5,128 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 2021 enrollment data for Part D plans. These data provide the number of dual eligibles enrolled in each Part D plan as of January 2021.

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 2018 MCBS. We excluded respondents from territories because they are not

³⁵ In 2020, we used 2017 MCBS data to create the list of the 200 drugs with the highest utilization by dual eligibles. In 2019, we used 2016 MCBS data to create the list.

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.

eligible to receive cost-sharing assistance under Part D. The MCBS listed 145,646 drug events for 2,246 dual eligibles who did not reside in territories.³⁷

2. We collapsed this list to a list of drugs based on their active ingredients. To do this, we used 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 145,646 drug events associated with 861 drugs.
3. We ranked the 861 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 453 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.

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 453 formularies covered each drug. We considered a drug to have a low rate of inclusion if it was included by less than 75 percent of formularies. For such drugs, we counted the number of drugs (if any) that each formulary covered in the same

³⁷ For the purposes of this report, a drug event is an MCBS survey response indicating that the responding beneficiary was prescribed a specific drug at least once in 2018. For example, 1 MCBS survey respondent was prescribed lorazepam 13 times in 2018. We counted this beneficiary/drug combination as 13 drug events.

therapeutic category or class. We conducted this analysis to ensure that dual eligibles have access to therapeutically similar drugs.

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 2021 to Part D plans available in 2021.

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 2018 MCBS survey account for 88 percent of all prescriptions dispensed to the dual-eligible respondents in the 2018 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 do 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 respective Part D plans because certain drugs are not covered for all indications. However, CMS noted that very few Part D plans are using indication-based formulary design in 2021.

Standards

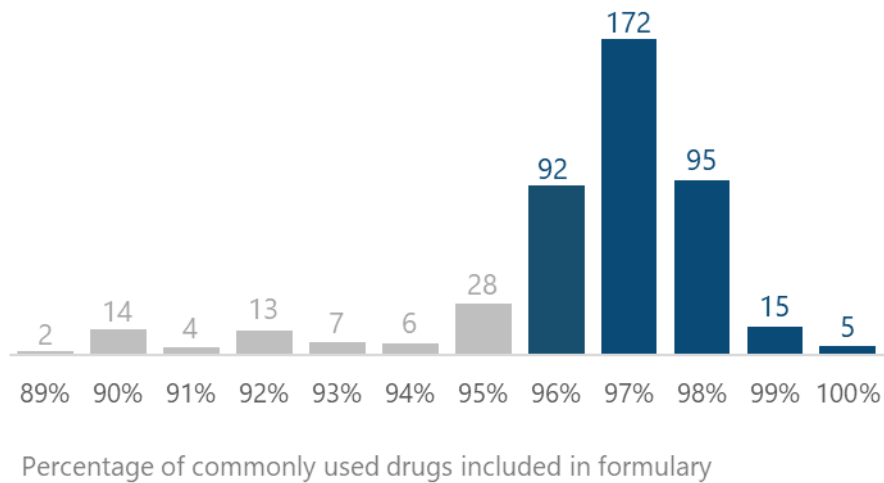
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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 453 unique formularies used by Part D plans in 2021, 5 formularies include 100 percent of the commonly used drugs. At the other end of the inclusion range, two formularies include 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: More than 4 in 5 of the 453 Part D plan formularies cover at least 96 percent of the drugs commonly used by dual eligibles.



Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2021.

Part D plan formularies' rates of inclusion of the drugs commonly used by dual eligibles in 2021 did not change from the rates in 2020. The average rate of inclusion remained at 97 percent between 2020 and 2021. The range of inclusion rates also remained the same between 2020 and 2021; inclusion rates ranged from 89 to 100 percent in both 2020 and 2021.

Nationally, PDP and MA-PD formularies have similar rates of inclusion of the drugs commonly used by dual eligibles, averaging 95 percent and 97 percent, respectively. For PDP formularies, the rates of inclusion range from 89 to 99 percent. For MA-PD formularies, the rates of inclusion range from 89 to 100 percent. Nine formularies—

2 percent of the 453 unique formularies used by Part D plans in 2021—are used 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 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 in formularies used 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 91 percent to 100 percent. Approximately 66 percent of dual eligibles are enrolled in Part D plans with premiums below the regional benchmark.

Almost all 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, almost 100 percent are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. Less than 1 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.

100% of commonly used drugs	4,414	0.04%
95% to 99% of commonly used drugs	10,167,355	91.17%
90% to 94% of commonly used drugs	950,374	8.52%
86% to 89% of commonly used drugs	30,150	0.27%
Total	11,152,293	100%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles and dual eligibles' enrollment, 2021.

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 from 95 percent in 2020 to nearly 100 percent in 2021.

Seventy-four 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 43 percent to 100 percent. At one end of the range, there is a drug that is included in 43 percent of Part D plan formularies; at the other end, 145 drugs are included in all plan formularies. The average drug’s 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 453 Formularies	Percentage of the 195 Commonly Used Drugs Included in Formularies
100%	74% (145 drugs)
85% to 99%	17% (33 drugs)
76% to 84%	3% (6 drugs)
43% to 75%	6% (11 drugs)
Total	100% (195 drugs)

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2021.

The percentage of drugs commonly used by dual eligibles that were included in all formularies decreased slightly in 2021. All formularies included 74 percent of the commonly used drugs in 2021, compared to 75 percent in 2020.

Part D plan formularies include certain drugs less frequently than others

Of the commonly used drugs, 6 percent (11 drugs) are included by less than 75 percent of Part D plan formularies. Exhibit 4 provides the percentage of formularies covering each of these 11 drugs.

All 11 drugs are brand-name drugs, which are typically more costly than generic drugs. Six of the 11 drugs had a primary indication for diabetes therapy, and the remaining 5 drugs treat a variety of conditions, including heartburn and chronic obstructive pulmonary disease.

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

Budesonide/formoterol fumarate*	Asthma	73%
Insulin detemir*	Diabetes	70%
Insulin aspart*	Diabetes	70%
Umeclidinium bromide	Chronic obstructive pulmonary disease	69%
Dapagliflozin propanediol	Diabetes	66%
Insulin degludec	Diabetes	66%
Tiotropium bromide*	Chronic obstructive pulmonary disease	66%
Dexlansoprazole*	Gastroesophageal reflux disease	50%
Lubiprostone	Chronic constipation	49%
Insulin lispro*	Diabetes	44%
Canagliflozin*	Diabetes	43%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2021.

* These drugs also had low rates of formulary inclusion in 2020.

Although Part D formularies frequently omit these 11 drugs, they all cover other drugs in the same respective therapeutic classes. For each of these 11 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 increased between 2020 and 2021—from 8 drugs in 2020 to 11 drugs in 2021. There are seven drugs with low inclusion rates in 2021 that were also on the list of commonly used drugs with low inclusion rates in our 2020 report; we note these seven drugs with asterisks in Exhibit 4 (above). Five of these seven drugs were also on the list of drugs with low inclusion rates in our 2019 report.

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.³⁸
- 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.³⁹

The average percentage of commonly used drugs to which plan formularies applied utilization management tools remained the same between 2020 and 2021

For the unique drugs that compose the list of commonly used drugs, the average percentage to which Part D plan formularies applied utilization management tools was 29 percent in both 2020 and 2021. Plans with premiums below the regional benchmarks used utilization management tools less frequently than all plans; on average, formularies of these plans used utilization management tools for 24 percent of their drugs. See Exhibit 5 for a breakdown of the 2020 percentage of unique drugs to which Part D plan formularies applied utilization management tools as well as the 2021 percentage.

³⁸ CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, ch. 18, § 40.5.

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

Exhibit 5: Part D plan formularies’ application of utilization management tools shifted slightly between 2020 and 2021 for commonly used drugs.

Percentage of Unique Drugs to Which Plan Formularies Applied Utilization Management Tools	Number of 2020 Part D Plan Formularies	Percentage of 2020 Part D Plan Formularies	Number of 2021 Part D Plan Formularies	Percentage of 2021 Part D Plan Formularies
Greater than 40%	72	16%	75	17%
30% to 39%	118	26%	179	40%
20% to 29%	151	34%	90	20%
10% to 19%	100	22%	88	19%
Less than 10%	7	2%	21	5%
Totals	448	100%	453	100%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2021.

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.⁴⁰

The percentage of unique drugs for which formularies applied the utilization management tools of quantity limits, prior authorization, or step therapy⁴¹ changed slightly between 2020 and 2021. On average, formularies applied quantity limits to 27 percent of drugs in 2021 (an increase of 1 percentage point from 2020); required prior authorization for 3 percent of drugs; and required step therapy for 1 percent of unique drugs.

The percentage of drugs to which plan formularies apply specific utilization management tools varies widely. In 2021, some formularies apply utilization management tools to very few of the unique drugs, whereas at the other end of the range, some formularies applied tools to 45 percent of the unique drugs. More specifically, formularies apply quantity limits to between 0 and 44 percent of unique drugs; require prior authorization for between less than 0 percent and 9 percent of unique drugs; and require step therapy for between 0 and 7 percent of unique drugs.

Looking at enrollment across plans provides a slightly different picture than looking only at plans themselves. On average, plan formularies in 2021 apply utilization management tools to 29 percent of unique drugs. However, dual eligibles tend to be enrolled in plans with formularies that apply these tools at a slightly higher rate. In

⁴⁰ 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, 2021.

⁴¹ See footnote 3 for explanations of quantity limits, prior authorization, and step therapy.

2021, the median plan weighted by dual-eligible enrollment applies such tools to 34 percent of unique drugs; in 2020, the figure was 31 percent. Similarly, the median plan weighted by overall Medicare enrollment applies these tools to 34 percent of unique drugs in 2021; in 2020, the figure was 32 percent.

Both dual eligibles and Medicare beneficiaries overall tend to be enrolled in plans with formularies that apply utilization management tools to between 20 and 39 percent of unique drugs. In 2021, 85 percent of dual eligibles and 78 percent of Medicare beneficiaries overall were enrolled in plans with formularies in this range.

In 2021, there was a decrease 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 2020, 17 percent of dual eligibles and 22 percent of Medicare beneficiaries overall were enrolled in plans that applied utilization management tools to more than 40 percent of unique drugs. These figures decreased to 10 percent and 16 percent, respectively, in 2021. However, there was an increase in the percentage of beneficiaries who were enrolled in plans that applied utilization management tools to 30 percent to 39 percent of unique drugs. 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 decreased from 2020 to 2021.

Percentage of Unique Drugs to Which Plan Formularies Applied Utilization Management Tools	Percentage of Dual Eligibles Enrolled, 2020	Percentage of Medicare Beneficiaries Enrolled, 2020	Percentage of Dual Eligibles Enrolled, 2021	Percentage of Medicare Beneficiaries Enrolled, 2021
Greater than 40%	17%	22%	10%	16%
30% to 39%	40%	44%	74%	68%
20% to 29%	37%	27%	11%	10%
10% to 19%	4%	4%	3%	3%
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, 2021.

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 11 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 1 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 the plans 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, to the extent that Part D sponsors implement indication-based formulary designs in the future, some dual eligibles may be unable to access all drugs covered by their plans' formularies.

Inclusion rates for the 195 drugs commonly used by dual eligibles are largely unchanged from those listed in OIG's 2020 report. Part D plan formularies include roughly the same percentage of these commonly used drugs in 2021 as they did in 2020. Enrollment in plans that cover at least 90 percent of unique drugs increased, with almost 100 percent of dual eligibles enrolled in such plans in 2021, compared to 95 percent of dual eligibles in 2020.

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. OIG has no recommendations based on this or previous annual mandated reports examining dual eligibles' access to drugs under Medicare Part D.

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 Office of Inspector General 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-05-13-00090, 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

OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020*, OEI-05-20-00190, June 2020

APPENDIX C

Commonly used drugs and rates of inclusion by formularies

The 200 drugs with the highest utilization by dual eligibles

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	3,384	28,174,319	24,569,308	31,779,331	453	100%
Amlodipine besylate	3,364	27,598,148	23,526,192	31,670,105	453	100%
Lisinopril	3,076	23,968,857	20,237,213	27,700,502	453	100%
Metformin hydrochloride	2,525	22,650,779	19,576,827	25,724,732	453	100%
Levothyroxine sodium	4,314	22,350,773	19,607,142	25,094,404	453	100%
Omeprazole	3,181	21,621,199	18,653,646	24,588,753	453	100%
Gabapentin	3,166	18,873,306	16,453,162	21,293,451	453	100%
Furosemide	3,583	17,938,241	15,809,058	20,067,425	453	100%
Hydrocodone/acetaminophen	2,318	12,892,790	10,679,170	15,106,409	453	100%
Simvastatin	1,600	12,845,632	10,935,571	14,755,694	453	100%
Losartan potassium	1,491	12,048,428	10,199,279	13,897,577	453	100%
Metoprolol succinate	1,505	11,889,664	9,848,185	13,931,143	453	100%
Potassium chloride	2,453	11,691,408	10,098,504	13,284,311	453	100%
Nystatin	2,743	11,639,448	6,891,503	16,387,393	453	100%
Metoprolol tartrate	1,887	11,555,637	9,744,667	13,366,606	453	100%
Albuterol sulfate	1,676	11,511,998	9,679,130	13,344,865	453	100%
Pantoprazole sodium	1,849	10,253,207	8,649,510	11,856,905	453	100%
Sertraline hydrochloride	1,513	9,690,874	7,778,666	11,603,083	453	100%
Hydrochlorothiazide	1,318	9,601,137	7,762,928	11,439,346	453	100%
Carvedilol	1,211	9,464,034	7,629,305	11,298,763	453	100%
Ranitidine hydrochloride*	1,308	9,151,420	7,129,381	11,173,458	Excluded	Excluded
Montelukast sodium	1,210	8,737,913	6,615,464	10,860,362	453	100%
Clopidogrel bisulfate	1,243	8,609,383	7,068,282	10,150,484	453	100%
Trazodone hydrochloride	1,423	7,991,832	6,539,218	9,444,447	453	100%
Fluticasone propionate	1,120	7,393,022	5,939,647	8,846,397	453	100%
Quetiapine fumarate	1,415	7,348,812	5,186,019	9,511,605	453	100%
Glipizide	671	7,162,346	5,596,320	8,728,371	453	100%
Pravastatin sodium	796	7,107,304	5,696,312	8,518,297	453	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		
Tramadol hydrochloride	1,538	7,094,167	5,816,108	8,372,226	453	100%
Insulin glargine, hum.rec.anlog	913	7,043,943	5,665,225	8,422,662	453	100%
Tamsulosin hydrochloride	1,121	6,459,519	5,386,026	7,533,011	453	100%
Rosuvastatin calcium	623	6,455,969	5,022,005	7,889,932	453	100%
Warfarin sodium	1,461	6,227,617	4,948,224	7,507,009	453	100%
Citalopram hydrobromide	1,193	6,162,335	4,905,285	7,419,386	453	100%
Duloxetine hydrochloride	1,027	5,762,753	4,686,629	6,838,877	453	100%
Alprazolam	1,001	5,721,511	4,070,707	7,372,316	431	95%
Bupropion hydrochloride	842	5,671,080	4,278,586	7,063,573	453	100%
Allopurinol	700	5,611,769	4,097,596	7,125,942	453	100%
Escitalopram oxalate	1,005	5,458,985	3,980,923	6,937,048	453	100%
Clonazepam	1,021	5,412,372	3,844,548	6,980,196	453	100%
Alendronate sodium	634	5,311,767	4,332,803	6,290,730	453	100%
Fluoxetine hydrochloride	778	5,305,711	3,886,373	6,725,049	453	100%
Prednisone	926	5,071,601	4,328,413	5,814,790	453	100%
Hydralazine hydrochloride	671	5,038,406	3,892,650	6,184,161	453	100%
Divalproex sodium	1,376	5,034,585	3,828,665	6,240,504	453	100%
Sitagliptin phosphate	725	5,030,546	4,050,532	6,010,559	433	96%
Meloxicam	812	4,961,315	3,941,103	5,981,528	453	100%
Diltiazem hydrochloride	679	4,680,461	3,560,154	5,800,768	453	100%
Lisinopril/hydrochlorothiazide	424	4,523,987	3,156,159	5,891,816	453	100%
Risperidone	1,065	4,499,424	2,818,568	6,180,279	453	100%
Lovastatin	436	4,474,108	3,137,442	5,810,774	452	100%
Isosorbide mononitrate	617	4,433,861	3,172,550	5,695,171	453	100%
Oxycodone hydrochloride/acetaminophen	867	4,258,435	3,083,475	5,433,395	453	100%
Pregabalin	634	4,209,760	3,059,720	5,359,800	453	100%
Losartan/hydrochlorothiazide	409	4,196,780	3,104,339	5,289,220	453	100%
Baclofen	756	4,153,577	3,192,191	5,114,963	453	100%
Latanoprost	728	4,152,578	3,393,595	4,911,561	453	100%
Esomeprazole magnesium	614	4,106,582	3,259,331	4,953,832	365	81%
Mirtazapine	1,073	4,083,960	3,336,113	4,831,806	453	100%
Ibuprofen	657	4,067,142	3,310,197	4,824,087	453	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		
Donepezil hydrochloride	1,105	3,994,691	3,054,709	4,934,674	453	100%
Diclofenac sodium	679	3,948,979	2,933,779	4,964,178	453	100%
Atenolol	471	3,897,251	3,144,084	4,650,417	453	100%
Insulin detemir	743	3,745,481	2,591,971	4,898,991	318	70%
Insulin aspart	626	3,702,127	2,696,097	4,708,157	315	70%
Cyclobenzaprine hydrochloride	547	3,701,331	2,741,016	4,661,647	453	100%
Oxybutynin chloride	567	3,666,305	2,493,019	4,839,591	453	100%
Lorazepam	958	3,647,683	2,921,958	4,373,407	453	100%
Famotidine	833	3,609,674	2,855,735	4,363,612	453	100%
Levetiracetam	803	3,536,946	2,654,103	4,419,789	453	100%
Buspirone hydrochloride	608	3,428,445	2,231,218	4,625,673	453	100%
Tizanidine hydrochloride	561	3,423,732	2,332,892	4,514,573	452	100%
Rivaroxaban	555	3,259,590	2,384,089	4,135,092	446	98%
Budesonide/formoterol fumarate	420	3,241,842	2,346,422	4,137,263	330	73%
Memantine hydrochloride	1,044	3,144,442	2,443,810	3,845,073	453	100%
Zolpidem tartrate	467	3,113,250	2,083,100	4,143,400	443	98%
Naproxen	460	3,036,105	2,409,834	3,662,375	453	100%
Venlafaxine hydrochloride	458	2,956,824	2,020,943	3,892,704	453	100%
Paroxetine hydrochloride	415	2,894,034	1,991,599	3,796,470	453	100%
Fluticasone propion/salmeterol	491	2,869,524	2,120,479	3,618,570	452	100%
Lamotrigine	655	2,839,897	1,979,208	3,700,587	453	100%
Apixaban	696	2,838,805	2,197,143	3,480,467	449	99%
Oxycodone hydrochloride	456	2,824,439	2,111,379	3,537,498	452	100%
Clonidine hydrochloride	489	2,806,732	2,019,967	3,593,496	453	100%
Glimepiride	362	2,775,354	1,967,525	3,583,183	453	100%
Topiramate	460	2,683,070	1,816,924	3,549,217	453	100%
Spironolactone	460	2,673,655	2,002,489	3,344,821	453	100%
Azithromycin	516	2,645,727	2,167,706	3,123,748	453	100%
Olanzapine	658	2,612,191	1,540,447	3,683,936	453	100%
Aripiprazole	591	2,533,246	1,784,392	3,282,100	453	100%
Ropinirole hydrochloride	333	2,507,981	1,560,854	3,455,107	453	100%
Insulin lispro	344	2,429,402	1,861,720	2,997,085	200	44%
Alcohol antiseptic pads*	255	2,422,330	1,535,549	3,309,111	Supply Item	Supply Item

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		
Valsartan	338	2,289,727	1,622,488	2,956,965	450	99%
Polyethylene glycol 3350*	716	2,272,209	1,727,596	2,816,821	Excluded	Excluded
Fluticasone/vilanterol	332	2,238,025	1,318,958	3,157,092	425	94%
Nifedipine	324	2,167,546	1,331,366	3,003,726	451	100%
Cephalexin	425	2,157,330	1,818,130	2,496,529	453	100%
Benzotropine mesylate	614	2,119,803	1,437,028	2,802,578	453	100%
Pioglitazone hydrochloride	194	2,102,417	1,711,803	2,493,030	453	100%
Finasteride	362	2,061,017	1,398,907	2,723,126	453	100%
Amitriptyline hydrochloride	347	2,058,618	1,316,343	2,800,892	453	100%
Diazepam	278	2,018,245	1,435,439	2,601,052	453	100%
Tiotropium bromide	251	1,989,312	1,369,967	2,608,658	297	66%
Celecoxib	265	1,923,378	1,257,384	2,589,373	436	96%
Amoxicillin	424	1,912,429	1,610,851	2,214,007	453	100%
Ciprofloxacin hydrochloride	421	1,910,739	1,674,779	2,146,699	453	100%
Sulfamethoxazole/trimethoprim	455	1,902,153	1,624,159	2,180,147	453	100%
Triamcinolone acetonide	340	1,823,720	1,483,571	2,163,868	453	100%
Ezetimibe	192	1,741,807	1,102,083	2,381,531	453	100%
Acetaminophen with codeine	361	1,710,452	1,338,958	2,081,946	453	100%
Carbamazepine	399	1,710,047	1,107,813	2,312,280	453	100%
Brimonidine tartrate	284	1,692,540	1,207,251	2,177,829	453	100%
Ipratropium/albuterol sulfate	374	1,647,948	1,129,841	2,166,055	431	95%
Sucralfate	245	1,630,572	1,056,470	2,204,675	453	100%
Morphine sulfate	333	1,600,279	679,057	2,521,500	453	100%
Fentanyl	255	1,591,038	966,177	2,215,899	453	100%
Lactulose	404	1,587,102	1,024,068	2,150,136	453	100%
Chlorthalidone	167	1,585,674	876,774	2,294,574	453	100%
Cyclosporine	220	1,573,140	1,030,914	2,115,366	453	100%
Linagliptin	295	1,571,344	927,047	2,215,642	359	79%
Pramipexole di-hydrochloride	188	1,570,546	1,046,664	2,094,428	453	100%
Timolol maleate	172	1,568,598	1,102,539	2,034,656	453	100%
Digoxin	323	1,562,903	1,037,589	2,088,216	453	100%
Amoxicillin/potassium clav	317	1,547,684	1,232,196	1,863,173	453	100%
Propranolol hydrochloride	317	1,540,435	865,875	2,214,994	453	100%
Sitagliptin phos/metformin hydrochloride	154	1,539,194	1,014,910	2,063,478	432	95%

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		
Ketoconazole	364	1,537,124	1,129,720	1,944,528	453	100%
Valsartan/hydrochlorothiazide	156	1,501,351	1,001,360	2,001,342	448	99%
Meclizine hydrochloride	310	1,500,876	1,055,398	1,946,353	453	100%
Enalapril maleate	115	1,476,000	828,752	2,123,248	453	100%
Fenofibrate	213	1,460,807	817,304	2,104,309	452	100%
Gemfibrozil	120	1,454,319	721,301	2,187,337	453	100%
Olopatadine hydrochloride	233	1,439,133	1,119,506	1,758,761	431	95%
Solifenacin succinate	224	1,430,873	763,888	2,097,857	342	75%
Bimatoprost	191	1,422,244	923,431	1,921,056	429	95%
Levofloxacin	315	1,416,217	1,139,333	1,693,100	453	100%
Temazepam	215	1,406,177	847,474	1,964,880	418	92%
Fenofibrate nanocrystallized	165	1,401,213	804,959	1,997,467	448	99%
Dulaglutide	214	1,379,221	715,892	2,042,551	411	91%
Doxycycline hyclate	280	1,348,381	1,058,266	1,638,496	452	100%
Methylprednisolone	228	1,339,280	1,122,951	1,555,608	453	100%
Doxazosin mesylate	195	1,336,241	739,025	1,933,456	453	100%
Linaclotide	253	1,324,567	790,461	1,858,672	419	92%
Dexlansoprazole	217	1,288,483	754,355	1,822,611	226	50%
Verapamil hydrochloride	128	1,268,049	653,702	1,882,395	453	100%
Insulin degludec	84	1,265,827	761,875	1,769,780	298	66%
Omega-3 acid ethyl esters	123	1,251,856	772,322	1,731,391	345	76%
Levocetirizine dihydrochloride	142	1,242,820	541,799	1,943,840	453	100%
Promethazine hydrochloride	292	1,203,756	702,031	1,705,480	450	99%
Triamterene/hydrochlorothiazid	131	1,201,873	653,212	1,750,534	453	100%
Dicyclomine hydrochloride	181	1,191,989	666,466	1,717,512	453	100%
Metoclopramide hydrochloride	201	1,186,831	555,336	1,818,326	453	100%
Umeclidinium bromide	141	1,170,164	795,429	1,544,899	314	69%
Torsemide	222	1,166,925	565,881	1,767,970	434	96%
Fluconazole	237	1,155,400	877,134	1,433,666	453	100%
Bumetanide	179	1,141,446	633,323	1,649,568	453	100%
Lidocaine	197	1,138,762	659,494	1,618,030	453	100%
Benazepril hydrochloride	153	1,135,052	729,076	1,541,027	452	100%
Ramipril	144	1,126,063	647,924	1,604,202	453	100%
Ondansetron hydrochloride	275	1,115,147	848,687	1,381,607	453	100%
Dextroamphetamine/amphetamine	237	1,100,231	411,222	1,789,240	453	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		
Colchicine	184	1,082,482	475,136	1,689,828	453	100%
Carbidopa/levodopa	312	1,072,686	557,328	1,588,044	453	100%
Methotrexate sodium	126	1,053,620	440,553	1,666,687	453	100%
Liraglutide	103	1,051,570	538,034	1,565,107	422	93%
Mupirocin	221	1,028,462	710,526	1,346,398	453	100%
Hydroxyzine hydrochloride	214	1,009,571	649,429	1,369,712	431	95%
Ammonium lactate	182	1,007,852	653,393	1,362,310	453	100%
Nitroglycerin	188	1,002,575	807,755	1,197,395	453	100%
Ipratropium bromide	186	993,728	468,799	1,518,656	453	100%
Ondansetron	225	985,202	657,129	1,313,276	453	100%
Prazosin hydrochloride	53	953,109	510,678	1,395,541	453	100%
Ranolazine	119	926,783	484,244	1,369,322	453	100%
Haloperidol	227	916,058	461,131	1,370,985	453	100%
Prednisolone acetate	136	897,900	578,153	1,217,647	453	100%
Amiodarone hydrochloride	163	896,941	595,377	1,198,505	453	100%
Doxepin hydrochloride	132	892,918	429,001	1,356,836	453	100%
Metronidazole	164	885,694	651,846	1,119,541	453	100%
Oxcarbazepine	243	885,091	502,053	1,268,130	453	100%
Lacosamide	269	873,237	457,471	1,289,004	453	100%
Chlorpromazine hydrochloride	82	872,727	330,681	1,414,773	453	100%
Hydroxychloroquine sulfate	97	869,105	411,229	1,326,981	453	100%
Dorzolamide hydrochloride/timolol maleat	105	863,762	460,381	1,267,142	453	100%
Lubiprostone	225	849,124	489,606	1,208,643	223	49%
Ergocalciferol (vitamin D ₂)*	171	840,429	464,809	1,216,050	Excluded	Excluded
Canagliflozin	95	831,706	286,521	1,376,890	196	43%
Isosorbide dinitrate	106	820,865	425,940	1,215,790	453	100%
Nitrofurantoin monohyd/m-cryst	176	814,269	617,527	1,011,011	443	98%
Dapagliflozin propanediol	59	809,582	235,628	1,383,535	301	66%
Valproic acid	107	809,352	289,961	1,328,743	453	100%
Clozapine	284	782,771	270,037	1,295,504	453	100%
Phenytoin sodium extended	107	763,138	340,031	1,186,244	453	100%
Dabigatran etexilate mesylate	88	761,362	337,532	1,185,191	351	77%
Empagliflozin	90	747,475	322,828	1,172,122	423	93%
Buprenorphine hydrochloride/naloxone hydrochloride*	81	733,267	-28,179	1,494,713	Excluded	Excluded

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		
Travoprost	179	729,170	502,768	955,573	362	80%
Anastrozole	93	726,636	353,068	1,100,204	453	100%
Brimonidine tartrate/timolol	151	725,204	461,848	988,560	412	91%
Desvenlafaxine succinate	83	719,524	212,410	1,226,638	451	100%

Source: OIG analysis of drugs commonly used by dual eligibles, 2021. Sample is from the 2018 MCBS. Projections and confidence intervals are derived from its survey methodology.

*Drugs excluded from the analysis. See Appendix D.

APPENDIX D

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

In 2021, 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 D ₂)	Vitamin or mineral product not covered under Part D
Buprenorphine hydrochloride/naloxone hydrochloride	Unable to confidently project use to entire dual-eligible population
Ranitidine hydrochloride	Drug no longer offered

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2021.

APPENDIX E

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

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

Across all 34 PDP regions, the rates of formularies' inclusion of commonly used drugs ranged from 89 percent to 99 percent. The average rate of inclusion was 96 percent for all PDP regions.

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	71	98%	97%	98%
2	Connecticut, Massachusetts, Rhode Island, Vermont	146	97%	92%	98%
3	New York	233	97%	92%	98%
4	New Jersey	74	97%	90%	98%
5	Delaware, the District of Columbia, Maryland	50	98%	96%	98%
6	Pennsylvania, West Virginia	204	97%	90%	98%
7	North Carolina, Virginia	197	98%	93%	99%
8	Georgia, South Carolina	207	98%	95%	99%
9	Florida	492	98%	90%	99%
10	Alabama, Tennessee	171	98%	96%	100%
11	Michigan	104	97%	95%	100%
12	Ohio	168	97%	92%	100%
13	Indiana, Kentucky	186	98%	95%	98%

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	225	97%	89%	100%
15	Arkansas, Missouri	166	97%	90%	99%
16	Louisiana, Mississippi	117	97%	95%	98%
17	Texas	237	98%	92%	99%
18	Kansas, Oklahoma	103	98%	96%	99%
19	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	165	97%	92%	98%
20	Colorado, New Mexico	102	98%	92%	98%
21	Arizona	113	97%	96%	98%
22	Nevada	72	97%	94%	98%
23	Idaho, Oregon, Utah, Washington	290	98%	92%	100%
24	California	413	97%	93%	99%
25	Hawaii	23	97%	92%	98%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2021.

* Region 26, which covers Alaska, had no MA-PDs available for 2021.

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Contact

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Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

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