An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans

June 2013

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UCB provided funding for this report. Avalere maintained editorial control and the conclusions expressed here are those of the author.

Table of Contents

Executive Summary

This study measures access to anticonvulsants by an examination of coverage, cost sharing, and utilization management of anticonvulsants in selected commercial health insurance plans and Medicare Prescription Drug Plans (PDPs). The study found that:

- Commercial plans had higher levels of coverage of anticonvulsants on formularies than PDPs;
- Commercial plans placed more covered anticonvulsants on lower tiers than PDPs;
- Cost sharing on tiers one and two were higher for commercial plans than PDPs; for tiers three and four, cost sharing was nearly level among both sets of plans; and
- Usage of utilization management (UM) techniques was fairly similar among PDPs and commercial plans.

CMS implemented the protected classes policy, which was subsequently included in statute by Congress in 2009, in order to ensure access to "all or substantially all" medications in six categories of drugs. The risk of poor access to a broad variety of medications in these six categories substantially increases risk of negative health outcomes. The statute requires PDPs to cover all medications in these classes, with the exception of multi-source brands of the identical molecular structure, extended release products (if the immediate release product is included), products that have the same active ingredient, and dosage forms that do not have a unique route of administration. The findings of this analysis indicate that, despite anticonvulsants' status as a protected class, PDPs had lower levels of access compared to commercial health insurance plan formularies.

Introduction

Epilepsy is a chronic neurological condition that makes affected individuals susceptible to recurrent seizures. An estimated 2.2 million people in the United States live with epilepsy, a complex brain disorder characterized by sudden and often unpredictable seizures, with prevalence tending to increase with age.[1] Epilepsy is most commonly treated with prescription drug therapy, often involving one or more medications classified as anticonvulsants (also known as anti-epilepsy drugs, or AEDs). Anticonvulsants often require a threshold level of concentration and careful maintenance of that level in the body to be effective.[2] Therefore, maintaining a strict adherence to anticonvulsants is critical to controlling epilepsy and seizures. Because of the sensitivity and complex nature of anticonvulsants, a significant number of patients report increased risk of seizures and side effects when switching from one anticonvulsant to another, whether the switch is between different manufacturers, between generic and brand, or between different formulations (e.g., immediate and extended release).[3]

Insurance coverage for prescription drug benefits varies greatly and can lead to different access to anticonvulsants for patients with different prescription drug benefit coverage. As explained below, access to a drug is not determined by coverage of the drug on the formulary alone. Patients face cost-sharing requirements as well as utilization management policies in filling their prescriptions.

PDPs must follow federal regulations on formulary and cost sharing set by the Centers for Medicare & Medicaid Services (CMS) including, as elaborated later in this report, the protected class policy. This study aimed to determine if the level of oversight in the Medicare program improves access to prescription drugs over the access found in leading commercial plans. In this analysis, Avalere compared three measures of access (i.e., coverage, cost sharing, and utilization management) for 56 brand and generic drugs categorized as anticonvulsants between 5 commercial health insurance plans and 10 stand-alone prescription drug plans (PDPs) in the Medicare Part D program. The 10 selected PDPs collectively account for nearly 40 percent of all Medicare beneficiaries enrolled in PDPs in 2013,[4] and the selected commercial plans are representative of coverage offered by large employers.

Background

Access to prescription drugs in a health insurance plan is determined by three factors: formulary coverage, cost sharing, and utilization management.

- **Formulary Coverage:** Insurers may choose to contract with specific pharmaceutical manufacturers and allow preferred access to a limited number of products. Depending on the scope of contracting that insurers have with manufacturers, prescription drug benefits may have lean or generous coverage of drugs.
- **Cost Sharing:** Even among covered products, insurers may further manage members' utilization through use of formulary tiers and cost sharing. In a tiered formulary, these policies often place generics on lower tiers with fixed copayments and brands and specialty drugs on higher tiers with higher copayments or coinsurance. These varying cost-sharing requirements give members financial incentive to seek drugs in the lowest-cost tier.
- **Utilization Management:** Lastly, insurers both in Medicare and the commercial market may also apply formulary benefit management tools, known as utilization management (UM), to manage or direct patient access. Typically, insurers' pharmacy and therapeutics (P&T) committees design and implement policies on utilization and access to medications, such as quantity limits, step therapy (ST), and prior authorization (PA) criteria.[5] PA requires providers to obtain authorization from the insurer prior to filling a particular drug for the patient. Insurers may review whether there is a more affordable available and whether the prescription is medically necessary before granting PA. ST requires providers and their patients to try and fail on a more cost effective drug before progressing to other costlier or higher risk drugs.

Different insurance programs have different rules that govern formulary coverage, cost sharing, and UM. This study focuses on Medicare Part D and commercial insurance, which have different levels of regulation and oversight by the federal government.

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which established the Part D program for outpatient prescription drug coverage, requires that CMS review Medicare PDP designs in order to ensure that they do not discriminate against any category of beneficiaries by discouraging their enrollment.[6] CMS has a series of rules to guide the development and management of PDP formularies, focusing on formulary adequacy, specialty tiers, protected classes, and other topics.

To ensure adequate formularies in the Part D program, CMS requires PDPs to offer

drugs that cover all disease states, to cover at least two unique chemical entities for each condition, and to review and determine coverage for new drugs to the market. CMS also defines rules for drugs assigned to a PDP's specialty tier—a tier for very high cost and unique medications. Rules include a cost threshold for a drug to be included on this tier as well as a cost-sharing limit of 25 percent.[7]

Further, CMS requires that PDPs include all or substantially all of the drugs in six "protected classes," one of which is the anticonvulsants class.[8] In developing Part D policies, CMS found that 10 of the top 15 groups of related diagnoses are treated by drugs in these six categories and that these diagnoses had high drug and medical spending, increasing the agency's concerns about beneficiary selection and discrimination by PDPs.[9] Moreover, CMS recognized that even a short interruption of therapy with these categories of drugs could significantly increase the risk of negative health outcomes for beneficiaries.[10] The requirement to cover all or substantially all drugs in these classes would ensure that Medicare beneficiaries transitioning into the Part D program have uninterrupted access to those drugs.

CMS codified the protected class policy in 2009.[11] According to the latest revision of the Part D Prescription Drug Benefit Manual, PDP formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.[12] CMS defines "substantially all" to mean all drugs in all of their unique dosage forms with the exception of multi-source brands of the identical molecular structure, extended release products (if the immediate release product is included), products that have the same active ingredient, and dosage forms that do not have a unique route of administration.[13] In addition, for patients already stabilized on these drugs before enrollment, PDPs may not use UM policies, such as PA and ST. However, PDPs may apply UM policies for beneficiaries beginning treatment with drugs in these categories (aside from HIV/AIDS drugs).[14]

For patients, the protected class policy is most effective for categories of medications with few generics or extended release products. In the anticonvulsants category, more than a third of drugs are generic, and nine products are extended release. PDPs can meet the protected class requirements without covering brands with generic equivalents or extended release formulations of medications.

Commercial Coverage

In contrast to the Medicare program, commercial coverage does not have federal requirements to protect access to certain classes of drugs. State laws and regulations apply to certain commercial plans. For the purpose of this study, commercial plans were defined as health insurance plans with a prescription drug benefit. Commercial plans selected for this study include five large insurers that offer such coverage to employers nationwide.

Methodology

In order to assess the differences in access to drugs in the anticonvulsants category between Medicare Part D and commercial plans, Avalere designed a study across three measures of access—coverage, cost sharing, and utilization management. To develop a full list of drugs classified as anticonvulsants, Avalere consulted the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) v.5.0 to obtain a listing of the USP Category, USP Class, and Example Drugs. Additional drugs were identified based on the Medi-Span® drug database and internal clinical assessment. For the full list of drugs in this analysis, see Appendix A.

In selecting PDPs and commercial plans for the analysis, we first identified the 10 PDPs with the highest enrollment in 2013 and then identified commercial plans issued by the selected PDP sponsors. All of the health insurers issuing these PDPs and commercial plans have significant presence in both the Medicare Part D and the commercial markets. The 10 selected PDPs collectively account for nearly 40 percent of all Medicare beneficiaries enrolled in PDPs in 2013,[15] and the selected commercial plans are representative of coverage offered by large employers. For the full list of plans in this analysis, see Appendix B.

To collect the coverage and UM information (i.e., PA and ST) for each anticonvulsant medication, we examined publicly available sources, including the drug coverage and UM information in the Medicare Plan Finder[16] for the PDPs and coverage and UM details in online formularies for the commercial plans. A drug's presence on a plan's formulary indicated coverage, and online formularies also specified each covered drug's tier placement. The varying cost-sharing amounts associated with the formulary tiers of the PDPs were obtained through an analysis using DataFrame®, a proprietary database of Medicare Part D plan features.[17] As the tier-associated cost-sharing amounts for commercial plans are negotiated in private between health insurers and their large employer clients, we used the average copayment and coinsurance amounts reported by the Kaiser Family Foundation (KFF) and the Health Research & Educational Trust (HRET) in the 2012 Employer Health Benefits Survey.[18]

The rates of anticonvulsant coverage, tier placement of covered drugs, and UM use as well as the cost-sharing amounts were averaged separately for PDPs and for commercial plans and are enrollment weighted, where noted.

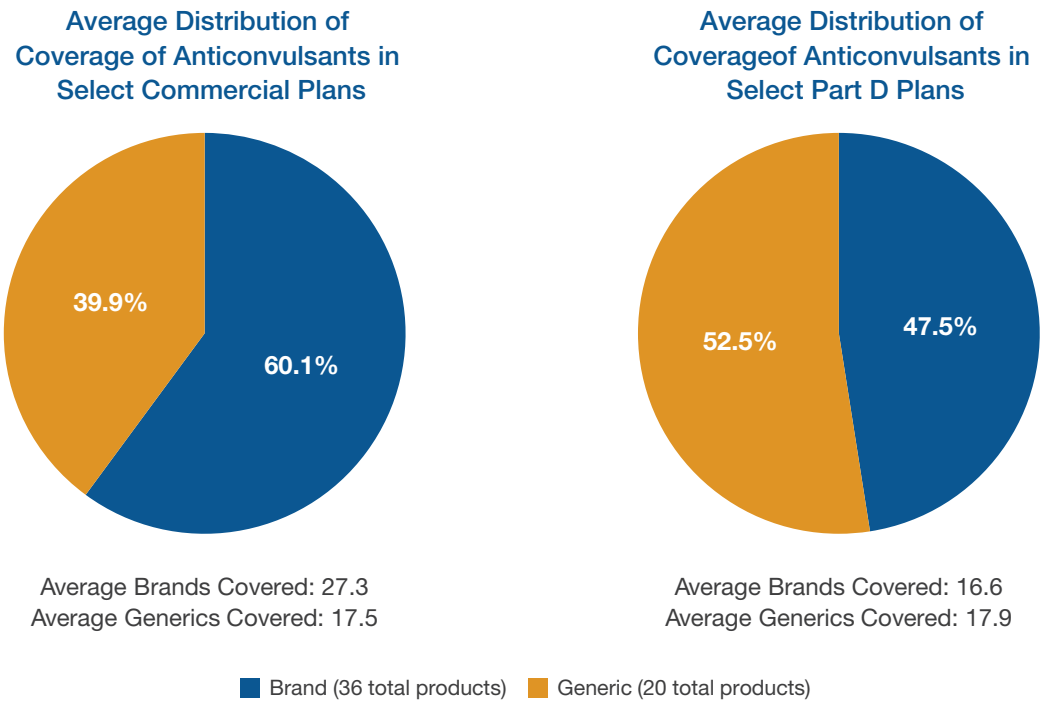
Findings

This analysis examined access to products in the anticonvulsants class of medication, measured by coverage on a plan's formulary, tier placement, cost sharing, and UM. To best illustrate these measures of access across plan types, we compiled data from the selected PDPs and commercial plans.

Coverage

Coverage of products in the anticonvulsants category in the selected Medicare PDPs is generally lower than coverage among those insurers' commercial plans. Commercial plan formularies include an average of 80 percent of drugs in the anticonvulsants category (44.8 products), while Part D plans cover an average of 62 percent (34.5 products) of the 56 total drugs in this category. Both PDPs and commercial plans covered nearly 18 generic products each (of 20 total generics in the category). The main difference in coverage between commercial plans and PDPs was for brand drugs in the category—with PDPs covering less than half (16.6 brands) and commercial plans covering about three-quarters (27.3 of the 36 brands in the category) on average.

Though anticonvulsants are one of Medicare's six protected classes, CMS policy does not require PDPs to cover multi-source brands of the identical molecular structure, extended release products, products that have the same active ingredient, and dosage forms that do not have a unique route of administration. The difference in coverage between commercial plans and PDPs in this study is for brand drugs that meet one or more of the exceptions above.



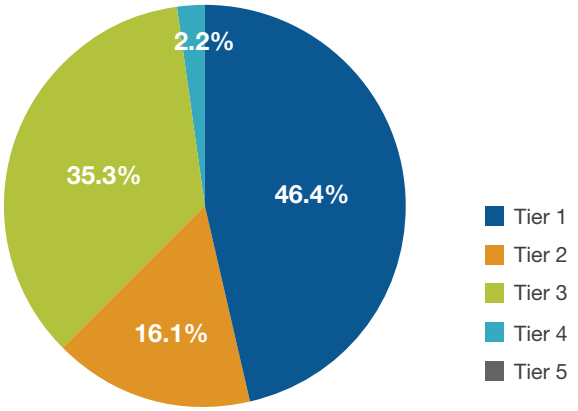
Tier Placement

Tier placement of anticonvulsants also differed between commercial and Part D plans. Commercial plans typically employ four-tier formularies,[19] while PDPs have trended towards five-tier formularies for the past several years.[20] Nearly half of products in the anticonvulsants category are assigned to the first tier of commercial plan formularies, with only 22 percent on tier one among Part D plans. Notably, rates of formulary placement in tiers one and two combined for PDPs nearly equals the rate of coverage in only tier one of commercial plans. This is attributable to the fact that commercial plans in this study typically use the first tier for generics, while six of the ten PDPs in this study use tiers one and two for preferred and non-preferred generics, respectively. Three of the four remaining PDPs use only one generics tier and included the majority of covered generic products on the first tier. In contrast, the highest tiers of coverage (tier four for commercial and tier five for PDPs) include approximately the same percent of medications across the category (2.2 percent for commercial and 2.5 percent for PDPs).

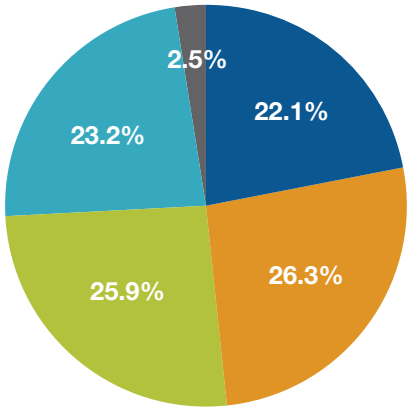
Among commercial plans, covered drugs are typically assigned to the following tiers: tier one = generics; tier two = preferred brands; tier three = nonpreferred brands; and tier four = biologics or lifestyle drugs. The PDPs in this analysis, on the other hand, have a

more varied structure. Of the 10 PDPs, 6 have 5 tiers, 3 have 4 tiers, and 1 has 3 tiers. Five tiered PDPs often place preferred and nonpreferred generics on tiers one and two, respectively. PDPs are also more likely than commercial plans to have a tier for specialty drugs—biologics or other very high cost drugs. PDPs must designate which tier is for specialty drugs, often placing these medications on the plan's highest tier—tier four or tier five.

Average Distribution of Coverage of Anticonvulsants Per Tier in Select Commercial Plans



Average Distribution of Coverage of Anticonvulsants Per Tier in Select Part D Plans



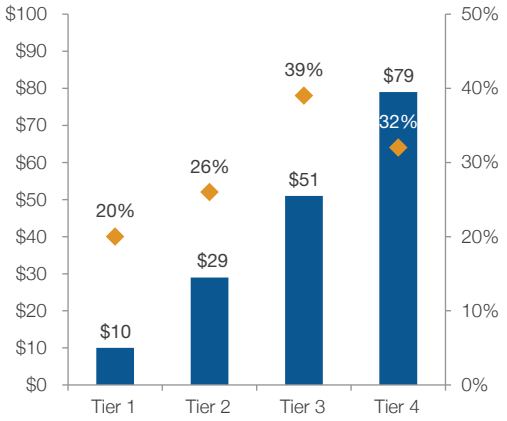
Cost Sharing

Cost sharing associated with tier placement varied across the tiers in commercial plans compared to PDPs.[21] The average cost sharing for medications placed in tier one is $10 in the 86 percent of commercial plans that use a copayment and 20 percent in the 11 percent of employer-sponsored plans using coinsurance. No PDPs in the analysis assign a coinsurance to the first tier; the average copayment for tier one drugs in these plans is $2.11.[22] For tier two, the average cost sharing among the 77 percent of commercial plans using a copayment was $29, while the 21 percent using coinsurance averaged 26 percent. Eight of the ten PDPs used copayments for the second tier, averaging $9.35; while the remaining two PDPs had an average coinsurance of 23 percent for this tier.

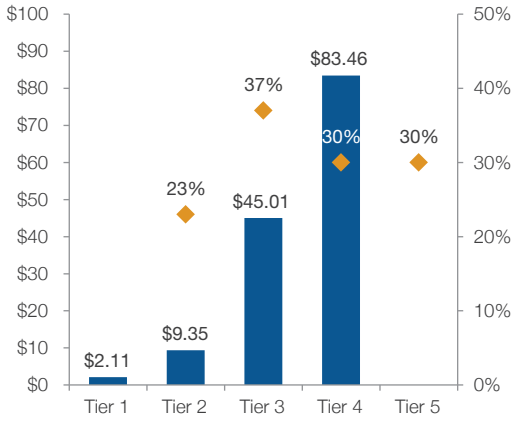
The 72 percent of commercial plans using a copayment averaged $51 for tier three medications; and 24 percent of these plans with coinsurance for the third tier charged 39 percent. Seven of the ten PDPs used copayments that average $45.01 on tier three

and the remaining plans charged coinsurance averaging 39 percent on this tier. Tier four medications for the 55 percent of employer-sponsored plans with copayments cost $79, while the 36 percent using coinsurance assign a rate of 32 percent. Among PDPs, four of nine plans using copayments for tier four averaged $83.46, with the other five plans charging an average coinsurance of 30 percent. No employer-sponsored plans in this study had a fifth tier. Among the six PDPs with a fifth tier, all assign a coinsurance; it averaged 30 percent for this tier.

Average Distribution of Cost Sharing Per Tier in Employer-Sponsored Plans



Average Distribution of Cost Sharing Per Tier in Select Part D Plans



Copayment ◆ Coinsurance

Utilization Management

Unlike the other elements of access (i.e., coverage, tier placement, and cost sharing), utilization management did not differ substantially between commercial plans and PDPs. Across the commercial plans in this study, 13.1 percent of covered anticonvulsants included either PA or ST to manage enrollees' utilization of these medications. Similarly, 11.7 percent of medications in this category included one of these utilization management techniques for the PDPs in this analysis.

Conclusion

In this study, access to anticonvulsants—measured by coverage, cost sharing, and utilization management—differed between commercial health insurance plans and Medicare PDPs. Commercial plans had higher levels of coverage than PDPs; they also placed more covered products on lower tiers than PDPs. Cost sharing on tiers one and two were higher for commercial plans than PDPs; for tiers three and four, cost sharing was nearly level among both sets of plans. Usage of utilization management techniques was fairly similar among PDPs and commercial plans.

For a medication placed on the specialty tier, the difference in cost sharing between coinsurance and a fixed copayment can also be substantial. According to a recent report by the Government Accountability Office (GAO), the median negotiated price of all specialty tier-eligible drugs in 2007 was $1,100.[23] Under a commercial plan with an $1,100 specialty drug on the highest tier, a patient would pay $79 per month on average. In contrast, a Medicare beneficiary enrolled in a PDP would pay 30 percent, or $330 per month, on average for this same medication.

CMS policies, including the protected class policy, were established to offer specific protections to Medicare beneficiaries at risk of discrimination on the basis of their healthcare needs. As demonstrated in this analysis, the protected class policy as it applies to anticonvulsants does not result in better coverage or access to medications in this category for PDPs compared to commercial health insurance.

Appendix A

Class	Drug Name	
Anticonvulsants, Other	Potiga	Levetiracetam
	Keppra	Levetiracetam XR
	Keppra XR	
Calcium Channel Modifying Agents	Zarontin	Lyrica
	Ethosuximide	Zonegran
	Celontin	Zonisamide
Gamma-aminobutyric Acid (GABA) Augmenting Agents	Depakote	Primidone
	Depakote ER	Gabitril
	Depakote Sprinkles	Tiagabine
	Divalproex Sodium	Depacon
	Divalproex Sodium ER	Depakene
	Divalproex Sodium Sprinkles	Stavzor
	Gabapentin	Valproic Acid
	Neurontin	Sabril
	Mysoline	
Glutamate Reducing Agents	Felbamate	Lamotrigine
	Felbatol	Topamax
	Lamictal	Topamax Sprinkle
	Lamictal ODT	Topiragen
	Lamictal XR	Topiramate
Sodium Channel Agents	Carbamazepine	Vimpat
	Carbamazepine ER	Oxcarbazepine
	Carbatrol	Trileptal
	Epitol	Dilantin
	Tegretol	Dilantin Infatabs
	Tegretol XR	Phenytek
	Peganone	Phenytoin
	Cerebyx	Phenytoin ER
	Fosphenytoin	Banzel

Appendix B

Commercial Plan	Formulary Link
United Healthcare	https://www.myuhc.com/content/myuhc/Member/Assets/Pdfs/2013_Advantage_PDL.pdf
Aetna	https://pbm.aetna.com/wps/portal/FRAMED_UNAUTH_MEDICATION_SEARCH_TOOL
Humana	http://www.humana.com/providers/pharmacy/drug_list.aspx
CIGNA	https://secure.cigna.com/cgi-bin/customer_care/member/drug_list/DrugList.cgi
Coventry	http://coventry.formularies.com/

Medicare PDP Plan	2013 Enrollment
AARP MedicareRx Preferred	3,864,051
SilverScript Basic	3,072,524
Humana Walmart-Preferred Rx Plan	1,746,283
Humana Enhanced	1,319,437
Cigna Medicare Rx Plan One	693,384
First Health Part D Premier	684,538
Wellcare Classic	638,030
First Health Part D Value Plus	622,429
AARP MedicareRx Saver Plus	515,275
Aetna CVS/pharmacy Prescription Drug Plan	448,027

Notes

[1] *Epilepsy Across the Spectrum: Promoting Health and Understanding.* Washington, DC: The National Academies Press, 2012.

[2] Epilepsy Foundation. "Medication Switching." Accessed on May 3, 2013. Available at: www.epilepsyfoundation.org/aboutepilepsy/treatment/medications/medicationswitching/index.cfm.

[3] Ibid.

[4] Avalere Health analysis using enrollment data released by CMS in February 2013 (reflecting enrollment accepted as of January 2013). Excludes lives in Part D plans with fewer than 10 enrollees, enrollment in the territories, and enrollment in employer plans.

[5] Academy of Managed Care Pharmacy. "Formulary Management." November 2009. Available at: amcp.org/WorkArea/DownloadAsset.aspx?id=9298.

[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1860D-11(e)(2)(D)(i), Pub. L. No. 108-173, 117 Stat. 2066.

[7] CMS. "Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements." 2010. Available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

[8] CMS. "Medicare Modernization Act Final Guidelines – Formularies, CMS Strategy for Affordable Access to Comprehensive Drug Coverage: Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures." 2005. Available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidance.pdf.

[9] CMS. "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" 2005. Available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf

[10] Ibid.

[11] Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies." 42 CFR 423. 2009. Available at: www.gpo.gov/fdsys/pkg/FR-2009-01-16/pdf/E9-783.pdf.

[12] CMS. "Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements." 2010. Available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf

[13] Ibid.

[14] Ibid.

[15] Avalere Health analysis using enrollment data released by CMS in February 2013 (reflecting enrollment accepted as of January 2013). Excludes lives in Part D plans with fewer than 10 enrollees, enrollment in the territories, and enrollment in employer plans.

[16] Medicare Plan Finder for Health, Prescription Drug, and Medigap Plans. Available at: www.medicare.gov/find-a-plan.

[17] CMS released the 2013 plan data in October 2012.

[18] KFF and HRET. "2012 Employer Health Benefits Survey." September 11, 2012. Available at: ehbs.kff.org/pdf/2012/8345.pdf.

[19] KFF and HRET. "2012 Employer Health Benefits Survey." September 11, 2012. Available at: ehbs.kff.org/pdf/2012/8345.pdf.

[20] Avalere Health analysis of CMS landscape files. Data not shown.

[21] As mentioned above, tier-associated cost-sharing amounts for commercial plans are negotiated in private between health insurers and their large employer clients. For this reason, we used average copayment and coinsurance amounts reported by the Kaiser Family Foundation (KFF) and the Health Research & Educational Trust (HRET) in the 2012 Employer Health Benefits Survey.

[22] Avalere analysis included enrollment-weighting to average the cost-sharing associated with each tier among the selected PDPs.

[23] GAO. "Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier." January 29, 2010. Available at: http://www.gao.gov/new.items/d10242.pdf.

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