DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

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SUBJECT: Memorandum Report: *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2013*, OEI-05-13-00090

This memorandum report fulfills the annual reporting mandate from the Patient Protection and Affordable Care Act of 2010 (ACA) for 2013. 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 (PDP) and Medicare Advantage prescription drug plans (MA-PD) under Medicare Part D include drugs commonly used by full-benefit dual-eligible individuals (i.e., individuals who are eligible for both Medicare and Medicaid and who receive full Medicaid benefits and assistance with Medicare premiums and cost-sharing).[1] Pursuant to the ACA, OIG must annually issue a report, with recommendations as appropriate. This is the third 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 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.

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[1] ACA, P.L. 111-148 § 3313(a), 42 U.S.C. § 1395w-101 note.
[2] MMA, P.L. 108-173 § 101, Social Security Act, § 1860D-1(a), 42 U.S.C. § 1395w-101(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 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 302 unique formularies used by the 3,330 Part D plans operating in 2013 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 96 percent of the commonly used drugs. In addition, 64 percent of the commonly used drugs are included by all Part D plan formularies.

We also found that from 2012 to 2013, plan formularies increased the proportion of unique drugs subject to utilization management tools. On average, formularies applied utilization management tools to 28 percent of the unique drugs we reviewed in 2013, compared to 24 percent of the unique drugs we reviewed in 2012.

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

[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), 42 U.S.C. § 1395w-104(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 most cost-effective or safest drug therapy 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.

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.[7] 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 March 2013, approximately 35.3 million of the 48.7 million Medicare beneficiaries were enrolled in a Part D plan.[8, 9]

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 2013, plan sponsors offer 3,330 unique Part D plans, with many plan sponsors offering multiple Part D plans.[11]

Dual Eligibles Under Medicare Part D

Approximately 9.5 million Medicare beneficiaries are dual eligibles.[12] About 7 million dual eligibles, referred to as "full-benefit dual eligibles," receive full Medicaid benefits and assistance with Medicare premiums and cost-sharing.[13, 14] Other dual eligibles receive assistance with only 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.[15] Additionally, dual eligibles are in worse health than the average Medicare beneficiary:

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[7] MMA, P.L. 108-173 § 101, Social Security Act, § 1860D-1(a), 42 U.S.C. § 1395w-101(a).
[8] OIG analysis of CMS data: dual-eligible beneficiary enrollment by 2013 Part D plan. Received March 4, 2013.
[9] Medicare Board of Trustees, *The 2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Accessed at http://www.treasury.gov/resource-center/economic-policy/ss-medicare/Documents/TR_2012_Medicare.pdf on January 17, 2013.
[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 October 19, 2012.
[11] OIG analysis of 2013 plan and premium information for Medicare plans offering Part D coverage. Accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html November 11, 2012.
[12] OIG analysis of CMS data: dual-eligible beneficiary enrollment by 2013 Part D plan. Received March 4, 2013.
[13] Ibid.
[14] Kaiser Family Foundation, *Dual Eligibles: Medicaid's Role for Low-Income Medicare Beneficiaries.* Access at http://www.kff.org/medicaid/upload/4091-08.pdf on November 20, 2012.
[15] Kaiser Family Foundation, *Medicare's Role for Dual Eligible Beneficiaries.* Accessed at http://www.kff.org/medicare/upload/8138-02.pdf on November 20, 2012.

half are in fair or poor health, more than twice the rate of others in Medicare.[16] 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.[17]

Medicare covers Part D plan premiums, deductibles, and other cost-sharing for dual eligibles up to a determined premium benchmark. The benchmark is a statutorily defined amount that is based on the average premium amounts for Part D plans for each region.[18, 19] 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.[20]

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.[21] 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).[22] 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.[23] When dual eligibles change plans, their prescription drug coverage under their new Part D plans 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.[24] CMS

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[16] Kaiser Family Foundation, *Medicare's Role for Dual Eligible Beneficiaries.*
[17] MMA, P.L. 108-173 § 101.
[18] 42 CFR § 423.780(b)(2)(i).
[19] Social Security Act, § 1860D-14(a)(3)(f), 42 U.S.C. § 1395w-114(a)(3)(f). 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.
[20] Patient Protection and Affordable Care Act (ACA), P.L. 111-148 § 3303, Social Security Act, § 1860D 14(a)(5), 42 U.S.C. § 1395w-114(a)(5). 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. For 2013, CMS set the de minimis amount at $2 above the regional benchmark.
[21] CMS, *PDBM*, ch. 3, § 40.1.4.
[22] Ibid.
[23] Ibid., § 30.3.2. In general, Medicare beneficiaries can switch Part D plans only once a year during a defined enrollment period.
[24] Ibid., § 40.1.5.

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.[25] 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 2013, CMS reported reassigning approximately 835,000 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 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.[26, 27] In addition, Part D plans must include Part D-covered drugs in certain categories and classes.[28]

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.[29] For example, prescription vitamins, prescription mineral products, and nonprescription drugs are excluded from Part D prescription drug coverage.[30]

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.[31, 32]

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

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[25] CMS, *PDBM*, ch. 3, § 40.1.5.

[26] CMS, *PDBM*, ch. 6, § 30.2.1.

[27] 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.

[28] ACA, P.L. 111-148 § 3307, Social Security Act, § 1860D 4(b)(3)(G), 42 U.S.C. § 1395w 104(b)(3)(G).

[29] MMA, P.L. 108-173 § 101, Social Security Act, § 1860D-2(e), 42 U.S.C. § 1395w-102(e).

[30] Social Security Act § 1860D-2(e)(2), 1927(d)(2), 42 U.S.C. § 1395w-102(e)(2), 1396r-8(d)(2).

[31] ACA, P.L. 111-148 § 2502, Social Security Act, § 1397r-8(d).

[32] Barbiturates are covered under Part D only when used to treat epilepsy, cancer, or a chronic mental disorder. 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 January 17, 2013.

include all drugs in specified therapeutic categories or classes.[33] 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.[34]

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.[35, 36, 37]

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.[38] If their plans make negative determinations, beneficiaries have the right to appeal.[39] 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.[40] 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

[33] CMS, *PDBM*, ch. 6, § 30.2.1 and 30.2.5.
[34] Ibid., § 30.2.7.
[35] Ibid., § 30.2.2.
[36] Ibid., § 30.2.7.
[37] 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.
[38] CMS, *PDBM*, ch. 18, §§ 130.1 and 130.2.
[39] Ibid., § 60.1.
[40] Ibid., ch. 6, § 30.4.4.

dual eligibles under Medicaid prior to the implementation of Part D. Approximately half of the 178 commonly used drugs were covered by all formularies.[41]

In 2011, OIG issued the first annual mandated memorandum report examining dual eligibles' access to drugs under Medicare Part D.[42] In 2012, OIG issued the second annual mandated memorandum report examining dual eligibles' access to drugs under Medicare Part D.[43] In the current memorandum report, we compare the results from 2012 and 2013.

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 2013. As part of our assessment, we included dual eligibles' enrollment data from March 2013, the most recent enrollment data available from CMS at the time of our study. We also compared the results of our 2013 study with those of our 2012 study.[44]

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 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."

The 200 drugs with the highest utilization by dual eligibles referenced in this 2013 memorandum report are similar but not identical to the list of drugs referenced in the 2012 memorandum report. Specifically, 185 of the 200 drugs (93 percent) listed in the 2012 memorandum report are also listed in this 2013 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.

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[41] OIG, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090, January 2006.
[42] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles*.
[43] OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2012*.
[44] Ibid.

We also went beyond the ACA's mandate in both the 2012 and 2013 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 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 2009 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 2009 MCBS Cost and Use data are the most recent data available.

The MCBS is a CMS-conducted continuous, multipurpose survey 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 2009, the MCBS surveyed 10,859 Medicare beneficiaries, of which 2,092 were dual eligibles who had used prescription drugs during the year (out of 2,299 dual-eligible survey respondents).

First Databank National Drug Data File. We used the December 2012 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 containing information—such as drug name, therapeutic category or class, and the unique combination of active ingredients—for each drug defined by the Food and Drug Administration's National Drug Code (NDC).[45]

Part D plan data. In November 2012, we collected from CMS the plan and formulary data for Part D plans operating in 2013. The 2013 Part D plan data provide 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. The 2013 Part D formulary data include Part D plans' formularies and utilization management tools. In 2013, there are 302 unique formularies offered by 3,330 Part D plans.

We also collected 2013 Part D plan enrollment data. These data provide the number of dual eligibles enrolled in each Part D plan as of March 2013.

Determining the Most Commonly Used Drugs

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

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

1. 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. There were 154,267 drug events listed for 2,090 dual eligibles in the MCBS that did not reside in territories.[46]

2. 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 multiple-source brand-name drug Prozac) has only one entry on our list, covering all strengths of both the brand-name drug Prozac and the generic versions of fluoxetine hydrochloride available. 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 153,789 drug events associated with 864 drugs. There were 478 drug events in the MCBS that could not be matched with an Ingredient List Identifier in First DataBank's National Drug Data File.

3. Ranked all drugs by frequency of utilization, weighting the drug-event information from MCBS by sample weight.

4. Selected the 200 drugs with the highest utilization by dual eligibles. For a full list of the top 200 drugs, see Appendix B.

5. Removed all drugs not covered under Part D. Of the 200 drugs with the highest utilization, 195 are eligible under Part D, 2 fell into drug categories excluded under Part D, 1 is no longer prescribed in the form taken by beneficiaries surveyed in the 2009 MCBS, and 1 is no longer available in the United States. 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 beneficiary population. For details on the four drugs excluded under Part D, see Appendix C.

Formulary Analysis

We analyzed the 302 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. 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 195 commonly used drugs had low rates of inclusion by formularies by counting how many of the

[46] For the purposes of this report, a drug event is a MCBS survey response indicating that the responding beneficiary took a specific drug at least once in 2009. For example, one MCBS survey respondent reported taking atenolol 8 times in 2009. We counted this beneficiary/drug combination as 8 drug events.

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

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

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

To determine the extent to which the 195 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 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 utilization management tool analysis by both dual-eligible enrollment and Medicare enrollment. To do this, we applied March 2013 enrollment data to 2013 Part D plans.

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 2009 account for 87 percent of all prescriptions dispensed to the dual-eligible respondents in the 2009 MCBS.

Because the lists of commonly used drugs in the 2012 and 2013 memorandum reports are not identical, changes in rates of inclusion by formularies and in application of utilization management tools between 2012 and 2013 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 reviewed in the 2012 memorandum report are the same as those reviewed in this 2013 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 85 and 100 Percent of the Drugs Commonly Used by Dual Eligibles

On average, Part D plan formularies include 96 percent of the drugs commonly used by dual eligibles. Of the 302 unique formularies used by Part D plans in 2013, 19 formularies include 100 percent of the commonly used drugs. At the other end of the inclusion range, one formulary includes 85 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' inclusion of the drugs commonly used by dual eligibles in 2013 is nearly identical to that of 2012. The average rate of inclusion—96 percent—was unchanged between 2012 and 2013. The ranges of inclusion in 2012 and 2013 are almost the same—in 2012, the rates of inclusion ranged from 83 to 100 percent of the drugs commonly used by dual eligibles, and in 2013, they ranged from 85 to 100 percent.

Nationally, PDP and MA-PD formularies include a similar average of the drugs commonly used by dual eligibles: 94 percent and 96 percent respectively. PDP formularies' rates of inclusion of the commonly used drugs ranged from 87 to 100 percent, and MA-PD formularies' rates ranged from 85 to 100 percent. Twenty-one formularies—7 percent of the 302 unique formularies used by Part D plans in 2013—are offered by both PDPs and MA-PDs.

Regionally, all dual eligibles have the choice of a Part D plan that includes at least 99 percent of the commonly used drugs. Every PDP region has a plan that includes at least 99 percent of the commonly used drugs, and every MA-PD region has a plan that covers at least 99 percent of these drugs. Appendix D provides a breakdown of formulary inclusion 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, these plans. For drugs commonly used by dual eligibles, formularies for Part D plans with premiums below the regional benchmark have a rate of inclusion that ranges from 87 percent to 100 percent. Approximately 73 percent of dual eligibles are enrolled in Part D plans with premiums below the regional benchmark.

Ninety-nine 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 9.5 million dual eligibles enrolled in Part D plans, 99 percent are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. Only 1 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	175,000	2%
95% to 99% of commonly used drugs	3,329,000	35%
90% to 94% of commonly used drugs	5,821,000	62%
85% to 89% of commonly used drugs	126,000	1%
Total	**9,451,000**	**100%**

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles and dual eligibles' enrollment, 2013.
*Rounded to the nearest 1,000.

The percentage of dual eligibles enrolled in Part D plans that include at least 90 percent of the drugs commonly used by dual eligibles stayed consistent between 2012 and 2013 at 99 percent.

Sixty-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 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 51 percent to 100 percent. In other words, one drug commonly used by dual eligibles is included in as few as 51 percent of Part D plan formularies, and 125 drugs are included in all plan formularies. The average rate of inclusion by formularies is 96 percent. Table 2 provides a summary of rates of inclusion by formularies. Appendix D provides rates of inclusion by formularies for each of the commonly used drugs.

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

Percentage of the 302 Formularies	Percentage of the 195 Commonly Used Drugs Included in Formularies
100%	64% (125 drugs)
85% to 99%	24% (47 drugs)
75% to 84%	4% (7 drugs)
51% to 74%	8% (16 drugs)
Total	**100% (195 drugs)**

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.

The rates of formulary inclusion of the drugs commonly used by dual eligibles in 2013 are similar to those in 2012. The percentage of commonly used drugs included in all formularies increased slightly between 2012 and 2013, from 61 percent to 64 percent.

Part D plan formularies include certain drugs less frequently than others. Of the commonly used drugs, 8 percent (16 drugs) are included by less than 75 percent of Part D plan formularies. Table 3 provides the percentage of formularies covering each of these 16 drugs.

The drugs that make up this group include both brand and generic drugs, and are used to treat a variety of primary indications. Seven of the sixteen drugs are brand-name drugs, which are typically more costly than generic drugs. In terms of primary indications, 4 of the 16 drugs are used to treat high blood pressure, 3 of the 16 drugs are muscle relaxants, and the remaining treat a variety of conditions including high cholesterol, asthma, and insomnia.

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

Generic Name of Drug	Primary Indication(s)	Rate of Inclusion by Formularies
Valsartan/hydrochlorothiazide	Hypertension (high blood pressure)	74%
Olmesartan/hydrochlorothiazide*	Hypertension (high blood pressure)	73%
Olmesartan medoxomil*	Hypertension (high blood pressure)	73%
Valsartan	Hypertension (high blood pressure)	73%
Cyclobenzaprine HCL	Muscle relaxant	70%
Methocarbamol	Muscle relaxant	70%
Diphenoxylate HCL/atropine	Antidiarrheal	66%
Ezetimibe/simvastatin*	Hyperlipidemia (high cholesterol)	62%
Fenofibrate nanocrystallized	Hyperlipidemia (high cholesterol), hypertriglyceridemia (high triglycerides)	62%
Temazepam	Insomnia	62%
Esomeprazole magnesium*	Dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, Zollinger-Ellison syndrome	60%
Alprazolam	Anxiety	59%
Eszopiclone*	Insomnia	59%
Rosiglitazone maleate*	Insulin sensitizer	56%
Carisoprodol*	Muscle relaxant	52%
Levalbuterol tartrate*	Asthma, chronic obstructive pulmonary disease	51%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.
* These drugs also had low formulary inclusion rates in 2012.

Although Part D formularies frequently omit these 16 drugs, they all cover other drugs in the same therapeutic classes. For 15 of these 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. Finally, 100 percent of formularies cover drugs in the same therapeutic class as the remaining low-inclusion drug, diphenoxylate HCl/atropine.[47]

[47] The drugs in the same therapeutic class as diphenoxylate HCl/atropine are not always on the list of 195 commonly used drugs.

The number of drugs included by less than 75 percent of formularies increased from 11 in 2012 to 16 in 2013. There are eight drugs with low inclusion rates in 2013 that were also on the list of commonly used drugs with low inclusion rates in our 2012 report; these drugs are noted in Table 3. An additional 5 of the 16 low-inclusion drugs in 2013 were on the list of commonly used drugs in our 2012 report, and the final 3 of the 16 low-inclusion drugs in our 2013 report were either not covered by Part D in 2012 or were not on the list of commonly used drugs in the 2012 report.

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

- Three of these drugs—cyclobenzaprine HCl, diphenoxylate HCl/atropine, and methocarbamol—are on CMS's list of high-risk Part D medications, which may explain the low inclusion rates for these drugs.[48] Part D formularies have increasingly excluded these drugs since they were placed on the high-risk medication list in 2011.
- Another two drugs—valsartan and valsartan/hydrochlorothiazide—received first-time generic drug approval from the Food and Drug Administration on September 21, 2012. Thus, Part D formularies may now cover different generic forms of these drugs.
- The decrease in formulary coverage of fenofibrate nanocrystallized may be driven by the fact that the nanocrystallized form of fenofibrate is more expensive than other forms of fenofibrate.
- Two drugs—temazepam and alprazolam—are benzodiazepines, which were excluded from Part D coverage until 2013. These two drugs were also on the list of commonly used drugs in our 2012 report. The low inclusion rates for these two drugs may be explained by CMS's recent change in Part D coverage guidelines.

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.[49] Finally, dual eligibles may switch to Part D

[48] 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 high-risk medication is a drug with a high risk of serious side effects in the elderly. 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 Part D patient safety measures 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.ncqa.org/HEDISQualityMeasurement/HEDISMeasures/HEDIS2012/HEDIS2012FinalNDCLists.aspx on January 14, 2013 and at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Technical-Notes-2013-.pdf on March 25, 2013.

[49] CMS, *PDBM*, ch. 18, § 30.2.2.

plans that include their drugs, with the new coverage becoming effective the following month.[50]

Plan Formularies Increased the Percentage of Commonly Used Drugs Subject to Utilization Management Tools Between 2012 and 2013

For the unique drugs that compose the list of commonly used drugs, Part D plan formularies increased the percentage subject to utilization management tools, from an average of 24 percent in 2012 to an average of 28 percent in 2013. Among the formularies, those for plans with premiums below the regional benchmark had a slightly larger increase in this percentage between 2012 and 2013, going from an average of 22 percent in 2012 to an average of 27 percent in 2013. See Table 4 for a breakdown of the percentage of unique drugs to which Part D plan formularies apply utilization management tools in 2012 and 2013.

Table 4: Part D Plan Formularies' Application of Utilization Management Tools to Commonly Used Drugs, 2012 to 2013

Percentage of Unique Drugs to Which Utilization Management Tools Are Applied	Number of 2012 Part D Plan Formularies	Percentage of 2012 Part D Plan Formularies	Number of 2013 Part D Plan Formularies	Percentage of 2013 Part D Plan Formularies
40% to 55%	31	11%	41	13%
30% to 39%	59	22%	116	38%
20% to 29%	92	34%	74	25%
10% to 19%	54	20%	34	11%
Less than 10%	36	13%	37	12%
Totals	**272**	**100%**	**302**	**100%***

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.
* Percentages do not add to 100 percent because of rounding.

This increase in Part D plan formularies' application of utilization management tools results partially from an increase in the rate at which formularies apply quantity limits to the unique drugs that make up commonly used drugs. In 2013, formularies applied such quantity limits to an average of 24 percent of unique drugs, up from 21 percent in 2012. There is also a slight increase in the rate at which formularies apply prior authorization to the unique drugs that make up commonly used drugs. In 2013, formularies applied prior authorization to an average of 5 percent of unique drugs, up from 3 percent in 2012. Formularies applied step therapy at virtually the same rate in 2013 as in 2012, that is, for an average of 3 percent of unique drugs.

Although there has been an overall increase in Part D plan formularies' use of utilization management tools, wide variation remains in the rate at which plan formularies apply these tools. In 2013, some formularies applied utilization management tools to none of the unique drugs, whereas at the other end of the range, some applied the tools to 55 percent of the unique drugs. More specifically, formularies apply quantity limits to between 0 and 44 percent of unique drugs, prior authorization to between 0 and 29 percent, and step therapy to between 0 and 20 percent.

[50] CMS, *PDBM*, ch. 3, § 30.3.2.

Looking at enrollment across plans provides a slightly different picture than looking only at plans themselves. On average, plan formularies in 2013 apply utilization management tools to 28 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 2013, the median plan weighted by dual-eligible enrollment applies such tools to 35 percent of unique drugs. This is an increase over 2012, when the median plan weighted by dual-eligible enrollment applied utilization management tools to 26 percent of unique drugs. Similarly, the median plan weighted by overall Medicare enrollment applies these tools to 32 percent of unique drugs in 2013, up from 26 percent in 2012.

Both dual eligibles and Medicare beneficiaries overall tend to be enrolled in plans with formularies that apply utilization management tools to between 30 and 55 percent of unique drugs. In 2013, 62 percent of dual eligibles and 54 percent of Medicare beneficiaries overall were enrolled in plans with formularies in this range. Table 5 provides a breakdown of dual eligibles and Medicare beneficiaries' enrollment in Part D plans by the plans' formularies' application of utilization management tools.

Table 5: Beneficiary Enrollment in Part D Plans by Application of Utilization Management Tools to Commonly Used Drugs, 2012 to 2013

Percentage of Unique Drugs to Which Plan Formularies Apply Utilization Management Tools	Percentage of Dual Eligibles Enrolled, 2012	Percentage of Medicare Beneficiaries Enrolled, 2012	Percentage of Dual Eligibles Enrolled, 2013	Percentage of Medicare Beneficiaries Enrolled, 2013
40% to 55%	22%	21%	18%	20%
30% to 39%	22%	23%	44%	34%
20% to 29%	44%	42%	16%	12%
10% to 19%	2%	4%	6%	5%
Less than 10%	9%	10%	17%	29%
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, 2013.
*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. Such limits may be intended to ensure appropriate utilization, as CMS's Part D 2013 guidance to Part D sponsors set forth expectations for opioid overutilization reviews to help ensure that opioids are prescribed and used correctly.[51]

CONCLUSION

When establishing formularies and applying utilization management tools, Part D plans need to balance Medicare beneficiaries' needs for adequate prescription drug coverage

[51] CMS, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D.* September 6, 2012. Accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf on January 16, 2013.

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 16 drugs that this memorandum report identifies as being included by less than 75 percent of Part D plan formularies, all Part D plan formularies cover at least one therapeutically 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 96 percent of the commonly used drugs. Part D plan formularies' inclusion of the commonly used drugs ranges from 85 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 195 drugs commonly used by dual eligibles are largely unchanged compared with those from OIG's 2012 memorandum report. Part D plan formularies include roughly the same percentage of these commonly used drugs in 2013 as they did in 2012. Enrollment in plans that cover at least 90 percent of unique drugs stayed consistent, with 99 percent of dual eligibles enrolled in such plans.

Although dual eligibles, like all Medicare beneficiaries, are largely enrolled in plans that apply utilization management tools to a higher than average percentage of unique drugs, this increase is largely a result of an increase in plans' use of quantity limits and prior authorization requirements. Plan formularies still vary widely in the rates at which they apply utilization management tools to unique drugs.

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-05-13-00090 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 Formulary Inclusion

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
Furosemide	3,888	14,488,713	12,777,105 - 16,200,322	302	100%
Simvastatin	3,459	13,936,580	12,555,541 - 15,317,618	301	100%
Hydrocodone bit/acetaminophen	3,846	13,670,886	11,729,808 - 15,611,964	302	100%
Lisinopril	3,483	13,610,671	12,242,398 - 14,978,945	302	100%
Levothyroxine sodium	3,371	12,400,820	10,971,169 - 13,830,471	302	100%
Omeprazole	3,093	11,964,177	10,423,382 - 13,504,972	302	100%
Potassium chloride	2,938	10,471,432	9,141,466 - 11,801,399	302	100%
Amlodipine besylate	2,595	10,238,851	8,725,274 - 11,752,429	302	100%
Metoprolol tartrate	2,393	9,382,516	8,286,197 - 10,478,834	302	100%
Metformin HCl	2,216	8,789,649	7,682,215 - 9,897,084	302	100%
Warfarin sodium	2,317	8,522,219	7,189,261 - 9,855,177	302	100%
Atorvastatin calcium	2,039	7,644,118	6,588,676 - 8,699,560	301	100%
Hydrochlorothiazide	1,717	7,268,389	6,083,158 - 8,453,620	302	100%
Clopidogrel bisulfate	1,828	6,899,724	5,924,280 - 7,875,167	302	100%
Atenolol	1,545	6,801,703	5,648,924 - 7,954,482	302	100%
Esomeprazole magnesium	1,435	5,973,325	4,771,051 - 7,175,599	180	60%
Gabapentin	1,630	5,843,387	4,861,226 - 6,825,548	302	100%
Albuterol sulfate	1,439	5,219,654	4,432,757 - 6,006,551	302	100%
Alendronate sodium	1,032	5,033,461	4,081,433 - 5,985,489	302	100%
Citalopram hydrobromide	1,273	4,853,755	3,828,500 - 5,879,010	302	100%
Zolpidem tartrate	1,378	4,757,715	3,812,965 - 5,702,464	302	100%
Quetiapine fumarate	1,569	4,428,322	3,491,367 - 5,365,277	302	100%
Metoprolol succinate	1,088	4,326,590	3,575,455 - 5,077,725	299	99%
Ranitidine HCl	1,282	4,241,484	3,386,165 - 5,096,803	302	100%
Valsartan	1,041	4,193,143	3,342,936 - 5,043,350	221	73%
Glipizide	977	4,040,914	3,269,449 - 4,812,379	302	100%
Fluticasone/salmeterol	1,067	4,035,986	3,198,380 - 4,873,592	289	96%
Insulin glargine, human recombinant analog	952	4,017,723	3,061,997 - 4,973,449	295	98%
Sertraline HCl	1,238	3,974,084	3,223,944 - 4,724,224	302	100%
Montelukast sodium	977	3,810,128	2,954,872 - 4,665,384	270	89%
Lovastatin	797	3,806,610	2,995,644 - 4,617,575	291	96%
Divalproex sodium	1,349	3,704,559	2,860,276 - 4,548,842	302	100%
Oxycodone HCl/acetaminophen	1,016	3,702,234	2,918,165 - 4,486,303	302	100%
Carvedilol	907	3,636,584	2,960,891 - 4,312,277	302	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
Donepezil HCl	1,121	3,620,751	2,858,713 - 4,382,789	302	100%
Diltiazem HCl	841	3,536,775	2,618,064 - 4,455,485	302	100%
Trazodone HCl	1,002	3,503,016	2,777,254 - 4,228,777	302	100%
Escitalopram oxalate	1,059	3,410,096	2,716,579 - 4,103,614	287	95%
Isosorbide mononitrate	933	3,409,185	2,681,156 - 4,137,215	302	100%
Pantoprazole sodium	891	3,284,951	2,531,046 - 4,038,855	297	98%
Risperidone	1,139	3,199,726	2,641,085 - 3,758,367	302	100%
Cyclobenzaprine HCl	862	3,161,124	2,448,504 - 3,873,745	212	70%
Tramadol HCl	925	3,106,442	2,396,534 - 3,816,350	302	100%
Rosuvastatin calcium	721	3,086,871	2,335,607 - 3,838,136	242	80%
Alprazolam	837	3,033,650	2,350,951 - 3,716,349	177	59%
Lansoprazole	824	3,002,134	2,342,667 - 3,661,601	262	87%
Pioglitazone HCl	795	2,986,021	2,270,495 - 3,701,547	301	100%
Ibuprofen	811	2,936,951	2,285,745 - 3,588,158	302	100%
Enalapril maleate	828	2,886,367	2,331,576 - 3,441,158	302	100%
Prednisone	838	2,882,757	2,383,115 - 3,382,399	302	100%
Fluticasone propionate	776	2,859,018	2,324,821 - 3,393,216	302	100%
Digoxin	733	2,857,313	2,231,221 - 3,483,406	302	100%
Clonidine HCl	734	2,800,964	2,107,146 - 3,494,782	302	100%
Propoxyphene nap/acetaminophen	814	2,694,310	2,078,897 - 3,309,723	Excluded	Excluded
Allopurinol	710	2,568,090	1,982,006 - 3,154,174	302	100%
Lisinopril/hydrochlorothiazide	657	2,558,335	1,908,086 - 3,208,583	301	100%
Paroxetine HCl	746	2,494,774	1,909,116 - 3,080,433	302	100%
Tiotropium bromide	573	2,456,029	1,935,499 - 2,976,559	302	100%
Mirtazapine	777	2,444,280	1,811,924 - 3,076,636	302	100%
Naproxen	689	2,410,096	1,864,556 - 2,955,635	302	100%
Pravastatin sodium	578	2,408,314	1,685,343 - 3,131,284	302	100%
Tamsulosin HCl	595	2,330,145	1,722,438 - 2,937,853	302	100%
Valsartan/hydrochlorothiazide	550	2,298,873	1,654,679 - 2,943,067	224	74%
Clonazepam	733	2,262,762	1,722,387 - 2,803,137	302	100%
Fluoxetine HCl	652	2,259,917	1,776,469 - 2,743,365	302	100%
Glimepiride	522	2,242,751	1,588,355 - 2,897,146	302	100%
Azithromycin	654	2,184,924	1,908,989 - 2,460,859	302	100%
Meloxicam	516	2,155,762	1,647,492 - 2,664,031	300	99%
Aripiprazole	709	2,149,920	1,452,541 - 2,847,298	302	100%
Spironolactone	488	2,087,297	1,511,754 - 2,662,839	302	100%
Pregabalin	616	2,055,748	1,458,317 - 2,653,179	302	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
Ezetimibe	541	2,021,031	1,478,673 - 2,563,389	302	100%
Nitroglycerin	583	2,012,596	1,622,179 - 2,403,014	302	100%
Sulfamethoxazole/ trimethoprim	619	2,011,424	1,619,682 - 2,403,167	302	100%
Famotidine	542	1,996,592	1,581,286 - 2,411,898	299	99%
Morphine sulfate	619	1,994,878	1,328,559 - 2,661,197	302	100%
Duloxetine HCl	546	1,992,643	1,293,371 - 2,691,915	302	100%
Ipratropium/albuterol sulfate	470	1,970,144	1,460,358 - 2,479,930	298	99%
Memantine HCl	631	1,961,892	1,456,342 - 2,467,442	302	100%
Glyburide	495	1,922,621	1,384,185 - 2,461,058	300	99%
Oxybutynin chloride	550	1,909,731	1,492,216 - 2,327,245	302	100%
Fexofenadine HCl	585	1,902,635	1,446,691 - 2,358,578	Excluded	Excluded
Olanzapine	693	1,896,640	1,319,011 - 2,474,270	302	100%
Amitriptyline HCl	564	1,885,388	1,372,287 - 2,398,489	302	100%
Ciprofloxacin HCl	568	1,865,328	1,639,946 - 2,090,710	302	100%
Losartan potassium	404	1,856,087	1,306,715 - 2,405,458	302	100%
Fenofibrate nanocrystallized	488	1,824,334	1,406,247 - 2,242,421	186	62%
Venlafaxine HCl	643	1,823,318	1,272,552 - 2,374,085	302	100%
Nifedipine	426	1,820,394	1,280,987 - 2,359,801	300	99%
Tolterodine tartrate	531	1,782,318	1,375,463 - 2,189,173	239	79%
Triamterene/ hydrochlorothiazide	446	1,773,800	1,164,934 - 2,382,666	302	100%
Levofloxacin	500	1,766,041	1,363,889 - 2,168,194	301	100%
Polyethylene glycol 3350	519	1,721,331	1,221,512 - 2,221,149	296	98%
Buspirone HCl	460	1,702,854	1,221,714 - 2,183,993	302	100%
Promethazine HCl	550	1,686,330	1,284,972 - 2,087,688	268	89%
Sitagliptin phosphate	360	1,667,857	1,148,378 - 2,187,336	295	98%
Bupropion HCl	472	1,666,187	1,186,998 - 2,145,377	302	100%
Human insulin neutral protamine hagedorn/regular human insulin	463	1,653,338	1,196,825 - 2,109,851	302	100%
Celecoxib	435	1,621,197	1,186,593 - 2,055,800	282	93%
Metoclopramide HCl	443	1,617,265	1,174,504 - 2,060,026	302	100%
Phenytoin sodium extended	547	1,613,514	1,163,676 - 2,063,352	302	100%
Carbamazepine	576	1,580,353	1,013,148 - 2,147,559	302	100%
Ezetimibe/simvastatin	341	1,541,184	977,289 - 2,105,078	186	62%
Risedronate sodium	396	1,540,508	1,101,037 - 1,979,980	228	75%
Clozapine	400	1,509,207	714,436 - 2,303,978	302	100%
Acetaminophen with codeine	359	1,484,631	1,013,126 - 1,956,136	302	100%
Meclizine HCl	415	1,463,788	1,091,434 - 1,836,142	297	98%

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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
Mometasone furoate	391	1,458,895	1,068,476 - 1,849,315	300	99%
Insulin regular, human	385	1,457,603	1,030,919 - 1,884,288	302	100%
Glyburide/metformin HCl	306	1,455,464	938,542 - 1,972,386	298	99%
Carisoprodol	502	1,442,655	995,945 - 1,889,365	156	52%
Oxycodone HCl	498	1,431,700	989,649 - 1,873,751	301	100%
Baclofen	468	1,406,908	987,451 - 1,826,366	302	100%
Fentanyl	421	1,401,086	952,557 - 1,849,616	302	100%
Cephalexin	440	1,396,294	1,165,811 - 1,626,778	302	100%
Insulin aspart	368	1,382,200	927,459 - 1,836,940	285	94%
Benztropine mesylate	524	1,378,431	955,176 - 1,801,686	302	100%
Diazepam	345	1,350,444	891,523 - 1,809,365	302	100%
Doxazosin mesylate	283	1,315,296	734,304 - 1,896,287	302	100%
Hydroxyzine HCl	327	1,309,855	797,158 - 1,822,551	257	85%
Ziprasidone HCl	473	1,283,163	838,260 - 1,728,066	302	100%
Benazepril HCl	307	1,275,932	720,547 - 1,831,316	301	100%
Triamcinolone acetonide	361	1,260,803	1,039,762 - 1,481,843	302	100%
Lidocaine	347	1,258,091	856,044 - 1,660,138	302	100%
Verapamil HCl	311	1,238,088	863,750 - 1,612,426	302	100%
Latanoprost	302	1,227,112	819,015 - 1,635,210	302	100%
Amoxicillin	405	1,226,521	1,044,796 - 1,408,246	302	100%
Carbidopa/levodopa	361	1,215,696	832,796 - 1,598,596	302	100%
Hydralazine HCl	333	1,201,268	836,146 - 1,566,389	302	100%
Amlodipine besylate/benazepril	298	1,201,014	803,666 - 1,598,361	293	97%
Torsemide	230	1,173,205	492,351 - 1,854,059	299	99%
Nystatin	326	1,170,065	857,188 - 1,482,941	302	100%
Lamotrigine	391	1,159,822	771,629 - 1,548,014	302	100%
Ramipril	289	1,142,525	665,969 - 1,619,081	296	98%
Gemfibrozil	313	1,132,380	777,795 - 1,486,966	302	100%
Ropinirole HCl	280	1,125,551	686,763 - 1,564,339	302	100%
Terazosin HCl	255	1,116,887	681,820 - 1,551,954	302	100%
Methocarbamol	307	1,110,468	663,592 - 1,557,343	210	70%
Isosorbide dinitrate	261	1,110,025	469,055 - 1,750,994	302	100%
Lorazepam	374	1,105,423	829,210 - 1,381,635	234	77%
Estrogens, conjugated	261	1,083,989	629,284 - 1,538,695	300	99%
Folic acid	268	1,074,524	785,018 - 1,364,029	Excluded	Excluded
Lactulose	335	1,073,756	696,324 - 1,451,188	302	100%
Lithium carbonate	319	1,056,530	544,694 - 1,568,365	302	100%
Levetiracetam	372	1,052,523	722,361 - 1,382,685	302	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
Omega-3 acid ethyl esters	270	1,034,241	593,395 - 1,475,087	299	99%
Doxycycline hyclate	337	1,033,606	751,965 - 1,315,246	302	100%
Methadone HCl	271	1,008,892	466,535 - 1,551,248	301	100%
Topiramate	397	1,000,887	583,646 - 1,418,128	302	100%
Neutral protamine hagedorn, human insulin isophane	217	988,784	639,247 - 1,338,320	302	100%
Ipratropium bromide	272	980,422	653,215 - 1,307,629	302	100%
Brimonidine tartrate	245	954,347	657,682 - 1,251,013	302	100%
Propranolol HCl	285	948,052	571,036 - 1,325,068	302	100%
Temazepam	250	946,044	610,453 - 1,281,635	187	62%
Dicyclomine HCl	276	943,314	607,856 - 1,278,771	253	84%
Finasteride	249	910,448	615,843 - 1,205,053	302	100%
Timolol maleate	245	861,731	565,750 - 1,157,712	302	100%
Fluconazole	242	860,524	466,493 - 1,254,555	302	100%
Albuterol	241	853,696	489,990 - 1,217,403	Excluded	Excluded
Pramipexole dihydrochloride	121	Excluded	Excluded	Excluded	Excluded
Labetalol HCl	183	841,200	174,911 - 1,507,488	302	100%
Olmesartan medoxomil	181	829,968	349,332 - 1,310,605	220	73%
Insulin lispro	204	819,910	516,648 - 1,123,172	241	80%
Nabumetone	206	814,711	481,191 - 1,148,232	298	99%
Quinapril HCl	150	813,879	351,190 - 1,276,569	298	99%
Raloxifene HCl	202	812,930	478,798 - 1,147,062	302	100%
Tizanidine HCl	280	812,885	545,990 - 1,079,780	301	100%
Diclofenac sodium	224	809,011	579,543 - 1,038,480	302	100%
Amoxicillin/potassium clavulanate	258	807,971	635,629 - 980,312	302	100%
Methylprednisolone	214	786,567	513,393 - 1,059,741	302	100%
Oxcarbazepine	213	779,355	266,529 - 1,292,181	302	100%
Nitrofurantoin monohydrate/ macrocrystals	226	772,565	585,184 - 959,945	292	97%
Eszopiclone	229	760,246	400,596 - 1,119,897	177	59%
Solifenacin succinate	210	751,939	442,997 - 1,060,881	249	82%
Levalbuterol tartrate	176	732,957	357,407 - 1,108,506	154	51%
Metolazone	203	726,108	417,302 - 1,034,915	300	99%
Cilostazol	148	719,471	324,291 - 1,114,651	302	100%
Rosiglitazone maleate	206	715,668	407,155 - 1,024,182	170	56%
Azelastine HCl	129	699,431	282,352 - 1,116,510	302	100%
Clotrimazole/ betamethasone dip	187	692,186	481,069 - 903,302	267	88%
Dutasteride	127	684,615	404,255 - 964,975	279	92%

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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
Sucralfate	213	681,391	408,441 - 954,342	302	100%
Diphenoxylate HCl/atropine	169	668,573	284,464 - 1,052,682	200	66%
Megestrol acetate	199	639,426	450,033 - 828,820	302	100%
Clobetasol propionate	146	636,503	322,115 - 950,891	302	100%
Metronidazole	185	625,506	460,269 - 790,743	302	100%
Amiodarone HCl	146	620,999	327,394 - 914,604	302	100%
Colchicine	200	607,224	314,858 - 899,591	302	100%
Sotalol HCl	152	596,852	245,850 - 947,853	302	100%
Aspirin/dipyridamole	165	594,285	347,901 - 840,668	302	100%
Losartan/hydrochlorothiazide	166	593,970	243,138 - 944,802	301	100%
Dorzolamide HCl/timolol maleate	151	592,202	305,698 - 878,706	302	100%
Ketoconazole	162	579,942	365,474 - 794,411	302	100%
Nitrofurantoin macrocrystal	177	577,871	349,562 - 806,181	294	97%
Hydroxychloroquine sulfate	155	577,507	251,571 - 903,442	302	100%
Calcium acetate	180	573,946	313,698 - 834,193	298	99%
Repaglinide	142	569,993	308,053 - 831,933	267	88%
Moxifloxacin HCl	137	568,317	364,110 - 772,525	287	95%
Hydrocortisone	154	554,472	305,094 - 803,851	302	100%
Olmesartan/ hydrochlorothiazide	113	552,362	259,710 - 845,014	220	73%

Source: Office of Inspector General analysis of drugs commonly used by dual eligibles, 2013.
*Sample is from the 2009 Medicare Current Beneficiary Survey. 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
Propoxyphene nap/acetaminophen*	No longer available in the United States

Source: Office of Inspector General analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.
* These drugs were also on the 2012 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 Formulary Inclusion

PDP Region	State(s)	Number of PDPs	Average Formulary Inclusions Rate	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	28	95%	87%	99%
2	Connecticut, Massachusetts, Rhode Island, Vermont	30	95%	87%	99%
3	New York	28	95%	87%	99%
4	New Jersey	29	94%	87%	99%
5	Delaware, the District of Columbia, Maryland	29	95%	87%	99%
6	Pennsylvania, West Virginia	38	95%	87%	100%
7	Virginia	31	94%	87%	99%
8	North Carolina	30	95%	87%	99%
9	South Carolina	31	94%	87%	99%
10	Georgia	30	95%	87%	99%
11	Florida	34	94%	87%	99%
12	Alabama, Tennessee	33	95%	87%	99%
13	Michigan	33	95%	87%	99%
14	Ohio	33	95%	87%	99%
15	Indiana, Kentucky	31	95%	87%	99%
16	Wisconsin	30	95%	87%	99%
17	Illinois	32	95%	87%	99%
18	Missouri	31	94%	87%	99%
19	Arkansas	30	94%	87%	99%
20	Mississippi	29	94%	87%	99%
21	Louisiana	30	94%	87%	99%
22	Texas	32	95%	87%	99%
23	Oklahoma	30	94%	87%	99%
24	Kansas	30	94%	87%	99%
25	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	32	95%	87%	99%
26	New Mexico	30	95%	87%	99%
27	Colorado	29	95%	87%	99%
28	Arizona	29	95%	87%	99%
29	Nevada	29	95%	87%	99%
30	Oregon, Washington	30	94%	87%	99%
31	Idaho, Utah	32	94%	87%	99%
32	California	32	94%	87%	99%
33	Hawaii	23	94%	87%	99%
34	Alaska	23	95%	87%	99%

Source: Office of Inspector General analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.

*PDP.
**MA-PD.

Table D-2: MA-PD Formulary Inclusion by Region

MA-PD Region***	State(s)	Number of MA-PDs	Average Formulary Inclusion Rate	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	36	96%	87%	99%
2	Connecticut, Massachusetts, Rhode Island, Vermont	72	96%	87%	99%
3	New York	189	96%	90%	99%
4	New Jersey	36	95%	91%	99%
5	Delaware, the District of Columbia, Maryland	28	96%	93%	100%
6	Pennsylvania, West Virginia	157	97%	90%	100%
7	North Carolina, Virginia	140	97%	87%	100%
8	Georgia, South Carolina	125	96%	87%	100%
9	Florida	302	97%	85%	100%
10	Alabama, Tennessee	77	96%	93%	99%
11	Michigan	61	97%	93%	100%
12	Ohio	80	96%	87%	100%
13	Indiana, Kentucky	88	96%	87%	100%
14	Illinois, Wisconsin	142	97%	87%	100%
15	Arkansas, Missouri	123	96%	87%	99%
16	Louisiana, Mississippi	80	96%	93%	99%
17	Texas	149	96%	90%	99%
18	Kansas, Oklahoma	65	97%	90%	99%
19	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	122	97%	88%	100%
20	Colorado, New Mexico	74	97%	87%	100%
21	Arizona	75	95%	89%	99%
22	Nevada	38	95%	87%	100%
23	Idaho, Oregon, Utah, Washington	160	96%	90%	100%
24	California	266	96%	87%	100%
25	Hawaii	20	97%	94%	100%

Source: Office of Inspector General analysis of formulary inclusion of drugs commonly used by dual eligibles, 2013.
***Region 26, which covers Alaska, has no MA-PDs available for 2013.