



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: 2016*, OEI-05-16-00090

This report fulfills the annual reporting mandate from the Patient Protection and Affordable Care Act (ACA) for 2016. The ACA requires the Office of Inspector General (OIG) to 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).<sup>1</sup> Pursuant to the ACA, OIG must annually issue a report, with recommendations as appropriate. This is the sixth 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).<sup>2</sup>

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.

<sup>1</sup> ACA, P.L. No. 111-148 § 3313(a), 42 U.S.C. § 1395w-101 note.

<sup>2</sup> 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.<sup>3</sup> These tools include prior authorization, quantity limits, and step therapy.<sup>4</sup>

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 report, we determined whether the 374 unique formularies used by the 3,116 Part D plans operating in 2016 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, 68 percent of the commonly used drugs are included by all Part D plan formularies.

We also found that from 2015 to 2016, the proportion of unique drugs subject to utilization management tools remained relatively the same. On average, formularies applied utilization management tools to 28 percent of the unique drugs we reviewed in 2016, compared to 29 percent of those we reviewed in 2015.

The results of our analysis for 2016 are largely unchanged from our findings in 2011, 2012, 2013, 2014, and 2015.<sup>5, 6, 7, 8, 9</sup>

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<sup>3</sup> 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).

<sup>4</sup> 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.

<sup>5</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2011*, OEI-05-10-00390, April 2011.

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

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

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

<sup>9</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2015*, OEI-05-15-00120, June 2015.

## 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.<sup>10</sup> 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 February 2016, approximately 40.8 million of the 56.2 million Medicare beneficiaries were enrolled in a Part D plan.

Part D plans are administered by private companies—known as plan sponsors—that contract with CMS to offer prescription drug coverage in one or more PDP or MA-PD regions. CMS has designated 34 PDP regions and 26 MA-PD regions. In 2016, plan sponsors offer 3,116 unique Part D plans, with many plan sponsors offering multiple Part D plans.

### **Dual Eligibles Under Medicare Part D**

Approximately 10.3 million Medicare beneficiaries are dual eligibles. For about 7.7 million dual eligibles, referred to as “full-benefit dual eligibles,” Medicaid provides full Medicaid benefits, including Medicaid-covered services, and may also assist beneficiaries with premiums and cost-sharing for Medicare fee-for-service or Medicare managed care.<sup>11</sup> For other dual eligibles, Medicaid does not provide Medicaid-covered services, but provides assistance with beneficiaries’ Medicare premiums or cost-sharing, depending on their level of income and assets.

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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

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<sup>10</sup> MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-1(a).

<sup>11</sup> Centers for Medicare & Medicaid Services, *Medicare-Medicaid Enrollee State and County Enrollment Snapshots, Updated Quarterly (June 2015)*. Accessed at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics.html> on March 22, 2016.

<sup>12</sup> Kaiser Family Foundation, *Medicare’s Role for Dual Eligible Beneficiaries*. Accessed at <http://www.kff.org/medicare/upload/8138-02.pdf> on March 22, 2016.

<sup>13</sup> Ibid.

<sup>14</sup> 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.<sup>15, 16</sup> 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.<sup>17</sup>

*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.<sup>18</sup> The PDPs to which CMS assigns dual eligibles must meet certain requirements, such as having a premium at or below the regional benchmark amount and offering basic prescription drug coverage (or equivalent).<sup>19</sup> 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 Part D plans at any time to find plans that cover the prescription drugs they require.<sup>20</sup> 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.<sup>21</sup> For dual eligibles who were randomly assigned to their current PDPs, CMS chooses new PDPs that will have premiums at or below the regional benchmark premium.<sup>22</sup> For dual eligibles who elected their current Part D plans, CMS notifies them that their plans will have premiums above the regional benchmark premium. For 2016, CMS reported reassigning approximately 501,000 Medicare beneficiaries, including but not exclusively dual eligibles, because of premium increases.

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<sup>15</sup> Social Security Act, § 1860D-14(b); 42 CFR § 423.780(b)(2)(i).

<sup>16</sup> Dual eligibles residing in territories are not eligible to receive cost-sharing assistance from Medicare. With this being the case, there are no benchmarks for Part D plans offered in the territories. Social Security Act, § 1860D-14(a)(3)(F).

<sup>17</sup> 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.

<sup>18</sup> CMS, *PDBM*, ch. 3, § 40.1.4.

<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.*, § 30.3.2. In general, Medicare beneficiaries can switch Part D plans only once a year during a defined enrollment period.

<sup>21</sup> *Ibid.*, § 40.1.5.

<sup>22</sup> *Ibid.*

### **Part D Prescription Drug Coverage**

Under Part D, plans can establish formularies from which they may exclude drugs and control drug utilization within certain parameters. These parameters are intended to balance Medicare beneficiaries' needs for adequate prescription drug coverage with Part D plan sponsors' needs to contain costs. Generally, a formulary must include at least two drugs in each therapeutic category or class.<sup>23, 24</sup> In addition, Part D plans must include Part D-covered drugs in certain categories and classes.<sup>25</sup>

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 that Part D plans make regarding individual formularies, certain categories of drugs are excluded from Medicare Part D prescription drug coverage as mandated by the MMA.<sup>26</sup> For example, prescription vitamins, prescription mineral products, and nonprescription drugs are excluded from Part D prescription drug coverage.<sup>27</sup>

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 such coverage.<sup>28, 29</sup>

### **CMS Efforts To Ensure Prescription Drug Coverage**

*Formulary review.* CMS annually reviews Part D plan formularies to ensure that they include a range of drugs in a broad distribution of therapeutic categories or classes, as well as all drugs in specified therapeutic categories or classes.<sup>30</sup> 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.<sup>31</sup>

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<sup>23</sup> CMS, *PDBM*, ch. 6, § 30.2.1.

<sup>24</sup> 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.

<sup>25</sup> Social Security Act, § 1860D-4(b)(3)(G).

<sup>26</sup> MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-2(e).

<sup>27</sup> Social Security Act § 1860D-2(e)(2), 1927(d)(2).

<sup>28</sup> ACA, P.L. No. 111-148 § 2502, Social Security Act, § 1927(d).

<sup>29</sup> 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/BezoandBarbituratesin2013.pdf>, on March 22, 2016.

<sup>30</sup> CMS, *PDBM*, ch. 6, § 30.2.7.

<sup>31</sup> *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.<sup>32, 33, 34</sup>

*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.<sup>35</sup> If their plans make negative determinations, beneficiaries have the right to appeal.<sup>36</sup> 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.<sup>37</sup> 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.<sup>38</sup>

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<sup>32</sup> Ibid., § 30.2.2.

<sup>33</sup> Ibid., § 30.2.7.

<sup>34</sup> 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.

<sup>35</sup> CMS, *PDBM*, ch. 18, §§ 30.1 and 30.2.

<sup>36</sup> Ibid., § 60.1.

<sup>37</sup> Ibid., ch. 6, § 30.4.4.

<sup>38</sup> OIG, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090, January 2006.

In 2011, OIG issued the first annual mandated report examining dual eligibles' access to drugs under Medicare Part D.<sup>39</sup> We have released an annual mandated report each year since then.<sup>40, 41, 42, 43</sup> The current report is the sixth report released.

## 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 2016. As part of our assessment, we included dual eligibles' enrollment data from February 2016, the most recent enrollment data available from CMS at the time of our study. We also compared the results of our 2016 study with those of our 2015 study.<sup>44</sup>

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)—i.e., the 2012 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, 198 are eligible for coverage under Part D. In this report, we refer to these 198 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 2016 report is similar but not identical to the list of drugs referenced in the 2015 report. Specifically, 182 of the 200 drugs (91 percent) listed in the 2015 report are also listed in this 2016 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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<sup>39</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2011*, OEI-05-10-00390, April 2011.

<sup>40</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2012*, OEI-05-12-00060, June 2012.

<sup>41</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2013*, OEI-15-13-00090, June 2013.

<sup>42</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2014*, OEI-05-14-00170, June 2014.

<sup>43</sup> OIG, *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2015*, OEI-05-15-00120, June 2015.

<sup>44</sup> *Ibid.*

We also went beyond the ACA’s mandate in the 2013, 2014, 2015, and 2016 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 the 2012 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 2012 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 2012, the MCBS surveyed 11,299 Medicare beneficiaries, of whom 2,244 were dual eligibles who had used prescription drugs during the year (out of 2,484 dual-eligible survey respondents).

*First Databank National Drug Data File.* We used the December 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).<sup>45</sup>

*Part D plan data.* In January 2016, we collected from CMS the formulary data and the plan data for Part D plans operating in 2016. The formulary data includes Part D plans’ formularies and utilization management tools for plans operating in 2016. In 2016, there are 374 unique formularies offered by 3,116 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 2016 enrollment data for Part D plans. These data provide the number of dual eligibles enrolled in each Part D plan as of February 2016.

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<sup>45</sup> 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 2012 MCBS. We excluded respondents from territories because they are not eligible to receive cost-sharing assistance under Part D. The MCBS listed 167,848 drug events for 2,244 dual eligibles who did not reside in territories.<sup>46</sup>
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 167,848 drug events associated with 868 drugs.
3. We ranked the 868 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, 198 are eligible under Part D. One fell into a drug category excluded under Part D, and one is no longer prescribed in the form taken by beneficiaries surveyed in the 2012 MCBS. For details on these two drugs, see Appendix C.

### **Formulary Analysis**

We analyzed the 374 unique Part D plan formularies to determine their rates of inclusion of the 198 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 198 commonly used drugs had low rates of inclusion by formularies by counting how many of the

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<sup>46</sup> 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 2012. For example, 1 MCBS survey respondent reported taking rosuvastatin calcium (Crestor) 12 times in 2012. We counted this beneficiary/drug combination as 12 drug events.

374 formularies covered each drug. We considered a drug to have a low rate of inclusion if it was included by less than 75 percent of formularies. For such drugs, we counted the number of drugs (if any) that each formulary covered in the same 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 198 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 198 drugs that we reviewed. The tools that we reviewed are prior authorization, quantity limits, and step therapy.

To determine the extent to which the 198 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 198 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 February 2016 to Part D plans available in 2016.

### **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 2012 account for 88 percent of all prescriptions dispensed to the dual-eligible respondents in the 2012 MCBS.

Because the lists of commonly used drugs in the 2015 and 2016 reports are not identical, the changes in rates of inclusion by formularies and in application of utilization management tools between 2015 and 2016 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; 91 percent of the drugs on the list in our 2015 report were also on the list in this 2016 report.

**Standards**

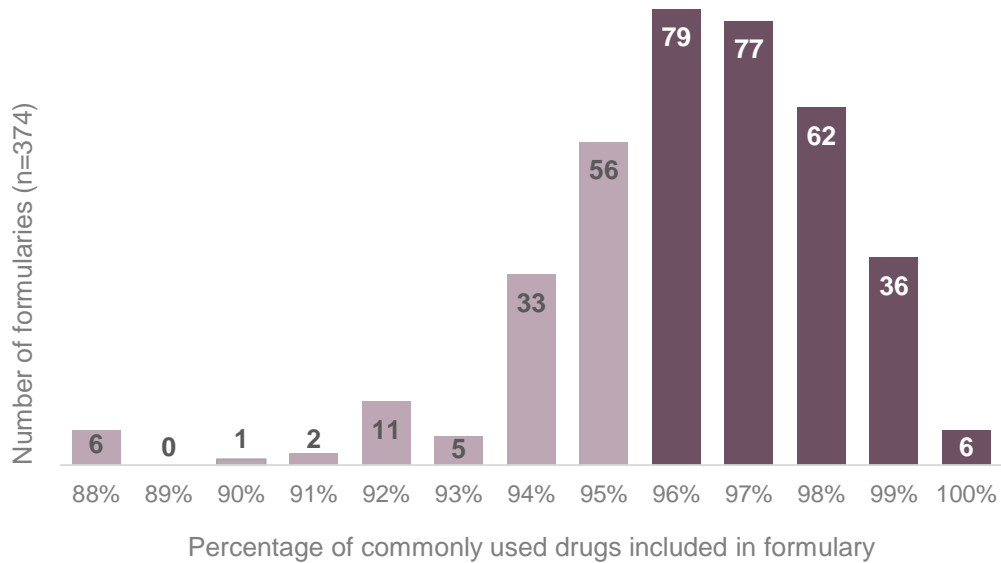
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

**RESULTS**

**Part D Plan Formularies Include Between 88 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 374 unique formularies used by Part D plans in 2016, 6 formularies include 100 percent of the commonly used drugs. At the other end of the inclusion range, six formularies include 88 percent of the commonly used drugs. Figure 1 provides a breakdown of the formularies’ inclusion rates for the drugs most commonly used by dual eligibles. CMS generally requires Part D plan formularies to include at least two drugs—rather than all drugs—in each therapeutic category or class. Therefore, Part D plan formularies may still meet CMS’s formulary requirements even if they do not include all of the drugs we identified as commonly used by dual eligibles.

**Figure 1: More than two-thirds of Part D plan formularies cover at least 96 percent of the drugs commonly used by dual eligibles.**



Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016.

Part D plan formularies’ rate of inclusion of the drugs commonly used by dual eligibles in 2016 is similar to that of 2015. The average rate of inclusion increased slightly between 2015 and 2016, from 95 percent to 96 percent. The range of inclusion rates in 2015 and 2016 are almost the same—in 2015, the rates of inclusion ranged from 86 to 100 percent of the drugs commonly used by dual eligibles, and in 2016, they ranged from 88 to 100 percent.

Nationally, PDP and MA-PD formularies have similar rates of inclusion of the drugs commonly used by dual eligibles, averaging 96 percent and 97 percent, respectively. For PDP formularies, the rates of inclusion ranged from 88 to 99 percent; for MA-PD formularies, they ranged from 88 to 100 percent. Fifteen formularies—4 percent of the 374 unique formularies used by Part D plans in 2016—are offered by both PDPs and MA-PDs.

Regionally, all dual eligibles have the choice of a Part D plan that includes at least 97 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 includes at least 97 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 96 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 85 percent of dual eligibles are enrolled in Part D plans with premiums below the regional benchmark.

Almost all dual eligibles are enrolled in Part D plans that include at least 90 percent of the drugs commonly used by dual eligibles. Of the approximately 10.2 million dual eligibles enrolled in Part D plans, nearly 100 percent are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. Less than 1 percent of dual eligibles are enrolled in Part D plans that use formularies that include less than 90 percent of these drugs. 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	136,868	1%
95% to 99% of commonly used drugs	3,802,667	37%
90% to 94% of commonly used drugs	6,213,107	61%
85% to 89% of commonly used drugs	45,487	<1%
<b>Total</b>	<b>10,198,129</b>	<b>100%*</b>

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles and dual eligibles’ enrollment, 2016.

\*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 increased from 94 percent in 2015 to nearly 100 percent in 2016.

### Sixty-Eight Percent of the Drugs Commonly Used by Dual Eligibles Are Included in All Part D Plan Formularies

Because most of the commonly used drugs are included in a large percentage of formularies, dual eligibles can be confident that regardless of the Part D plan in which they are enrolled, the plan’s formulary will include many of these drugs. By drug, formulary inclusion ranges from 37 percent to 100 percent. At one end of the range, there is a drug that is included in 37 percent of Part D plan formularies, and at the other end, 134 drugs are included in all plan formularies. The average rate of inclusion by formularies is 96 percent. Table 2 shows the rates at which formularies include the 198 drugs. Appendix B lists the 198 drugs and the rates at which formularies include them.

**Table 2: Formularies’ Rates of Inclusion of Commonly Used Drugs**

Percentage of the 374 Formularies	Percentage of the 198 Commonly Used Drugs Included in Formularies
100%	68% (134 drugs)
85% to 99%	24% (47 drugs)
76% to 84%	4% (8 drugs)
37% to 75%	5% (9 drugs)
<b>Total</b>	<b>100%*</b> <b>(198 drugs)</b>

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016.

\*Percentages do not add to 100 percent because of rounding.

The rates of formulary inclusion of the drugs commonly used by dual eligibles in 2016 are similar to those in 2015. The percentage of commonly used drugs included in all formularies increased slightly between 2015 and 2016, from 66 percent to 68 percent.

Part D plan formularies include certain drugs less frequently than others. Of the commonly used drugs, 5 percent (nine drugs) are included by less than 75 percent of Part D plan formularies. Table 3 provides the percentage of formularies covering each of these nine 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. Four of the nine drugs are brand-name drugs, which are typically more costly than generic drugs. As for the primary indications, 3 of the 9 drugs are used for diabetic therapy, 2 of the 11 drugs are muscle relaxants, and the remaining drugs treat a variety of conditions, including gastrointestinal conditions.

**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
Insulin aspart	Diabetes	74%
Lansoprazole	Stomach and intestinal ulcers, erosive esophagitis, excessive stomach acid, Zollinger-Ellison syndrome	73%
Dutasteride	Symptomatic benign prostatic hyperplasia	69%
Dexlansoprazole	Gastroesophageal reflux disease	64%
Insulin lispro	Diabetes	61%
Methocarbamol	Musculoskeletal pain	56%
Esomeprazole magnesium	Dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, Zollinger-Ellison syndrome	56%
Glyburide	Diabetes	46%
Carisoprodol	Musculoskeletal pain	37%

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016. The drugs in the shaded rows also had low formulary inclusion rates in 2015.

Although Part D formularies frequently omit these 9 drugs, they all cover other drugs in the same therapeutic classes. For these 9 drugs, 100 percent of formularies cover at least 1 drug in the same therapeutic class that is also on the list of 198 drugs commonly used by dual eligibles.

The number of drugs included by less than 75 percent of formularies decreased from 11 in 2015 to 9 in 2016. There are five drugs with low inclusion rates in 2016 that were also on the list of commonly used drugs with low inclusion rates in our 2015 report; we note these five drugs in Table 3. Two of these five drugs were also on the list of drugs with low inclusion rates in our 2014 report.

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

- Two of these drugs—carisoprodol and methocarbamol—are on CMS’s list of Part D medications that are high-risk for the elderly.<sup>47</sup>
- The two drugs above and a third drug—glyburide—are listed by the American Geriatrics Society as being potentially inappropriate for older adults.<sup>48</sup>

<sup>47</sup> 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 its prescription data and 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 decisions in choosing Part D plans 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](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPatientSafetyMeasures_071610.pdf) on March 22, 2016.

<sup>48</sup> The American Geriatrics Society, *American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*, 2015.

If a particular drug has a low rate of inclusion by formularies, a dual eligible may need 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.<sup>49</sup> Finally, dual eligibles may switch to Part D plans with formularies that include their drugs, with the new coverage becoming effective the following month.<sup>50</sup>

### **The Percentage of Commonly Used Drugs Subject to Utilization Management Tools by Plan Formularies Decreased Slightly Between 2015 and 2016**

For the unique drugs that compose the list of commonly used drugs, the percentage subject to utilization management tools by Part D plan formularies decreased slightly from an average of 29 percent in 2015 to an average of 28 percent in 2016. Formularies for plans with premiums below and those with premiums above the regional benchmarks had relatively similar percentages of drugs—25 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 2015 and 2016.

**Table 4: Part D Plan Formularies' Application of Utilization Management Tools to Commonly Used Drugs, 2015 and 2016**

Percentage of Unique Drugs to Which Utilization Management Tools Are Applied	Number of 2015 Part D Plan Formularies	Percentage of 2015 Part D Plan Formularies	Number of 2016 Part D Plan Formularies	Percentage of 2016 Part D Plan Formularies
Greater than 40%	49	14%	22	6%
30% to 39%	137	40%	189	50%
20% to 29%	66	19%	59	16%
10% to 19%	65	19%	74	20%
Less than 10%	24	7%	30	8%
<b>Totals</b>	<b>341</b>	<b>100%*</b>	<b>374</b>	<b>100%</b>

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016.

\* Percentages do not add to 100 percent because of rounding.

Although utilization management tools can restrict beneficiaries' access to drugs, they are important tools for managing costs in Medicare and ensuring appropriate utilization of drugs. For example, in 2013, CMS set forth expectations for reviews of opioid overutilization to help ensure that opioids are appropriately prescribed and used. As a result, formularies' application of utilization management controls to oxycodone HCl/acetaminophen drugs increased by 30 percent in 2013.<sup>51</sup>

<sup>49</sup> CMS, *PDBM*, ch. 18, § 30.2.2.

<sup>50</sup> *Ibid.*, ch. 3, § 30.3.2.

<sup>51</sup> CMS, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*, September 6, 2012. Accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf> on March 22, 2016.

The percentage of drugs subject to quantity limits or step therapy decreased slightly from 2015 to 2016, while the percentage of drugs subject to prior authorization remained the same. Formularies’ use of quantity limits and use of step therapy each decreased by 1 percent—from 25 to 24 percent and from 2 to 1 percent of unique drugs, respectively. The percentage of unique drugs for which formularies required prior authorization was 4 percent in both 2015 and 2016.

The rate at which plan formularies apply specific utilization management tools varies widely. In 2016, some formularies applied utilization management tools to none of the unique drugs, whereas at the other end of the range, some applied tools to 45 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 13 percent, and require step therapy for between 0 and 12 percent.

Looking at enrollment across plans provides a slightly different picture than looking only at plans themselves. On average, plan formularies in 2016 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 2016, the median plan weighted by dual-eligible enrollment applies such tools to 32 percent of unique drugs; in 2015, the figure was 35 percent. Similarly, the median plan weighted by overall Medicare enrollment applies these tools to 31 percent of unique drugs in 2016; in 2015, the figure was 34 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 2016, 80 percent of dual eligibles and 73 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 Medicare 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, 2015 and 2016**

Percentage of Unique Drugs to Which Plan Formularies Apply Utilization Management Tools	Percentage of Dual Eligibles Enrolled, 2015	Percentage of Medicare Beneficiaries Enrolled, 2015	Percentage of Dual Eligibles Enrolled, 2016	Percentage of Medicare Beneficiaries Enrolled, 2016
Greater than 40%	8%	16%	1%	1%
30% to 39%	54%	41%	79%	72%
20% to 29%	32%	34%	14%	18%
10% to 19%	4%	5%	3%	5%
Less than 10%	2%	3%	2%	4%
<b>Totals</b>	<b>100%</b>	<b>100%*</b>	<b>100%*</b>	<b>100%</b>

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016.

\* Percentages do not add to 100 percent because of rounding.



## CONCLUSION

When establishing formularies and applying utilization management tools, Part D plans need to balance Medicare beneficiaries' needs for adequate prescription drug coverage with the need to contain costs for plan sponsors and for the Part D program. By law, 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 nine drugs that this report identifies as being included by less than 75 percent of Part D plan formularies, all Part D plan formularies cover at least one therapeutically 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 88 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 198 drugs commonly used by dual eligibles are largely unchanged compared with those from OIG's 2015 report. Part D plan formularies include roughly the same percentage of these commonly used drugs in 2016 as they did in 2015. Enrollment in plans that cover at least 90 percent of unique drugs increased, with nearly 100 percent of dual eligibles enrolled in such plans in 2016 compared to 94 percent in 2015.

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 and produce annual reports on the extent to which Part D plan formularies cover drugs that dual eligibles commonly use. In addition, OIG will continue to monitor Part D plan formularies' application of utilization management tools to these drugs.

This 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 report, please provide them within 60 days. Please refer to report number OEI-05-16-00090 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 Inclusion by Formularies****The 200 Drugs With the Highest Utilization by Dual Eligibles**

\*Sample is from the 2012 MCBS. Projections and confidence intervals are derived from its survey methodology.

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Simvastatin	4,085	20,275,845	18,246,788–22,304,903	374	100%
Lisinopril	4,146	20,105,037	17,883,005–22,327,069	374	100%
Omeprazole	4,277	17,651,028	15,907,564–19,394,492	373	100%
Levothyroxine sodium	3,875	16,391,504	14,506,699–18,276,310	374	100%
Hydrocodone/acetaminophen	4,335	15,724,258	13,700,633–17,747,884	374	100%
Furosemide	3,594	15,682,269	13,969,198–17,395,341	374	100%
Metformin HCl	3,053	15,402,973	13,342,093–17,463,852	374	100%
Amlodipine besylate	3,084	14,334,829	12,552,775–16,116,883	374	100%
Potassium chloride	2,535	9,847,651	8,425,381–11,269,921	374	100%
Gabapentin	2,195	9,659,579	7,744,867–11,574,290	374	100%
Atorvastatin calcium	1,892	9,469,703	8,032,978–10,906,428	374	100%
Metoprolol tartrate	2,161	9,465,474	8,198,827–10,732,121	374	100%
Hydrochlorothiazide	1,684	8,538,793	7,204,227–9,873,358	374	100%
Warfarin sodium	2,143	8,176,792	6,782,635–9,570,949	374	100%
Albuterol sulfate	1,809	8,051,430	6,601,089–9,501,772	374	100%
Esomeprazole magnesium	1,623	7,345,547	5,669,748–9,021,345	208	56%
Tramadol HCl	1,814	7,033,265	5,908,206–8,158,324	374	100%
Citalopram hydrobromide	1,743	7,028,557	5,999,840–8,057,274	374	100%
Clopidogrel bisulfate	1,420	6,884,688	5,592,048–8,177,329	374	100%
Atenolol	1,341	6,622,365	5,452,738–7,791,992	374	100%
Zolpidem tartrate	1,479	6,486,938	5,054,325–7,919,552	363	97%
Carvedilol	1,354	6,189,667	5,070,687–7,308,647	374	100%
Insulin glargine, hum. rec. analog	1,299	5,924,792	4,861,244–6,988,340	361	97%
Promethazine HCl	2,023	5,868,471	4,226,080–7,510,861	372	99%
Glipizide	1,064	5,847,097	4,635,210–7,058,983	374	100%
Fluticasone/salmeterol	1,111	5,800,120	4,224,983–7,375,257	337	90%
Oxycodone HCl/acetaminophen	1,474	5,676,415	4,586,569–6,766,261	374	100%
Metoprolol succinate	1,120	5,665,210	4,616,324–6,714,096	373	100%
Ranitidine HCl	1,409	5,482,639	4,145,862–6,819,416	374	100%
Losartan potassium	1,153	5,482,241	4,424,476–6,540,005	374	100%
Trazodone HCl	1,285	5,420,884	4,236,837–6,604,931	374	100%
Clobetasol propionate	1,232	5,343,963	3,259,867–7,428,059	368	98%
Sertraline HCl	1,329	5,328,104	4,285,112–6,371,097	374	100%

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**The 200 Drugs With the Highest Utilization by Dual Eligibles, continued**

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Alendronate sodium	1,134	5,059,020	4,027,978–6,090,062	374	100%
Valsartan	999	4,988,907	3,709,041–6,268,773	364	97%
Quetiapine fumarate	1,580	4,695,543	3,580,822–5,810,265	374	100%
Pravastatin sodium	1,055	4,497,382	3,599,813–5,394,952	374	100%
Fluticasone propionate	1,031	4,475,369	3,782,797–5,167,942	374	100%
Montelukast sodium	983	4,241,912	3,276,654–5,207,171	374	100%
Prednisone	987	4,140,130	3,299,891–4,980,370	374	100%
Rosuvastatin calcium	862	4,079,698	3,143,992–5,015,404	326	87%
Donepezil HCl	1,067	3,945,615	3,220,946–4,670,284	374	100%
Risperidone	1,320	3,931,788	3,128,046–4,735,529	374	100%
Bupropion HCl	880	3,854,353	2,640,727–5,067,980	374	100%
Isosorbide mononitrate	797	3,805,846	3,135,306–4,476,386	374	100%
Clonidine HCl	765	3,747,550	2,494,439–5,000,661	374	100%
Tamsulosin HCl	741	3,702,932	2,870,655–4,535,209	374	100%
Lovastatin	760	3,603,172	2,680,255–4,526,090	373	100%
Aripiprazole	915	3,588,383	2,471,105–4,705,661	374	100%
Cyclobenzaprine HCl	884	3,576,109	2,862,722–4,289,496	288	77%
Duloxetine HCl	829	3,455,834	2,612,026–4,299,643	374	100%
Pantoprazole sodium	745	3,437,474	2,677,159–4,197,789	364	97%
Allopurinol	713	3,403,401	2,647,198–4,159,603	374	100%
Escitalopram oxalate	881	3,387,426	2,551,390–4,223,461	374	100%
Ibuprofen	953	3,311,577	2,684,384–3,938,770	374	100%
Fluoxetine HCl	793	3,256,783	2,506,927–4,006,640	374	100%
Alprazolam	852	3,243,748	2,306,161–4,181,334	325	87%
Oxycodone HCl	923	3,211,833	2,344,856–4,078,811	374	100%
Diltiazem HCl	804	3,112,978	2,356,110–3,869,845	374	100%
Glimepiride	596	3,102,504	2,097,429–4,107,579	374	100%
Azithromycin	826	2,990,930	2,651,776–3,330,084	374	100%
Divalproex sodium	1,147	2,956,347	2,371,699–3,540,994	374	100%
Memantine HCl	820	2,946,246	2,305,419–3,587,073	374	100%
Nystatin	778	2,877,573	1,728,167–4,026,980	374	100%
Pregabalin	620	2,874,390	1,945,883–3,802,897	374	100%
Olanzapine	826	2,743,691	1,746,975–3,740,406	374	100%
Famotidine	598	2,741,416	2,001,603–3,481,230	373	100%
Amitriptyline HCl	648	2,732,645	2,025,566–3,439,723	374	100%
Sitagliptin phosphate	563	2,731,020	1,929,937–3,532,103	363	97%
Tiotropium bromide	561	2,700,930	2,048,631–3,353,230	320	86%

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**The 200 Drugs With the Highest Utilization by Dual Eligibles, continued**

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Meloxicam	641	2,699,758	2,079,860–3,319,656	373	100%
Ketoconazole	778	2,678,585	1,642,081–3,715,089	374	100%
Mirtazapine	693	2,629,860	1,932,977–3,326,744	374	100%
Nifedipine	467	2,620,445	1,841,087–3,399,804	360	96%
Lisinopril/hydrochlorothiazide	561	2,602,432	2,034,129–3,170,735	374	100%
Lamotrigine	812	2,568,810	1,524,901–3,612,719	374	100%
Levetiracetam	774	2,542,145	1,772,630–3,311,661	374	100%
Clonazepam	696	2,474,602	1,754,467–3,194,736	374	100%
Enalapril maleate	551	2,442,608	1,834,260–3,050,956	374	100%
Triamterene/ hydrochlorothiazide	484	2,409,224	1,777,659–3,040,789	374	100%
Paroxetine HCl	608	2,399,150	1,706,298–3,092,003	374	100%
Celecoxib	482	2,386,463	1,634,429–3,138,497	341	91%
Benzotropine mesylate	796	2,344,725	1,666,426–3,023,025	373	100%
Carbamazepine	711	2,291,674	1,547,240–3,036,107	374	100%
Ciprofloxacin HCl	561	2,201,817	1,879,769–2,523,865	374	100%
Spirolactone	530	2,167,379	1,706,024–2,628,734	374	100%
Nitroglycerin	489	2,159,899	1,556,844–2,762,953	374	100%
Diclofenac sodium	459	2,071,649	1,535,708–2,607,591	374	100%
Valsartan/hydrochlorothiazide	411	2,043,602	1,418,412–2,668,792	365	98%
Digoxin	563	2,017,627	1,397,347–2,637,908	374	100%
Latanoprost	451	1,941,504	1,429,872–2,453,136	374	100%
Topiramate	676	1,919,140	1,225,777–2,612,502	374	100%
Morphine sulfate	482	1,917,895	1,323,903–2,511,887	374	100%
Fluocinonide	517	1,914,945	984,579–2,845,310	373	100%
Polyethylene glycol 335d	563	1,911,548	1,456,516–2,366,580	374	100%
Sulfamethoxazole/ trimethoprim	575	1,882,925	1,565,574–2,200,276	374	100%
Lorazepam	478	1,872,334	1,385,592–2,359,076	374	100%
Ipratropium/albuterol sulfate	475	1,863,411	1,265,089–2,461,734	361	97%
Carbidopa/levodopa	469	1,847,813	1,150,958–2,544,668	374	100%
Fenofibrate nanocrystallized	393	1,802,940	1,311,234–2,294,646	355	95%
Glyburide	333	1,800,905	1,292,057–2,309,754	171	46%
Levofloxacin	450	1,776,547	1,439,401–2,113,694	374	100%
Oxybutynin chloride	465	1,772,254	1,130,986–2,413,522	374	100%
Venlafaxine HCl	565	1,769,289	1,293,093–2,245,485	374	100%
Verapamil HCl	386	1,768,870	1,232,568–2,305,172	374	100%
Pioglitazone HCl	350	1,765,584	1,267,958–2,263,210	374	100%

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**The 200 Drugs With the Highest Utilization by Dual Eligibles, continued**

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Naproxen	481	1,712,919	1,305,637–2,120,202	374	100%
Cephalexin	461	1,708,905	1,354,546–2,063,263	374	100%
Insulin aspart	438	1,697,897	1,236,282–2,159,511	278	74%
Meclizine HCl	354	1,694,107	1,166,438–2,221,776	374	100%
Cinacalcet HCl	273	1,686,744	228,751–3,144,737	374	100%
Benazepril HCl	314	1,662,487	1,061,779–2,263,195	373	100%
Amoxicillin	449	1,645,349	1,440,430–1,850,269	374	100%
Ezetimibe	315	1,630,531	1,137,372–2,123,691	373	100%
Hydralazine HCl	352	1,626,562	1,040,354–2,212,770	374	100%
Losartan/hydrochlorothiazide	323	1,616,723	1,126,209–2,107,237	374	100%
Methocarbamol	332	1,604,238	957,852–2,250,624	210	56%
Carisoprodol	468	1,569,542	1,069,916–2,069,169	138	37%
Lansoprazole	300	1,517,331	937,732–2,096,931	273	73%
Lidocaine	392	1,497,702	1,062,229–1,933,176	374	100%
Baclofen	432	1,496,342	901,759–2,090,925	374	100%
Propranolol HCl	441	1,466,579	989,903–1,943,256	374	100%
Tizanidine HCl	465	1,402,405	922,152–1,882,657	374	100%
Buspirone HCl	345	1,392,828	771,720–2,013,936	374	100%
Lactulose	352	1,376,489	858,083–1,894,894	374	100%
Brimonidine tartrate	270	1,364,643	814,036–1,915,250	374	100%
Omega-3 acid ethyl esters	337	1,340,484	863,754–1,817,215	350	94%
Methadone HCl	233	1,334,501	668,812–2,000,191	373	100%
Metoclopramide HCl	272	1,311,286	790,771–1,831,801	374	100%
Ropinirole HCl	318	1,304,881	795,681–1,814,080	374	100%
Phenytoin sodium extended	414	1,299,826	893,247–1,706,406	374	100%
Budesonide/formoterol fumarate	297	1,282,394	897,195–1,667,593	287	77%
Timolol maleate	251	1,278,484	801,832–1,755,136	374	100%
Hydrocortisone	279	1,276,518	768,357–1,784,678	374	100%
Travoprost	325	1,223,842	898,838–1,548,847	332	89%
Olopatadine HCl	288	1,210,924	776,919–1,644,928	330	88%
Hydroxyzine HCl	296	1,208,115	813,793–1,602,437	298	80%
Bimatoprost	206	1,206,009	747,306–1,664,713	353	94%
Insulin detemir	325	1,203,894	807,216–1,600,572	310	83%
Ziprasidone HCl	331	1,183,365	639,947–1,726,783	374	100%
Doxazosin mesylate	253	1,166,572	705,708–1,627,436	374	100%
Insulin lispro	243	1,165,251	612,842–1,717,661	229	61%
Diazepam	336	1,163,773	805,788–1,521,758	374	100%

*continued on next page*

**The 200 Drugs With the Highest Utilization by Dual Eligibles, continued**

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Pramipexole di-HCl	269	1,163,159	716,859–1,609,460	374	100%
Dexlansoprazole	255	1,154,307	605,989–1,702,624	240	64%
Acetaminophen with codeine	324	1,146,119	835,514–1,456,724	374	100%
Finasteride	193	1,142,207	645,801–1,638,614	374	100%
Metronidazole	277	1,082,251	740,294–1,424,207	374	100%
Estrogens, conjugated	207	1,062,210	680,581–1,443,839	307	82%
Ramipril	216	1,044,656	618,660–1,470,651	374	100%
Mometasone furoate	273	1,041,955	738,062–1,345,847	373	100%
Doxycycline hyclate	306	1,039,974	803,052–1,276,896	374	100%
Gemfibrozil	317	1,002,452	655,398–1,349,505	374	100%
Insulin regular, human	321	997,047	448,381–1,545,713	374	100%
Clozapine	377	996,800	256,796–1,736,805	374	100%
Amoxicillin/potassium clav	296	992,326	798,742–1,185,910	374	100%
Fentanyl	283	950,958	630,440–1,271,475	374	100%
Fenofibrate	200	947,241	530,041–1,364,441	373	100%
Terazosin HCl	196	944,375	600,107–1,288,642	374	100%
Quinapril HCl	176	941,788	521,252–1,362,324	371	99%
Amlodipine besylate/benazepril	210	938,298	638,282–1,238,313	359	96%
Tolterodine tartrate	218	934,963	602,658–1,267,269	358	96%
Insulin nph hum/reg insulin hm	223	926,025	503,322–1,348,729	374	100%
Fluconazole	268	906,521	631,479–1,181,562	374	100%
Sucralfate	252	899,714	608,736–1,190,692	374	100%
Niacin	249	884,662	476,245–1,293,079	370	99%
Colchicine	183	874,820	496,096–1,253,544	374	100%
Solifenacin succinate	189	861,786	578,376–1,145,197	306	82%
Megestrol acetate	226	860,045	569,049–1,151,041	374	100%
Ciclopirox olamine	190	846,025	291,480–1,400,570	361	97%
Calcitriol	181	844,443	510,574–1,178,312	374	100%
Hydroxychloroquine sulfate	227	843,974	546,086–1,141,862	374	100%
Dicyclomine HCl	258	835,905	510,720–1,161,090	357	95%
Sevelamer carbonate	181	834,843	473,155–1,196,532	362	97%
Dorzolamide HCl/ timolol maleate	183	820,248	535,827–1,104,669	368	98%
Raloxifene HCl	170	817,458	404,826–1,230,090	374	100%
Ergocalciferol (vitamin D <sub>2</sub> )	238	815,762	577,444–1,054,081	0	0%**
Dutasteride	175	812,367	421,163–1,203,571	258	69%
Cyclosporine	206	811,780	542,087–1,081,473	374	100%

\*\*See Appendix C.

continued on next page

**The 200 Drugs With the Highest Utilization by Dual Eligibles, *continued***

Generic Name	Sample Size*	Projected Drug Events*	95-Percent Confidence Interval*	Number of Formularies Including Drug	Percentage of Formularies Including Drug
Ipratropium bromide	212	809,312	479,306–1,139,318	374	100%
Prednisolone acetate	186	793,727	589,346–998,109	348	93%
Clotrimazole/ betamethasone dip	215	793,462	607,917–979,006	301	80%
Estradiol	152	785,815	436,414–1,135,216	374	100%
Primidone	200	780,692	193,858–1,367,527	374	100%
Torsemide	197	780,054	485,186–1,074,923	365	98%
Nitrofurantoin monohyd/m-cryst	192	773,126	516,975–1,029,278	361	97%
Albuterol	176	770,589	478,225–1,062,953	0	0%**
Sumatriptan succinate	146	767,599	-30,501–1,565,698	374	100%
Risedronate sodium	147	763,979	295,176–1,232,781	294	79%
0.9% sodium chloride	216	754,836	155,720–1,353,952	372	99%
Cilostazol	202	751,130	399,943–1,102,317	374	100%
Amiodarone HCl	149	750,614	391,667–1,109,561	374	100%
Chlorthalidone	150	735,530	370,480–1,100,580	371	99%
Doxepin HCl	202	724,154	404,293–1,044,015	374	100%
Mupirocin	204	697,884	520,300–875,469	374	100%
Ondansetron HCl	183	663,507	421,480–905,535	374	100%
Metolazone	127	657,608	251,543–1,063,674	366	98%
Clonidine	114	654,668	234,616–1,074,720	336	90%

Source: OIG analysis of drugs commonly used by dual eligibles, 2016.

\*\*See Appendix C.



## APPENDIX C

### Two 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
Ergocalciferol (vitamin D <sub>2</sub> )*	Vitamin or mineral product

Source: OIG analysis of formulary inclusion of drugs commonly used by dual eligibles, 2016.  
\*These drugs were also on the 2015 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 PDP Region**

<b>PDP Region</b>	<b>State(s)</b>	<b>Number of PDPs</b>	<b>Average Rate of Inclusion by Formularies</b>	<b>Minimum Rate</b>	<b>Maximum Rate</b>
1	Maine, New Hampshire	25	96%	93%	99%
2	Connecticut, Massachusetts, Rhode Island, Vermont	23	96%	93%	99%
3	New York	19	96%	93%	99%
4	New Jersey	22	96%	93%	99%
5	Delaware, the District of Columbia, Maryland	21	96%	93%	99%
6	Pennsylvania, West Virginia	26	96%	93%	99%
7	Virginia	25	96%	93%	99%
8	North Carolina	23	96%	88%	99%
9	South Carolina	24	96%	88%	99%
10	Georgia	24	96%	93%	99%
11	Florida	19	96%	93%	99%
12	Alabama, Tennessee	24	96%	93%	99%
13	Michigan	25	96%	93%	99%
14	Ohio	24	96%	93%	99%
15	Indiana, Kentucky	25	96%	93%	99%
16	Wisconsin	25	95%	92%	99%
17	Illinois	25	96%	88%	99%
18	Missouri	25	96%	93%	99%
19	Arkansas	25	96%	93%	99%
20	Mississippi	21	96%	93%	99%
21	Louisiana	22	96%	93%	99%
22	Texas	25	96%	88%	99%
23	Oklahoma	24	95%	88%	99%
24	Kansas	23	96%	93%	99%
25	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	23	96%	92%	99%
26	New Mexico	24	96%	88%	99%
27	Colorado	24	96%	93%	99%
28	Arizona	23	96%	92%	99%
29	Nevada	25	96%	93%	99%
30	Oregon, Washington	24	96%	93%	99%
31	Idaho, Utah	26	96%	92%	99%
32	California	25	96%	93%	99%
33	Hawaii	19	96%	93%	99%
34	Alaska	25	96%	93%	99%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2016.

\*PDP.

\*\*MA-PD.

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

MA-PD Region***	State(s)	Number of MA-PDs	Average Rate of Inclusion by Formularies	Minimum Rate	Maximum Rate
1	Maine, New Hampshire	46	96%	95%	99%
2	Connecticut, Massachusetts, Rhode Island, Vermont	88	97%	92%	99%
3	New York	205	97%	92%	99%
4	New Jersey	42	96%	88%	99%
5	Delaware, the District of Columbia, Maryland	36	97%	95%	100%
6	Pennsylvania, West Virginia	143	97%	92%	100%
7	North Carolina, Virginia	109	97%	88%	100%
8	Georgia, South Carolina	66	97%	94%	100%
9	Florida	229	97%	90%	99%
10	Alabama, Tennessee	88	97%	94%	98%
11	Michigan	60	97%	92%	99%
12	Ohio	114	97%	92%	100%
13	Indiana, Kentucky	92	97%	94%	98%
14	Illinois, Wisconsin	127	97%	91%	100%
15	Arkansas, Missouri	73	97%	88%	98%
16	Louisiana, Mississippi	61	97%	94%	97%
17	Texas	139	97%	94%	99%
18	Kansas, Oklahoma	53	97%	95%	99%
19	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	78	97%	91%	99%
20	Colorado, New Mexico	59	97%	94%	100%
21	Arizona	68	97%	94%	99%
22	Nevada	29	97%	94%	99%
23	Idaho, Oregon, Utah, Washington	167	97%	92%	100%
24	California	281	97%	93%	100%
25	Hawaii	18	97%	94%	100%

Source: OIG analysis of formularies' inclusion of drugs commonly used by dual eligibles, 2016.

\*\*\*Region 26, which covers Alaska, had no MA-PDs available for 2016.