DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

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/S/

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SUBJECT: Memorandum Report: *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2015*, OEI-05-15-00120

This memorandum report fulfills the annual reporting mandate from the Patient Protection and Affordable Care Act (ACA) for 2015. The ACA requires that the Office of Inspector General (OIG) conduct a study of the extent to which formularies used by stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) under Medicare Part D include drugs commonly used by full-benefit dual-eligible individuals (i.e., individuals who are eligible for both Medicare and full Medicaid benefits).[1] Pursuant to the ACA, OIG must annually issue a report, with recommendations as appropriate. This is the fifth report that OIG has produced to meet this mandate. For the relevant text of the ACA, see Appendix A.

SUMMARY

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 PDPs and MA-PDs (hereinafter referred to collectively as Part D plans).[2]

For beneficiaries who are eligible for both Medicare and Medicaid (hereinafter referred to as dual eligibles), Medicare covers 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.

[1] ACA, P.L. No. 111-148 § 3313(a), 42 U.S.C. § 1395w-101 note.
[2] MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-1(a).

To control costs and ensure the safe use of drugs, Part D plans are allowed to establish formularies from which they may omit drugs from prescription coverage and are allowed to control drug utilization through utilization management tools.[3] These tools include prior authorization, quantity limits, and step therapy.[4]

The Centers for Medicare & Medicaid Services (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.

For this memorandum report, we determined whether the 341 unique formularies used by the 3,152 Part D plans operating in 2015 cover the 200 drugs most commonly used by dual eligibles. We also determined the extent to which those commonly used drugs are subject to utilization management tools.

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. On average, Part D plan formularies include 95 percent of the commonly used drugs. In addition, 71 percent of the commonly used drugs are included by all Part D plan formularies.

We also found that from 2014 to 2015, the proportion of unique drugs subject to utilization management tools remained relatively the same. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2015, compared to 28 percent of those we reviewed in 2014.

The results of our analysis for 2015 are largely unchanged from OIG's findings in 2011, 2012, 2013, and 2014.[5, 6, 7, 8]

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

[4] 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 risky drug therapy.

[5] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles*, OEI-05-10-00390, April 2011.

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

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

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

BACKGROUND

The Medicare Prescription Drug Benefit

Beginning in 2006, the MMA made comprehensive prescription drug coverage under Medicare Part D available to all Medicare beneficiaries.[9] 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. As of April 2015, approximately 39.1 million of the 53.6 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.[10] In 2015, plan sponsors offer 3,152 unique Part D plans, with many plan sponsors offering multiple Part D plans.

Dual Eligibles Under Medicare Part D

Approximately 10.7 million Medicare beneficiaries are dual eligibles. About 7.7 million dual eligibles, referred to as "full-benefit dual eligibles," receive full Medicaid benefits and may receive assistance with premiums and cost-sharing for Medicare fee-for-service or Medicare managed care.[11] Other dual eligibles receive only assistance with their Medicare premiums or cost-sharing, depending on their level of income and assets.

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.[12] 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.[13] 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.[14]

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[9] MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-1(a).
[10] CMS, *Prescription Drug Benefit Manual (PDBM)*, Pub. 100-18, ch. 5, Appendixes 2 and 3. Accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html on April 14, 2015.
[11] Centers for Medicare & Medicaid Services, Data Tables for Medicare-Medicaid Enrollment and Eligibility Trends, 2013. Accessed at http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics.html on April 22, 2015.
[12] Kaiser Family Foundation, *Medicare's Role for Dual Eligible Beneficiaries.* Accessed at http://www.kff.org/medicare/upload/8138-02.pdf on April 20, 2015.
[13] Ibid.
[14] MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-1(a).

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.[15, 16] 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.[17]

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.[18] CMS assigns dual eligibles to PDPs that meet certain requirements, such as having a premium at or below the regional benchmark amount and offering basic prescription drug coverage (or equivalent).[19] Basic prescription drug coverage is defined in terms of benefit structure (initial coverage, coverage gap, and catastrophic coverage) and costs (initial deductible and coinsurance).

Some dual eligibles may be randomly assigned to PDPs that do not cover the specific drugs they use. However, unlike the general Medicare population, dual eligibles can switch plans at any time to find Part D plans that cover the prescription drugs they require.[20] When dual eligibles 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 their current PDPs will have premiums above the regional benchmark premium for the following year.[21] CMS reassigns dual eligibles who were randomly assigned to their current PDPs to new PDPs that will have premiums at or below the regional benchmark premium.[22] In addition, CMS notifies dual eligibles who elected their current Part D plans that their plans will have premiums above the regional benchmark premium. For 2015, CMS reported reassigning approximately 372,000 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

[15] Social Security Act, § 1860D-14(b); 42 CFR § 423.780(b)(2)(i).

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

[17] 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. Patient Protection and Affordable Care Act (ACA), P.L. No. 111-148 § 3303, Social Security Act, § 1860D-14(a)(5). For 2014, CMS set the de minimis amount at $2 above the regional benchmark.

[18] CMS, *PDBM*, ch. 3, § 40.1.4.

[19] Ibid.

[20] Ibid., § 30.3.2. In general, Medicare beneficiaries can switch Part D plans only once a year during a defined enrollment period.

[21] Ibid., § 40.1.5.

[22] Ibid.

balance Medicare beneficiaries' needs for adequate prescription drug coverage with Part D plans' needs to contain costs. Generally, a formulary must include at least two drugs in each therapeutic category or class.[23, 24] In addition, Part D plans must include Part D-covered drugs in certain categories and classes.[25]

Part D plans may also control drug utilization by applying utilization management tools. These tools include 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 made regarding individual formularies, certain categories of drugs are excluded from Medicare Part D prescription drug coverage as mandated by the MMA.[26] For example, prescription vitamins, prescription mineral products, and nonprescription drugs are excluded from Part D prescription drug coverage.[27]

Until 2013, barbiturates and benzodiazepines were excluded from Part D prescription drug coverage. However, the ACA reversed this exclusion, removing these two drug types from the list of drug classes ineligible for Part D prescription drug coverage.[28,29]

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 and include all drugs in specified therapeutic categories or classes.[30] 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 (e.g., 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.[31]

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[23] CMS, *PDBM*, ch. 6, § 30.2.1.
[24] 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.
[25] Social Security Act, § 1860D-4(b)(3)(G).
[26] MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-2(e).
[27] Social Security Act § 1860D-2(e)(2), 1927(d)(2).
[28] ACA, P.L. No. 111-148 § 2502, Social Security Act, § 1397r-8(d).
[29] 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 April 29, 2015.
[30] CMS, *PDBM*, ch. 6, § 30.2.7.
[31] Ibid.

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.[32, 33, 34]

Exceptions and appeals process. CMS has implemented an exceptions and appeals process whereby beneficiaries can request coverage of nonformulary drugs. Beneficiaries apply to their Part D plans for exceptions to obtain coverage of nonformulary drugs. Generally, Part D plans must make determinations within 72 hours or, for expedited requests, within 24 hours.[35] If their plans make negative determinations, beneficiaries have the right to appeal.[36] If their plans deny their appeals, beneficiaries would need to get prescriptions from their physicians for therapeutically alternative drugs that are covered by their plans.

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 refill of a prescription when beneficiaries request 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.[37] The temporary fill accommodates beneficiaries' immediate drug needs the first time they attempt to fill a prescription. The transition period also allows beneficiaries time to work with their prescribing physicians to obtain prescriptions for therapeutically alternative drugs or to request formulary exceptions from Part D plans.

Related OIG Work

In 2006, 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.[38]

In 2011, OIG issued the first annual mandated memorandum report examining dual eligibles' access to drugs under Medicare Part D.[39] In 2012, OIG issued the second annual mandated memorandum report examining dual eligibles' access to drugs under

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[32] Ibid., § 30.2.2.
[33] Ibid., § 30.2.7.
[34] CMS looks to appropriate guidelines from expert organizations such as the National Committee for Quality Assurance, the Academy of Managed Care Pharmacy, and the National Association of Insurance Commissioners.
[35] CMS, *PDBM*, ch. 18, §§ 30.1 and 30.2.
[36] Ibid., § 60.1.
[37] Ibid., ch. 6, § 30.4.4.
[38] OIG, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090, January 2006.
[39] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles*, OEI-05-10-00390, April 2011.

Medicare Part D.[40] In 2013, OIG issued the third annual mandated memorandum report examining dual eligibles' access to drug under Medicare Part D.[41] In 2014, OIG issued the fourth annual mandated memorandum report.[42] In the current memorandum report, we compare the results from 2014 and 2015.

METHODOLOGY

Scope

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 2015. As part of our assessment, we included dual eligibles' enrollment data from April 2015, the most recent enrollment data available from CMS at the time of our study. We also compared the results of our 2015 study with those of our 2014 study.[43]

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 latest Medicare Current Beneficiary Survey (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, 196 are eligible for coverage under Part D. In this report, we refer to these 196 Part D-eligible high-utilization drugs as "commonly used drugs."

The list of 200 drugs with the highest utilization by dual eligibles referenced in this 2015 memorandum report is similar but not identical to the list of drugs referenced in the 2014 memorandum report. Specifically, 185 of the 200 drugs (93 percent) listed in the 2014 memorandum report are also listed in this 2015 memorandum report.

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.

We also went beyond the ACA's mandate in the 2013, 2014, and 2015 reports 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 where formularies include the commonly used drugs. Analyzing the extent

[40] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2012,* OEI-05-12-00060, June 2012.
[41] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2013*, OEI-15-13-00090, June 2013.
[42] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2014*, OEI-05-14-00170, June 2014.
[43] Ibid.

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 2011 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, and prescription drug costs and utilization. The 2011 MCBS Cost and Use data are the most recent data available.

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 what 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 2011, the MCBS surveyed 10,901 Medicare beneficiaries, of whom 2,149 were dual eligibles who had used prescription drugs during the year (out of 2,402 dual-eligible survey respondents).

First Databank National Drug Data File. We used the April 2015 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).[44]

Part D plan data. In January 2015, we collected from CMS the formulary data and the plan data for Part D plans operating in 2015. The formulary data includes Part D plans' formularies and utilization management tools for plans operating in 2015. In 2015, there are 341 unique formularies offered by 3,152 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 2015 enrollment data for Part D plans. These data provide the number of dual eligibles enrolled in each Part D plan as of April 2015.

[44] 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 MCBS. We excluded respondents from territories because they are not eligible to receive cost-sharing assistance under Part D. The MCBS listed 155,265 drug events for 2,149 dual eligibles who did not reside in territories.[45]

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 155,265 drug events associated with 872 drugs.

3. We ranked the 872 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 B.

5. We removed all drugs not covered under Part D. Of the 200 drugs with the highest utilization, 196 are eligible under Part D. Three fell into drug categories excluded under Part D, and one is no longer prescribed in the form taken by beneficiaries surveyed in the 2011 MCBS. For details on these four drugs, see Appendix C.

Formulary Analysis

We analyzed the 341 unique Part D plan formularies to determine their rates of inclusion of the 196 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. When a drug included multiple ingredients that could be dispensed separately and combined by the patient to the same effect as the combined drug, we treated the drug as included if the ingredients were included in the formulary either separately or in combination.

Low rates of inclusion by formularies. We determined which of the 196 commonly used drugs had low rates of inclusion by formularies by counting how many of the

[45] 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 2011. For example, one MCBS survey respondent reported taking zolpidem tartrate (Ambien) seven times in 2011. We counted this beneficiary/drug combination as seven drug events.

341 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 196 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 196 drugs that we reviewed. The tools that we reviewed are prior authorization, quantity limits, and step therapy.

To determine the extent to which the 196 commonly used drugs are subject to utilization management tools, 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 196 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 April 2015 to Part D plans available in 2015.

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 relied on a sample of dual eligibles responding to the MCBS to develop our list of commonly used drugs, a particular dual eligible might not use any of the drugs on our list. However, the drugs most commonly used by dual-eligible MCBS survey participants in 2011 account for 88 percent of all prescriptions dispensed to the dual-eligible respondents in the 2011 MCBS.

Because the lists of commonly used drugs in the 2014 and 2015 memorandum reports are not identical, the changes in rates of inclusion by formularies and in application of utilization management tools between 2014 and 2015 may reflect changes as to which specific drugs were included in the lists, rather than changes regarding any specific drug. However, the two lists largely overlap; 93 percent of the drugs on the list in our 2014 report were also on the list in this 2015 memorandum report.

Standards

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

RESULTS

Part D Plan Formularies Include Between 86 and 100 Percent of the Drugs Commonly Used by Dual Eligibles

On average, Part D plan formularies include 95 percent of the drugs commonly used by dual eligibles. Of the 341 unique formularies used by Part D plans in 2015, 12 formularies include 100 percent of the commonly used drugs. At the other end of the inclusion range, one formulary includes 86 percent of the commonly used drugs. 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 they do not include all of the drugs we identified as commonly used by dual eligibles.

Part D plan formularies' rate of inclusion of the drugs commonly used by dual eligibles in 2015 is nearly identical to that of 2014. The average rate of inclusion decreased slightly between 2014 and 2015, from 96 percent to 95 percent. The range of inclusion rates was the same in 2015 as in 2014—from 86 to 100 percent of the drugs.

Nationally, PDP and MA-PD formularies have similar rates of inclusion of the drugs commonly used by dual eligibles, averaging 94 percent and 95 percent, respectively. For PDP formularies, the rates of inclusion ranged from 88 to 100 percent; for MA-PD formularies, they ranged from 86 to 100 percent. Eighteen formularies—5 percent of the 341 unique formularies used by Part D plans in 2015—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 98 percent of the commonly used drugs, and every MA-PD region has a plan that includes at least 98 percent of these drugs. Appendix D 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 95 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 88 percent to 100 percent. Approximately 86 percent of dual eligibles are enrolled in Part D plans with premiums below the regional benchmark.

Ninety-four percent of 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 9.7 million dual eligibles enrolled in Part D plans, 94 percent are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. Only 6 percent of dual eligibles are enrolled in Part D plans that use formularies that include less than 90 percent of these drugs. Table 1 provides a breakdown of dual eligibles' enrollment in Part D plans by the plans' formulary inclusion rates.

Table 1: Enrollment of Dual Eligibles in Part D Plans and Formulary Inclusion of Commonly Used Drugs

Part D Plans With Formularies That Include:	Number of Dual Eligibles Enrolled*	Percentage of Dual Eligibles Enrolled
100% of commonly used drugs	159,954	2%
95% to 99% of commonly used drugs	2,209,253	23%
90% to 94% of commonly used drugs	6,866,185	70%
85% to 89% of commonly used drugs	548,415	6%
Total	**9,783,807**	**100%****

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles and dual eligibles' enrollment, 2015.
*Rounded to the nearest 1,000.
**Percentages do not add to 100 percent because of 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 decreased from 99 percent in 2014 to 94 percent in 2015.

Sixty-Six 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 are guaranteed that regardless of the Part D plan in which they are enrolled, the plan's formulary will include many of these drugs. By drug, formulary inclusion ranges from 33 percent to 100 percent. At one end of the range, there is a commonly used drug that is included in 33 percent of Part D plan formularies, and at the other end, 130 drugs are included in all plan formularies. The average rate of inclusion by formularies is 95 percent. Table 2 provides a summary of rates of inclusion by formularies. Appendix B lists the commonly used drugs and their respective rates of inclusion by formularies.

Table 2: Formularies' Rates of Inclusion of Commonly Used Drugs

Percentage of the 341 Formularies	Percentage of the 196 Commonly Used Drugs Included in Formularies
100%	66% (130 drugs)
85% to 99%	21% (42 drugs)
76% to 84%	7% (13 drugs)
33% to 75%	6% (11 drugs)
Total	**100% (196 drugs)**

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2015.

The rates of formulary inclusion of the drugs commonly used by dual eligibles in 2015 are similar to those in 2014. The percentage of commonly used drugs included in all formularies increased slightly between 2014 and 2015, from 64 percent to 66 percent.

Part D plan formularies include certain drugs less frequently than others. Of the commonly used drugs, 6 percent (11 drugs) are included by 75 percent or less of Part D plan formularies. Table 3 provides the percentage of formularies covering each of these 11 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. Six of the eleven drugs are brand-name drugs, which are typically more costly than generic drugs. As for the primary indications, 3 of the 11 drugs are used for diabetic therapy, 2 of the 11 drugs are muscle relaxants, and the remaining drugs treat a variety of conditions including overactive bladder, high cholesterol, anxiety, and hypertension.

Table 3: Drugs Included by 75 Percent or Less of Part D Plan Formularies

Generic Name of Drug	Primary Indication(s)	Rate of Inclusion by Formularies
Insulin lispro	Diabetes	75%
Valsartan*	Hypertension (high blood pressure)	67%
Glyburide/metformin HCl	Diabetes	62%
Glyburide	Diabetes	61%
Conjugated estrogen/medroxyprogesterone acet	Menopause	59%
Ezetimibe/simvastatin*	Hyperlipidemia (high cholesterol)	57%
Methocarbamol*	Musculoskeletal pain	55%
Esomeprazole magnesium*	Dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, Zollinger-Ellison syndrome	49%
Hydroxyzine pamoate*	Anxiety	46%
Carisoprodol*	Musculoskeletal pain	42%
Darifenacin hydrobromide*	Overactive bladder	33%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2015.
* These drugs also had low formulary inclusion rates in 2014.

Although Part D formularies frequently omit these 11 drugs, they all cover other drugs in the same therapeutic classes. For these 11 drugs, 100 percent of formularies cover at least 1 drug in the same therapeutic class that is also on the list of 196 drugs commonly used by dual eligibles.

The number of drugs included by 75 percent or less of formularies stayed the same—11 drugs—in 2014 and 2015. There are seven drugs with low inclusion rates in 2015 that were also on the list of commonly used drugs with low inclusion rates in our 2014 report; these drugs are noted in Table 3. Five of these seven drugs were also on the list of drugs with low inclusion rates in our 2013 report.

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

- Four of these drugs—methocarbamol, carisoprodol, conjugated estrogen/medroxyprogesterone, and hydroxyzine pamoate—are on CMS's list of Part D medications that are high-risk for the elderly.[46]
- Further, seven of these drugs—carisoprodol, darifenacin hydrobromide, hydroxyzine pamoate, methocarbamol, glyburide, glyburide/metformin HCl, and estrogens—are listed by the American Geriatrics Society as being potentially inappropriate for older adults.[47]

Low rates of inclusion by formularies may require dual eligibles to obtain a nonformulary drug. There are several means by which dual eligibles can obtain a nonformulary drug, all of which require them to take additional action. Obtaining therapeutically alternative drugs requires that dual eligibles get new prescriptions from their doctors. Dual eligibles may also submit statements of medical necessity from their physicians as part of appeals to obtain coverage of nonformulary drugs.[48] Finally, dual eligibles may switch to Part D plans that include their drugs, with the new coverage becoming effective the following month.[49]

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[46] This list—"Use of High-Risk Medications in the Elderly: High-Risk Medications" —is part of the Healthcare Effectiveness and Information Set national drug code measures published by the National Committee for Quality Assurance. A drug that is listed as being high risk for the elderly is one that has a high risk of serious side effects in that population. CMS uses this medication list to calculate the percentage of Medicare beneficiaries who received at least one high-risk medication in the past year. CMS publishes this percentage and other measures of Part D patient safety so that Medicare beneficiaries can make informed decision in choosing a Part D plan for their prescription drug coverage. National Committee on Quality Assurance, *HEDIS 2012 NDC List.* Accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPatientSafetyMeasures_071610.pdf on April 15, 2015.
[47] The American Geriatrics Society, *American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*, 2012.
[48] CMS, *PDBM*, ch. 18, § 30.2.2.
[49] Ibid., ch. 3, § 30.3.2.

The Percentage of Commonly Used Drugs Subject to Utilization Management Tools by Plan Formularies Increased Slightly Between 2014 and 2015

For the unique drugs that compose the list of commonly used drugs, the percentage subject to utilization management tools by Part D plan formularies increased slightly from an average of 28 percent in 2014 to an average of 29 percent in 2015. Formularies for plans with premiums below and those with premiums above the regional benchmarks had a similar percentage of drugs—27 percent and 29 percent, respectively—that were subject to utilization management tools. See Table 4 for a breakdown of the percentage of unique drugs to which Part D plan formularies apply utilization management tools in 2014 and 2015.

Table 4: Part D Plan Formularies' Application of Utilization Management Tools to Commonly Used Drugs, 2014 and 2015

Percentage of Unique Drugs to Which Utilization Management Tools Are Applied	Number of 2014 Part D Plan Formularies	Percentage of 2014 Part D Plan Formularies	Number of 2015 Part D Plan Formularies	Percentage of 2015 Part D Plan Formularies
Greater than 40%	30	9%	49	14%
30% to 39%	136	41%	137	40%
20% to 29%	65	20%	66	19%
10% to 19%	75	23%	65	19%
Less than 10%	23	7%	24	7%
Totals	**329**	**100%**	**341**	**100%***

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2015.
* Percentages do not add to 100 percent because of rounding.

The percentage of drugs subject to quantity limits or prior authorization increased slightly from 2014 to 2015, while the percentage of drugs subject to step therapy remained the same. Formularies' use of quantity limits and use of prior authorization each increased by 1 percent—from 24 to 25 percent and from 3 to 4 percent of unique drugs, respectively. The percentage of unique drugs for which formularies required step therapy was 2 percent in both 2014 and 2015.

The rate at which plan formularies apply specific utilization management tools varies widely. In 2015, some formularies applied utilization management tools to none of the unique drugs, whereas at the other end of the range, some applied tools to 47 percent of the unique drugs. More specifically, formularies apply quantity limits to between 0 and 43 percent of unique drugs, require prior authorization for between 0 and 10 percent, and require step therapy for between 0 and 15 percent.

Looking at enrollment across plans provides a slightly different picture than looking only at plans themselves. On average, plan formularies in 2015 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 2015, the median plan weighted by dual-eligible enrollment applies such tools to 35 percent of unique drugs; in 2014, the figure was 34 percent. Similarly, the median plan weighted by overall Medicare enrollment applies these tools to 34 percent of unique drugs in 2015; in 2014, the figure was 33 percent.

Both dual eligibles and Medicare beneficiaries overall tend to be enrolled in plans with formularies that apply utilization management tools to between 30 and 47 percent of unique drugs. In 2015, 63 percent of dual eligibles and 57 percent of Medicare beneficiaries overall were enrolled in plans with formularies in this range. Table 5 shows enrollment in Part D plans by dual eligibles and Mediciare beneficiaries, as broken down by the percentages at which the plans' formularies' apply utilization management tools.

Table 5: Beneficiary Enrollment in Part D Plans by Application of Utilization Management Tools to Commonly Used Drugs, 2014 and 2015

Percentage of Unique Drugs to Which Plan Formularies Apply Utilization Management Tools	Percentage of Dual Eligibles Enrolled, 2014	Percentage of Medicare Beneficiaries Enrolled, 2014	Percentage of Dual Eligibles Enrolled, 2015	Percentage of Medicare Beneficiaries Enrolled, 2015
Greater than 40%	5%	14%	8%	16%
30% to 39%	63%	44%	54%	41%
20% to 29%	7%	6%	32%	34%
10% to 19%	24%	32%	4%	5%
Less than 10%	2%	4%	2%	3%
Totals	**100%***	**100%**	**100%**	**100%***

Source: OIG analysis of dual-eligible enrollment and Medicaid beneficiary enrollment by rates of utilization management tool application to drugs commonly used by dual eligibles, 2015.
*Percentages do not add to 100 percent because of rounding.

Further, although utilization management tools control access to drugs, they are important tools for managing costs in Medicare and ensuring appropriate utilization of drugs. For example, oxycodone HCl/acetaminophen drugs saw more than a 30-percent increase in formulary application of utilization management controls in 2013. Such limits may be intended to ensure appropriate utilization, as CMS's Part D 2013 guidance to Part D sponsors set forth expectations for reviews of opioid overutilization to help ensure that opioids are prescribed and used correctly.[50]

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 themselves and for the Part D program. By law, Part D plan formularies do not 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 memorandum report identifies as being included by 75 percent or less of Part D plan formularies, all Part D plan formularies cover at least one therapeutically alternative drug. 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

[50] CMS, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf on April 29, 2015.

95 percent of the commonly used drugs. Part D plan formularies' inclusion of the commonly used drugs ranges from 86 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.

Inclusion rates for the 196 drugs commonly used by dual eligibles are largely unchanged compared with those from OIG's 2014 memorandum report. Part D plan formularies include roughly the same percentage of these commonly used drugs in 2015 as they did in 2014. Enrollment in plans that cover at least 90 percent of unique drugs decreased slightly, with 94 percent of dual eligibles enrolled in such plans in 2015 compared to 99 percent in 2014.

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

As mandated by the ACA, OIG will continue to monitor 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.

This memorandum report is being issued directly in final form because it contains no recommendations. We have included the list of the 200 drugs with the highest utilization by dual eligibles. If you have comments or questions about this memorandum report, please provide them within 60 days. Please refer to report number OEI-05-15-00120 in all correspondence.

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

Commonly Used Drugs and Rates of Inclusion by Formularies

Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Simvastatin	3,900	17,347,406	15,514,367–19,180,445	340	100%
Lisinopril	3,853	17,267,881	15,114,378–19,421,384	341	100%
Hydrocodone/acetaminophen	4,632	16,947,722	15,258,697–18,636,747	341	100%
Omeprazole	4,014	15,672,875	14,093,417–17,252,333	341	100%
Levothyroxine sodium	3,476	14,830,579	13,126,542–16,534,615	341	100%
Furosemide	3,428	14,434,347	12,915,250–15,953,443	341	100%
Amlodipine besylate	2,919	13,077,400	11,368,250–14,786,550	341	100%
Metformin HCl	2,865	12,804,478	11,154,960–14,453,996	341	100%
Potassium chloride	2,745	10,583,238	9,213,268–11,953,209	341	100%
Metoprolol tartrate	2,352	9,997,980	8,527,265–11,468,696	341	100%
Gabapentin	1,856	7,678,814	6,546,945–8,810,682	341	100%
Warfarin sodium	1,969	7,669,750	6,220,257–9,119,244	341	100%
Atorvastatin calcium	1,658	7,345,895	6,149,446–8,542,344	341	100%
Hydrochlorothiazide	1,557	6,986,485	5,967,217–8,005,753	341	100%
Clopidogrel bisulfate	1,544	6,943,517	5,750,562–8,136,471	341	100%
Albuterol sulfate	1,594	6,785,246	5,751,649–7,818,843	341	100%
Esomeprazole magnesium	1,409	6,620,580	5,333,170–7,907,989	167	49%
Citalopram hydrobromide	1,680	6,426,818	5,291,102–7,562,533	341	100%
Atenolol	1,308	6,334,483	5,181,329–7,487,637	341	100%
Tramadol HCl	1,443	5,544,220	4,444,084–6,644,356	341	100%
Zolpidem tartrate	1,310	5,454,634	4,429,932–6,479,336	328	96%
Carvedilol	1,236	5,320,616	4,330,462–6,310,771	341	100%
Ranitidine HCl	1,381	5,134,725	3,948,479–6,320,972	341	100%
Valsartan	1,074	4,944,768	3,960,182–5,929,353	228	67%
Trazodone HCl	1,289	4,925,948	3,836,052–6,015,844	341	100%
Oxycodone HCl/acetaminophen	1,346	4,865,501	3,572,611–6,158,391	341	100%
Glipizide	1,118	4,768,378	3,897,329–5,639,428	341	100%
Sertraline HCl	1,186	4,657,331	3,757,053–5,557,609	341	100%
Fluticasone/salmeterol	1,037	4,647,993	3,735,988–5,559,997	304	89%
Metoprolol succinate	874	4,576,199	3,687,311–5,465,088	340	100%
Insulin glargine,hum.rec.anlog	1,057	4,519,573	3,638,096–5,401,051	329	96%
Alendronate sodium	1,098	4,517,069	3,714,312–5,319,827	341	100%
Risperidone	1,337	4,321,416	3,370,755–5,272,076	341	100%
Quetiapine fumarate	1,486	4,139,968	3,230,748–5,049,188	341	100%

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Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles, *continued*

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Prednisone	1,043	4,060,613	3,342,786–4,778,439	341	100%
Fluticasone propionate	967	3,994,341	3,322,845–4,665,836	341	100%
Rosuvastatin calcium	749	3,946,728	3,150,322–4,743,134	279	82%
Pravastatin sodium	792	3,669,913	2,920,688–4,419,137	341	100%
Donepezil HCl	1,100	3,629,564	2,875,141–4,383,988	341	100%
Isosorbide mononitrate	748	3,561,729	2,815,323–4,308,136	341	100%
Cyclobenzaprine HCl	802	3,507,572	2,743,874–4,271,270	340	100%
Montelukast sodium	845	3,433,580	2,539,837–4,327,323	341	100%
Pioglitazone HCl	740	3,315,739	2,511,944–4,119,534	341	100%
Diltiazem HCl	791	3,236,508	2,409,349–4,063,667	341	100%
Clonidine HCl	785	3,207,052	2,329,831–4,084,273	341	100%
Lovastatin	655	3,180,423	2,491,792–3,869,054	338	99%
Divalproex sodium	1,080	3,083,963	2,353,057–3,814,868	341	100%
Meloxicam	715	3,045,674	2,442,247–3,649,102	340	100%
Famotidine	716	3,002,313	2,222,260–3,782,365	340	100%
Allopurinol	721	2,959,137	2,201,749–3,716,525	341	100%
Ibuprofen	828	2,920,144	2,333,892–3,506,396	341	100%
Escitalopram oxalate	858	2,894,303	2,278,119–3,510,486	340	100%
Losartan potassium	587	2,883,618	2,142,589–3,624,648	341	100%
Bupropion HCl	689	2,871,472	2,059,562–3,683,383	341	100%
Amitriptyline HCl	666	2,871,130	1,827,969–3,914,291	341	100%
Glimepiride	632	2,851,481	2,001,228–3,701,734	341	100%
Lisinopril/hydrochlorothiazide	563	2,838,412	2,174,963–3,501,861	341	100%
Pantoprazole sodium	620	2,784,126	2,004,950–3,563,302	340	100%
Tiotropium bromide	593	2,775,253	2,119,646–3,430,860	332	97%
Tamsulosin HCl	670	2,757,815	2,144,214–3,371,415	341	100%
Azithromycin	723	2,640,943	2,265,620–3,016,265	341	100%
Oxycodone HCl	773	2,593,236	1,865,688–3,320,784	341	100%
Paroxetine HCl	692	2,592,058	1,793,177–3,390,938	341	100%
Duloxetine HCl	664	2,529,408	1,768,441–3,290,374	341	100%
Aripiprazole	784	2,509,941	1,849,321–3,170,561	341	100%
Alprazolam	722	2,507,449	1,908,250–3,106,648	313	92%
Celecoxib	549	2,487,716	1,753,302–3,222,130	272	80%
Enalapril maleate	628	2,486,122	1,773,448–3,198,796	341	100%
Triamterene/hydrochlorothiazide	489	2,472,394	1,698,398–3,246,390	341	100%
Fluoxetine HCl	671	2,442,283	1,858,877–3,025,689	341	100%
Lansoprazole	520	2,432,783	1,664,326–3,201,239	272	80%

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Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles, *continued*

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Memantine HCl	676	2,342,026	1,726,810–2,957,242	341	100%
Clonazepam	646	2,266,382	1,667,334–2,865,431	341	100%
Fexofenadine HCl	516	2,230,968	1,530,394–2,931,543		
Benztropine mesylate	805	2,226,864	1,615,882–2,837,845	340	100%
Ezetimibe	418	2,160,362	1,594,728–2,725,996	339	99%
Naproxen	557	2,141,422	1,665,511–2,617,333	341	100%
Carisoprodol	504	2,069,351	1,346,367–2,792,335	144	42%
Spironolactone	481	2,061,652	1,505,827–2,617,477	341	100%
Sulfamethoxazole/ trimethoprim	636	2,057,059	1,708,114–2,406,003	341	100%
Diclofenac sodium	477	2,044,525	1,547,162–2,541,887	341	100%
Valsartan/ hydrochlorothiazide	430	2,030,978	1,418,545–2,643,412	331	97%
Ciprofloxacin HCl	608	2,001,235	1,755,947–2,246,522	341	100%
Topiramate	720	1,991,977	1,240,195–2,743,760	341	100%
Mirtazapine	641	1,962,056	1,543,919–2,380,194	341	100%
Carbamazepine	595	1,924,763	1,352,454–2,497,073	341	100%
Promethazine HCl	527	1,911,351	1,452,229–2,370,473	293	86%
Meclizine HCl	399	1,906,646	1,148,154–2,665,138	341	100%
Cephalexin	511	1,899,305	1,508,958–2,289,651	341	100%
Fenofibrate nanocrystallized	413	1,898,960	1,336,984–2,460,935	315	92%
Ipratropium/albuterol sulfate	463	1,888,932	1,347,400–2,430,464	333	98%
Venlafaxine HCl	627	1,861,582	1,234,559–2,488,604	341	100%
Oxybutynin chloride	568	1,849,363	1,498,605–2,200,122	341	100%
Morphine sulfate	491	1,845,759	1,195,157–2,496,362	341	100%
Digoxin	515	1,845,656	1,427,800–2,263,512	341	100%
Olanzapine	627	1,790,633	1,160,005–2,421,261	341	100%
Lorazepam	540	1,786,878	1,296,097–2,277,659	341	100%
Verapamil HCl	387	1,786,033	1,240,416–2,331,649	341	100%
Levetiracetam	543	1,782,579	1,162,363–2,402,794	341	100%
Nitroglycerin	436	1,738,085	1,318,075–2,158,095	341	100%
Propranolol HCl	420	1,722,294	989,518–2,455,070	341	100%
Pramipexole di-HCl	340	1,721,576	526,539–2,916,613	341	100%
Pregabalin	498	1,699,388	1,279,765–2,119,011	341	100%
Glyburide	357	1,698,601	1,266,404–2,130,799	207	61%
Travoprost	378	1,669,219	1,101,440–2,236,998	300	88%
Nifedipine	409	1,664,761	1,178,345–2,151,176	329	96%
Insulin aspart	452	1,659,889	1,219,121–2,100,657	276	81%

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Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles, *continued*

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Lidocaine	432	1,643,259	1,137,819–2,148,699	341	100%
Phenytoin sodium extended	514	1,576,690	1,162,249–1,991,130	341	100%
Polyethylene glycol 3350	471	1,567,563	1,246,909–1,888,216	341	100%
Buspirone HCl	395	1,563,876	1,033,893–2,093,859	341	100%
Hydroxyzine HCl	432	1,563,435	1,170,925–1,955,945	266	78%
Baclofen	457	1,536,847	996,284–2,077,411	341	100%
Hydralazine HCl	369	1,460,232	1,067,908–1,852,555	341	100%
Sitagliptin phosphate	308	1,451,576	857,459–2,045,694	326	96%
Ipratropium bromide	283	1,406,253	766,035–2,046,471	341	100%
Benazepril HCl	269	1,401,998	938,298–1,865,698	340	100%
Fentanyl	420	1,388,578	870,924–1,906,232	341	100%
Latanoprost	360	1,377,318	1,061,923–1,692,713	341	100%
Amoxicillin	384	1,369,672	1,162,573–1,576,772	341	100%
Lamotrigine	522	1,343,506	915,124–1,771,888	341	100%
Insulin regular, human	387	1,330,468	885,107–1,775,828	341	100%
Doxazosin mesylate	322	1,326,945	924,407–1,729,482	341	100%
Acetaminophen with codeine	358	1,306,922	931,475–1,682,370	341	100%
Levofloxacin	338	1,289,250	1,014,165–1,564,336	341	100%
Gemfibrozil	322	1,271,415	854,041–1,688,788	341	100%
Ropinirole HCl	306	1,239,322	736,045–1,742,599	341	100%
Tizanidine HCl	416	1,235,871	775,568–1,696,175	341	100%
Ezetimibe/simvastatin	258	1,190,684	703,085–1,678,284	195	57%
Dicyclomine HCl	290	1,188,897	669,792–1,708,001	339	99%
Nph, human insulin isophane	228	1,176,930	617,196–1,736,663	341	100%
Losartan/hydrochlorothiazide	263	1,176,050	755,814–1,596,286	341	100%
Metoclopramide HCl	296	1,167,293	728,971–1,605,615	341	100%
Methocarbamol	297	1,140,023	818,332–1,461,714	187	55%
Finasteride	197	1,134,898	652,093–1,617,704	341	100%
Lactulose	323	1,134,620	627,955–1,641,286	341	100%
Tolterodine tartrate	272	1,129,540	738,696–1,520,385	320	94%
Carbidopa/levodopa	345	1,121,177	715,869–1,526,485	341	100%
Bimatoprost	206	1,094,783	676,449–1,513,117	298	87%
Budesonide/formoterol fumarate	240	1,086,250	644,063–1,528,437	285	84%
Nystatin	330	1,084,400	818,338–1,350,463	341	100%
Doxycycline hyclate	361	1,082,007	834,313–1,329,702	341	100%
Methadone HCl	230	1,080,920	418,188–1,743,653	337	99%
Triamcinolone acetonide	327	1,076,999	882,920–1,271,077	341	100%
Glyburide/metformin HCl	205	1,063,514	723,157–1,403,871	210	62%

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Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles, *continued*

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Ramipril	187	1,036,844	646,839–1,426,849	339	99%
Brimonidine tartrate	233	1,003,480	659,803–1,347,156	341	100%
Omega-3 acid ethyl esters	224	999,736	606,370–1,393,102	339	99%
Estrogens, conjugated	208	984,811	642,302–1,327,320	324	95%
Mometasone furoate	247	972,134	684,519–1,259,748	340	100%
Amlodipine besylate/benazepril	228	959,920	603,084–1,316,756	325	95%
Niacin	284	950,310	593,958–1,306,662	338	99%
Folic acid	234	917,230	579,814–1,254,647		
Diazepam	242	914,849	602,056–1,227,643	341	100%
Risedronate sodium	177	909,354	496,506–1,322,202	262	77%
Solifenacin succinate	212	905,807	544,630–1,266,985	261	77%
Hum insulin nph/reg insulin hm	277	891,664	585,937–1,197,392	341	100%
Insulin lispro	204	886,766	488,887–1,284,646	255	75%
Fluconazole	244	876,604	629,792–1,123,416	341	100%
Megestrol acetate	190	860,802	550,566–1,171,039	341	100%
Olopatadine HCl	233	856,208	531,929–1,180,487	297	87%
Amoxicillin/potassium clav	249	842,524	675,798–1,009,249	341	100%
Ergocalciferol (vitamin D_2)	246	840,670	572,795–1,108,546		
Metolazone	175	821,115	473,109–1,169,121	337	99%
Ibandronate sodium	180	811,781	469,371–1,154,191	319	94%
Clozapine	258	810,313	187,555–1,433,071	341	100%
Insulin detemir	219	791,709	502,659–1,080,758	289	85%
Timolol maleate	171	791,425	446,936–1,135,915	341	100%
Fenofibrate	217	789,433	472,615–1,106,252	340	100%
Estradiol	139	779,861	406,740–1,152,981	341	100%
Quinapril HCl	166	767,100	405,556–1,128,644	338	99%
Dutasteride	144	766,689	374,966–1,158,412	306	90%
Nitrofurantoin monohyd/ m-cryst	211	754,425	528,967–979,883	326	96%
Terazosin HCl	182	749,047	398,590–1,099,504	341	100%
Calcitriol	174	742,544	394,387–1,090,700	341	100%
Amiodarone HCl	159	726,161	428,049–1,024,273	341	100%
Fenofibric acid (choline)	183	697,843	242,136–1,153,549	274	80%
Temazepam	183	696,803	364,561–1,029,045	259	76%
Olmesartan medoxomil	133	691,273	352,024–1,030,523	269	79%
Cinacalcet HCl	204	689,875	378,315–1,001,435	341	100%
Ziprasidone HCl	335	685,268	386,358–984,178	341	100%

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Table B-1: 200 Drugs With the Highest Utilization by Dual Eligibles, *continued*

Generic Name	Sample Size*	Projected Drugs*	95-Percent Confidence Interval*	Number of Formularies Including	Percentage of Formularies Including
Estrogen,con/m-progest acet	89	680,598	163,753–1,197,443	201	59%
Hydroxyzine pamoate	176	673,614	299,916–1,047,312	155	45%
Prednisolone acetate	148	647,730	466,124–829,336	301	88%
Clotrimazole/betamethasone dip	170	645,039	374,168–915,909	284	83%
Darifenacin hydrobromide	167	643,527	364,924–922,130	113	33%
Hydrocortisone	152	613,981	360,669–867,293	341	100%
Ketoconazole	175	609,470	407,703–811,237	341	100%
Mycophenolate mofetil	184	603,446	282,168–924,724	341	100%
Hydroxychloroquine sulfate	112	602,009	406,799–797,218	341	100%
Haloperidol	261	594,843	343,034–846,652	341	100%
Sevelamer carbonate	157	592,190	348,152–836,228	316	93%
Cyclosporine	157	589,434	314,216–864,653	341	100%
Isosorbide dinitrate	121	578,099	267,561–888,636	341	100%
Doxepin HCl	169	578,028	275,021–881,036	341	100%
Bumetanide	115	574,123	220,061–928,186	341	100%
Mupirocin	166	559,222	377,854–740,591	341	100%
Labetalol HCl	146	559,195	303,504–814,886	341	100%
Albuterol	131	553,548	388,411–718,684		
Theophylline anhydrous	137	552,738	232,889–872,588	341	100%

Source: OIG analysis of drugs commonly used by dual eligibles, 2015.
*Sample is from the 2011 MCBS. Projections and confidence intervals are derived from its survey methodology.

APPENDIX C

Four Drugs Commonly Used by Dual Eligibles and Not Covered Under Part D

Generic Name	Reason Excluded Under Part D
Albuterol*	No longer prescribed without sulfate
Fexofenadine HCl*	Nonprescription drug
Folic acid*	Vitamin or mineral product
Ergocalciferol (Vitamin D_2)*	Vitamin or mineral product

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2015.
*These drugs were also on the 2014 report's list of drugs commonly used by dual eligibles and not covered under Part D.

APPENDIX D

Formulary Inclusion of Stand-Alone Prescription Drug Plans* and Medicare Advantage Prescription Drug Plans**, by Region

Table D-1: PDP Formularies' Inclusion of Commonly Used Drugs, by Region

PDP Region	State(s)	Number of PDPs	Average Rate of Inclusion by Formularies	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	27	94%	89%	99%
2	Connecticut, Massachusetts, Rhode Island, Vermont	26	94%	89%	98%
3	New York	24	94%	89%	98%
4	New Jersey	28	94%	89%	99%
5	Delaware, the District of Columbia, Maryland	26	94%	89%	99%
6	Pennsylvania, West Virginia	26	94%	89%	100%
7	Virginia	30	94%	89%	99%
8	North Carolina	28	94%	89%	99%
9	South Carolina	30	95%	89%	99%
10	Georgia	29	94%	89%	99%
11	Florida	26	94%	89%	98%
12	Alabama, Tennessee	29	94%	89%	99%
13	Michigan	30	94%	89%	99%
14	Ohio	30	94%	89%	99%
15	Indiana, Kentucky	30	94%	89%	99%
16	Wisconsin	28	94%	89%	99%
17	Illinois	32	94%	88%	99%
18	Missouri	30	94%	89%	99%
19	Arkansas	28	95%	89%	99%
20	Mississippi	27	94%	89%	99%
21	Louisiana	27	94%	89%	99%
22	Texas	31	94%	89%	99%
23	Oklahoma	30	94%	89%	99%
24	Kansas	28	94%	89%	99%
25	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	29	94%	89%	99%
26	New Mexico	30	94%	89%	99%
27	Colorado	29	94%	89%	99%
28	Arizona	29	94%	89%	99%
29	Nevada	31	94%	89%	99%
30	Oregon, Washington	29	94%	89%	99%
31	Idaho, Utah	30	94%	89%	99%
32	California	31	94%	89%	99%
33	Hawaii	24	94%	89%	99%
34	Alaska	23	94%	89%	99%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2015.

*PDP.
**MA-PD.

Table D-2: MA-PD Formularies' Inclusion of Commonly Used Drugs, by Region

MA-PD Region***	State(s)	Number of MA-PDs	Average Rate of Inclusion by Formularies	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	37	95%	89%	100%
2	Connecticut, Massachusetts, Rhode Island, Vermont	85	96%	90%	100%
3	New York	187	95%	90%	99%
4	New Jersey	37	94%	89%	98%
5	Delaware, the District of Columbia, Maryland	25	95%	91%	100%
6	Pennsylvania, West Virginia	129	96%	90%	100%
7	North Carolina, Virginia	107	96%	89%	100%
8	Georgia, South Carolina	62	96%	89%	100%
9	Florida	219	96%	89%	100%
10	Alabama, Tennessee	83	96%	92%	98%
11	Michigan	61	96%	90%	100%
12	Ohio	91	95%	89%	100%
13	Indiana, Kentucky	79	96%	89%	98%
14	Illinois, Wisconsin	124	96%	86%	100%
15	Arkansas, Missouri	70	96%	89%	99%
16	Louisiana, Mississippi	62	96%	93%	98%
17	Texas	128	95%	89%	99%
18	Kansas, Oklahoma	49	96%	89%	98%
19	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	79	96%	88%	100%
20	Colorado, New Mexico	66	97%	89%	100%
21	Arizona	72	96%	89%	99%
22	Nevada	30	95%	89%	99%
23	Idaho, Oregon, Utah, Washington	157	96%	88%	100%
24	California	283	95%	89%	100%
25	Hawaii	17	97%	94%	100%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2015.
***Region 26, which covers Alaska, had no MA-PDs available for 2015.