



# Medicare Part D's Six Protected Classes Policy

*A Balanced Approach to Provide Patients  
Access to Medications While Allowing  
Powerful Tools to Control Costs*

**Partnership for Part D Access**

*[www.PartDPartnership.org](http://www.PartDPartnership.org)*





# EXECUTIVE SUMMARY

**A** new study performed by Avalere Health, a leading strategic advisory company, and sponsored by the Partnership for Part D Access provides new insights into the tools Medicare Part D plans are currently employing to manage utilization of drugs under Medicare’s six protected classes policy. The protected classes policy is designed to ensure that Medicare patients with some of the most serious health conditions — cancer, HIV, transplant recipients, epilepsy, and mental illness among others — have access to the full range of medicines recommended by their physician.

According to the Avalere analysis Part D plans are using formularies and employing a range of utilization management and other tools such as coinsurance and “fail first” policies to encourage Medicare beneficiaries to use lower-costing medications for both brand and generic medications across the protected classes. For example, nearly three-quarters of all drugs in the six protected classes are placed in a non-preferred or specialty category, with 78% of branded products categorized as non-preferred or specialty and 66% of generics also subject to placement on the higher tiers. Part D plans place drugs from the protected classes on high tiers (non-preferred or specialty) 73% of the time. For brand drugs, plans use this high tier placement 78% of the time and 66% of the time for generics.

Plans are using the wide regulatory authority granted to them to direct patients to the lowest cost option available. For the Medicare patients who need a particular formulation of a drug, the six protected classes policy is intended to ensure patients are able to access the medication their physician prescribes. Yet, even with this protection, many patients must overcome layers of restrictive barriers that plans put in place to access their needed medications.

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# Part One

## *Overview of Medicare's Protected Classes Policy*

When Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Senators repeatedly emphasized the role of protections, including the protected classes, available to beneficiaries who need “exactly the right medicine for them.”<sup>1</sup> During implementation of the MMA, which created the Medicare Part D drug program, the Centers for Medicare and Medicaid Services (CMS) issued sub-regulatory guidance directing prescription drug plans (PDPs), through contract provisions, to cover “all or substantially all” medications within six classes and categories that the agency identified.<sup>2</sup> These categories are: anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants (for the treatment of transplant rejection).

However, over time it became clear that adherence to the sub-regulatory guidance was uneven among plans. In 2008, Congress established under Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA), the Six Protected Classes of drugs under Medicare Part D. MIPPA codified CMS’ existing guidance. Specifically, it required Medicare Part D plan sponsors to include in their formularies access to all or substantially all drugs in the six identified classes and categories of priority. MIPPA also specified two statutory criteria that CMS had to use in identifying additional classes of clinical concern: (1) where restrictions on that class would have major or life threatening consequences; and (2) where there is a significant need for individuals which a disease or disorder treated by the drugs in the class to have access to multiple drugs within that class.

In the Affordable Care Act (ACA) Congress reaffirmed its reliance on the two-part test established under MIPPA. The ACA also codified the six existing protected classes and categories by name, and expanded coverage to include all drugs within these six classes and categories until such time as the Secretary makes changes. The regulations that have governed the policy allow for plans to cover one drug of clinical equivalence in each class.<sup>3</sup> For example, if there is one brand product in a category and three generic products, the health plan sponsor may choose to cover just one of the four drugs in this category.

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<sup>1</sup> 149 Cong. Rec. S5882-03.

<sup>2</sup> Centers for Medicare & Medicaid Services, “Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements” (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>

<sup>3</sup> According to the 2016 iteration of the CMS’ “Medicare Prescription Drug Benefit Manual,” “substantially all” in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions: multi-source brands of the identical molecular structure; extended release products when the immediate-release product is included; products that have the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration.

In January 2014, based on a belief that plans did not have the tools to adequately manage the drug benefit, the Centers for Medicare and Medicaid (CMS) proposed changes that would have denied access to these vital medications. Under the proposal, CMS would have removed the protected status of antidepressants and immunosuppressants for the 2015 coverage year, and antipsychotics in 2016.

In response to strong congressional and stakeholder opposition, CMS eventually announced that the agency would not finalize the proposal to eliminate protected class status, although they acknowledged that they may look to advance these proposed changes “in future years.” More recently, in June 2016, the Medicare Payment Advisory Committee (MedPAC) renewed stakeholder concerns by again recommending that two of the protected classes be eliminated. And in May 2018, the Department of Health and Human Services (HHS) released a new Request for Information seeking further input on whether they should pursue additional changes to the protected classes policy.

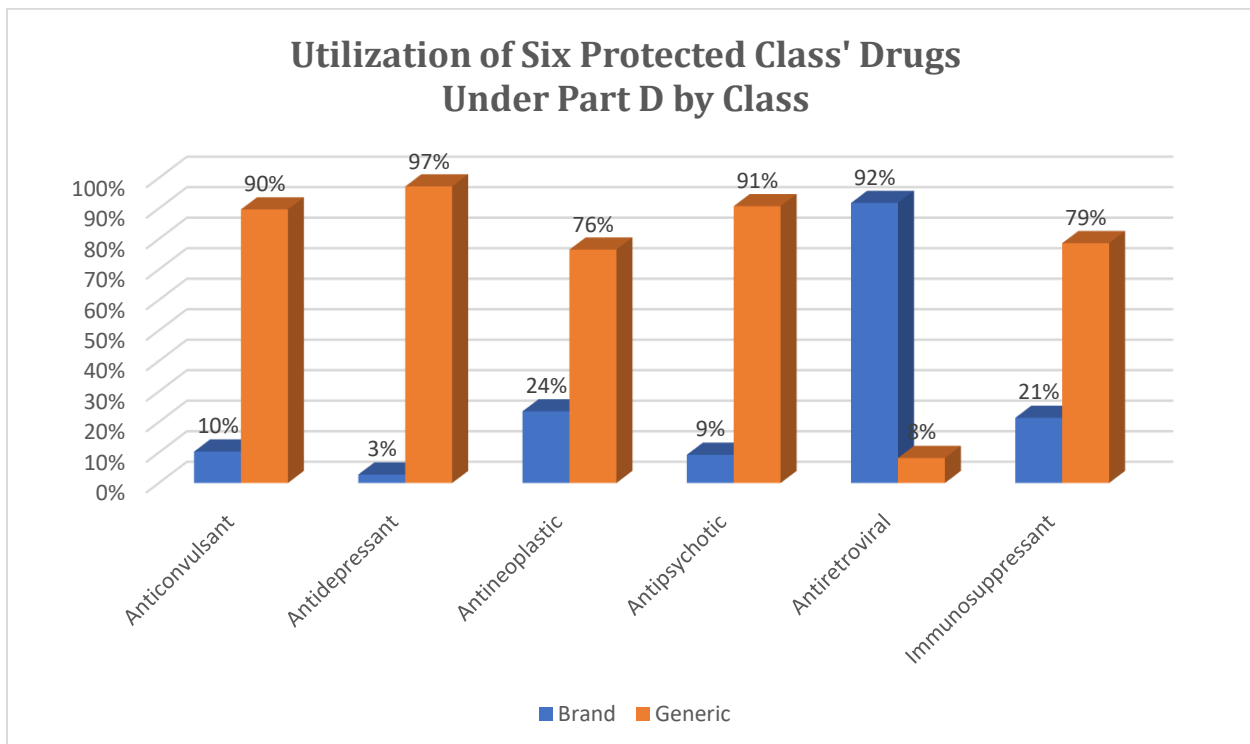
# Part Two

## Key Findings

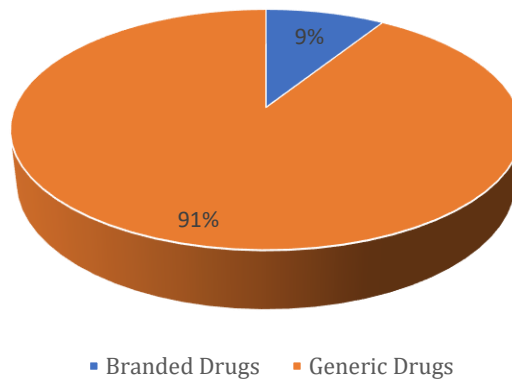
The following results from the Avalere study demonstrate that as currently implemented, Medicare’s six protected classes policy is “threading the needle” by ensuring access to a full range of drugs for patients who have specialized treatment needs while also providing plans with meaningful tools to manage front end access as well as overall costs.

**A significant majority of all prescriptions filled for drugs in the protected classes are for generic products.**

- Across all protected classes, 35% of covered drugs are generic, yet 91% of prescriptions filled in 2016 are for generic products.
- Generics represented more than 90% of the prescriptions filled within each of the categories for anticonvulsants (90%), antidepressants (97%), and antipsychotics (91%).



### Utilization of Protected Classes Drugs Under Part D Overall



*Key takeaway: Part D plan benefit design for drugs in the protected classes results in much higher utilization of generic drugs than brand drugs.*

**A small number of Medicare beneficiaries depend on medications that are on the highest tiers.**

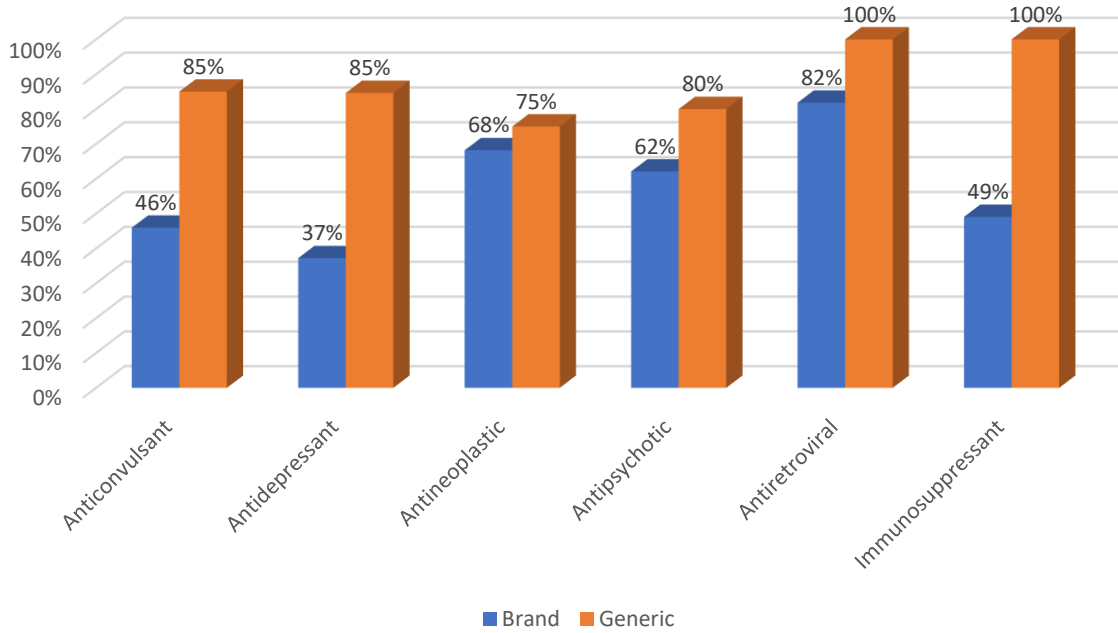
- Only 1% of all the prescriptions filled for drugs across the protected classes were for products that are always placed on high tiers — meaning the most difficult for patients to access.

*Key takeaway: The protected classes policy ensures access to all unique medications and encourages the use of lower cost options.*

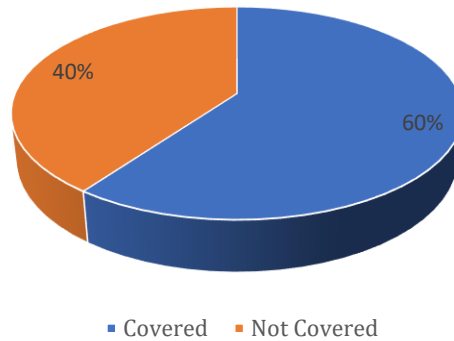
**On average, plans cover just over two-thirds of drugs across all six of Medicare's protected classes.**

- Across all classes, plans cover 67% of drugs (brand and generic combined) and 60% of the available brand name products, on average.
- In the class for antidepressants, plans cover only 37% of brand name medications and for anticonvulsants they cover 46% of the brand name products.

### Coverage of Six Protected Class' Drugs Under Part D



### Branded Drugs Covered Within the Protected Classes\*



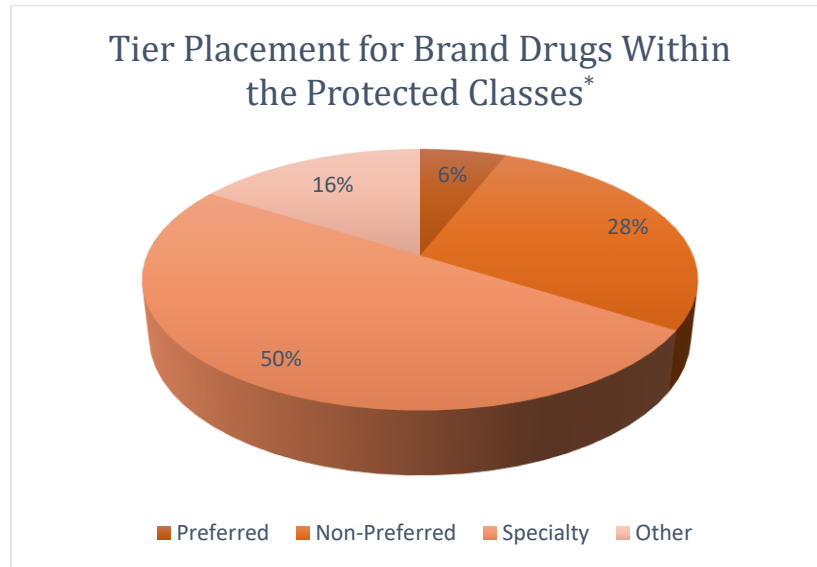
\*Drugs reflect a count of unique drugs.

*Key takeaway: While Part D plans are required to cover all unique products in the protected classes, this requirement does not result in universal coverage of brands when clinically equivalent generic drugs are available.*



**Tier placement is the primary tool plans use to manage access and utilization of medications in the six protected classes.**

- The average Part D beneficiary is enrolled in a plan that places drugs from the protected classes on high tiers (non-preferred or specialty) 73% of the time.
- Specifically, branded products are placed on high tiers 78% of the time and generics 66% of the time — meaning they are subject to higher cost sharing, additional authorization for coverage, and other requirements.

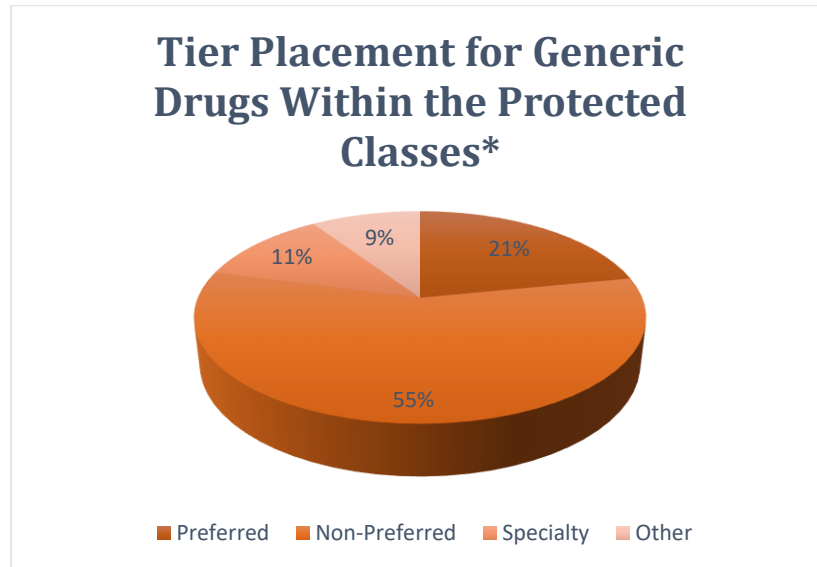


\* Other tier types reflect "Injectable" and "Non-Medicare"

*Key takeaway: Part D plans already can – and do – use tier placement to manage utilization and encourage greater use of generic drugs.*

**Generic products in the six protected classes are selectively placed on plan formularies as non-preferred or specialty products.**

- Two-thirds (66%) of the covered generics in the protected classes are placed on non-preferred (55%) or specialty tiers (11%).
- Within the class of antidepressants, plans covered 85% of generic products, but the majority of these (57%) were still placed on non-preferred tiers, making them more difficult for patients to access.

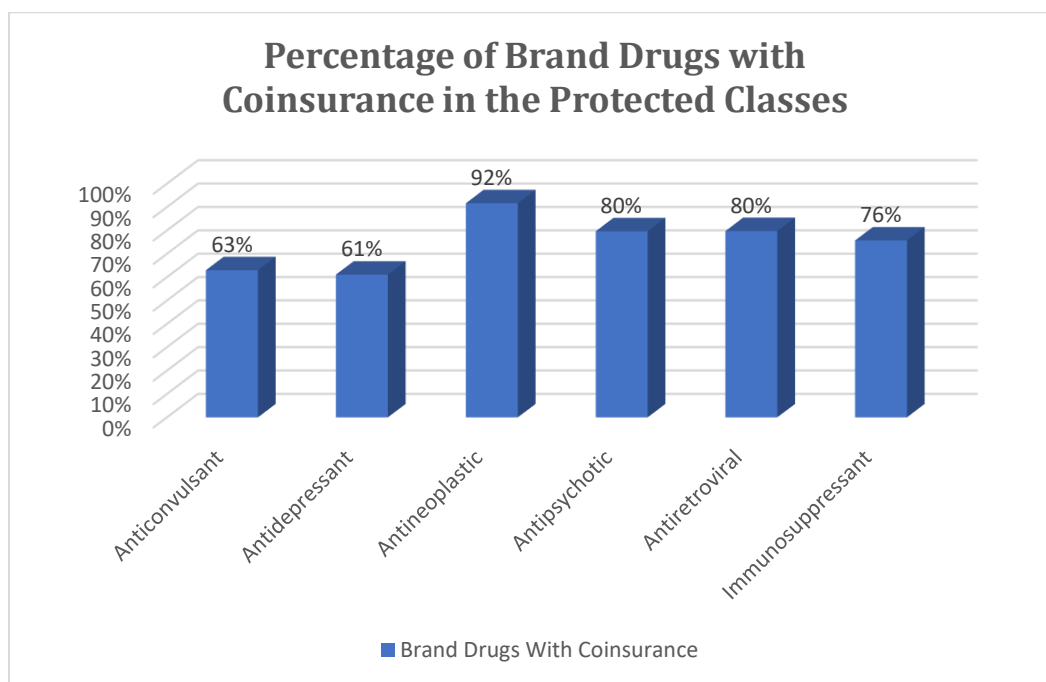


\*Other tier types reflect "Injectable" and "Non-Medicare"

*Key takeaway: Even with the safeguards that the six protected classes policy affords, patients still must overcome layers of restrictive barriers that plans put in place to access needed medications — ultimately driving patients to lower-cost options.*

**For the average Part D beneficiary, most drugs in the protected classes are placed on tiers that require coinsurance.**

- Nearly 60% of the time, beneficiaries are enrolled in plans where drugs in the protected classes require coinsurance.
- Among brand name medications across the protected classes, patients are subject to a coinsurance payment for an overwhelming 80% of products.
- Plans apply a coinsurance for most of the brand antineoplastics (92%) and at least 60% of the brand products for antipsychotics (80%), antiretrovirals (80%), anticonvulsants (63%), antidepressants (61%) and immunosuppressants (72%).
- The average patient cost sharing amount for a brand name medication across the six protected classes was \$1,045 in 2016.<sup>4</sup>

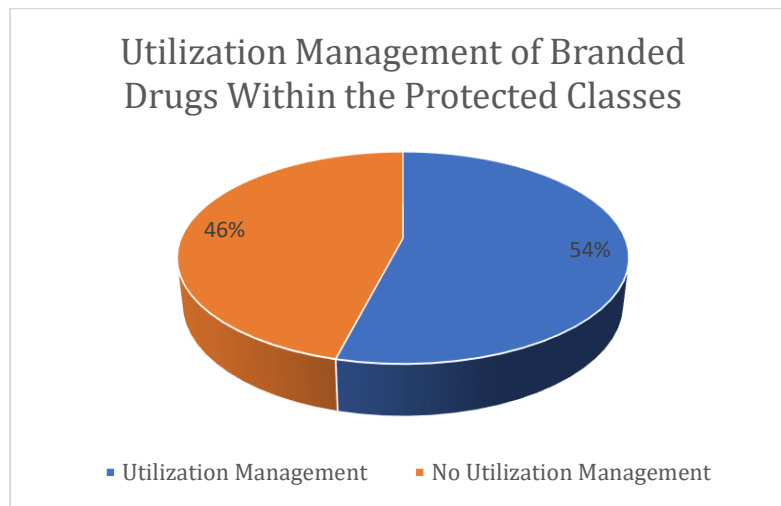


*Key takeaway: When beneficiaries are subjected to coinsurance, which requires them to pay a percent of total costs, it may result in higher out-of-pocket expenses than when a copayment is assessed, depending on the benefit design.*

<sup>4</sup> Cost sharing is defined here as the share of costs covered by the health plan sponsor that is the responsibility of the Medicare Part D enrollee. This term generally includes deductibles, coinsurance, and copayments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services.

**In addition to tier placement, plans frequently deploy other utilization management approaches to control patient access to drugs across all protected classes.**

- Across the six protected classes, plan sponsors employ utilization management tools at least 40% of the time.
- Plans apply utilization management policies for a majority of branded drugs (54%) in the protected classes.
- Prior authorization (PA) is required for nearly half of the brand drugs (49%) in the protected classes.



*Key takeaway: Utilization management requirements placed on drugs in protected classes can add access barriers for the Medicare Part D enrollees.*

# Part Three

## *Discussion*

**T**his study uncovered the range of strategies and tools that Medicare Part D plan sponsors employ to control spending for prescription drugs in the protected classes. As described below, these include strategic plan design and meaningful financial requirements as well as administrative hurdles that tend to favor patient use of lower cost generic alternatives wherever possible.

### **UTILIZATION OF GENERIC PRODUCTS**

Medicare Part D plan sponsors are overwhelmingly advancing strategies that lead patients to fill generic products. The extent of genericization hinges on the availability of such clinically equivalent products. However, once a generic market is established, plans seek to incentivize use of generic products, including by placing generics on tiers that carry lower cost sharing obligations or that are subject to fewer clinical or administrative hurdles.

### **COVERAGE WITHIN THE PROTECTED CLASSES**

While Medicare's protected classes policy precludes plans from entirely excluding a drug, plans do avail themselves of existing authority that permits exceptions to this coverage requirement.<sup>5,6,7,8</sup> In practice, this means plans are varying the scope of coverage for drugs in a class or category. The study results demonstrate that plans are using this flexibility to exclude brand medications within some of the protected classes. The majority of time, when there are multiple clinically equivalent drugs in a

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<sup>5</sup> The protected classes policy requires Medicare Part D drug plans to include in their formularies access to all drugs in the six identified classes and categories of priority. The latest version of the CMS "Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements", last revised in 2016 identifies specific exceptions where plans may exclude a drug from a formulary. These exceptions are for multi-source brands of the identical molecular structure; extended release products when the immediate-release product is included; products that have the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration.

<sup>6</sup> Within the categories of protected classes, Congress has provided additional protections. Specifically, Part D plans are required to cover *all* approved antiretrovirals (ARVs) used in treatment for Medicare patients with HIV. There may be some exceptions in coverage, such as medications with the same active ingredient. See: <https://medicare.com/health/hiv-and-aids-treatment-options/>

<sup>7</sup> CMS' Medicare manual also advises Part D plan sponsors that for HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models. See: <https://medicare.com/health/hiv-and-aids-treatment-options/>

<sup>8</sup> Plans may be limited in their ability to direct patients to generic alternatives for antineoplastics used to treat cancer since there are a limited number of alternatives and treatments typically follow specific clinical protocols.

class, plans choose to cover one or more of the available lower cost generic products. This can allow plans to hold down costs and may enhance a plan sponsor's negotiating power with manufacturers.

### **TIER PLACEMENT**

Non-preferred and specialty drugs are placed on higher tiers, which serves as a first line check to identify patients who might not otherwise need a higher cost medication. Medicare Part D plan sponsors plans can – and do – place drugs in the protected classes on higher tiers. Higher tiers generally require a greater financial contribution from the patient and are subject to additional layers of review by plan administrators.

The data support that higher tier placement may lead to a low rate of utilization for these products, as evidenced by the low rate of patient utilization for brand medications. This preferential tier placement serves to redirect patients away from higher cost to lower cost medications, when these options are available. For example, the vast majority of patients needing antidepressants and antipsychotics are using generic medications. Formulary placement is a primary tool plans utilize to secure favorable pricing during negotiations with drug manufacturers.

### **UTILIZATION MANAGEMENT TOOLS**

While the protected classes policy provides additional safeguards for Medicare patients with certain complex health conditions, health plans have significant control to design plan structure and the ability to employ a range of utilization management tools, including prior authorization, cost-sharing, step therapy, coinsurance, and others that drive patients to low cost, preferred medications. Taken together, these flexibilities add to the suite of tools plans employ to direct patients to use lower cost medications, when they are available. In particular, prior authorization is a frequent tool employed by health plans for patients that request brand medications. This additional layer is designed to further limit the number of Medicare patients that access the higher-cost products within the protected classes.

### **COST SHARING**

Plans also design cost-sharing and coinsurance policies to direct patients to lower-cost alternatives. A clear majority of beneficiaries are enrolled in Part D plans where protected classes medications require coinsurance. Plans are particularly consistent in applying a significant coinsurance for brand medications across the protected classes, which presents another hurdle for patients seeking higher-cost medications.

# Part Four

## *Conclusion*

**T**his study provides new information regarding the impact Medicare’s protected classes policy has on patient access to prescription drugs and Part D plans’ ability to manage prescription drug costs. The results demonstrate that the safety valve of Medicare’s protected classes is working as intended to provide a balanced approach for Medicare Part D enrollees with complex medical conditions to access the medications that work best for them.

The majority of Part D enrollees may not necessarily need a particular formulation of a medication, and those patients are already choosing lower-cost generic alternatives within the protected classes, even when there are several brand options available in a protected class. The findings also provide evidence that the protected classes policy ensures that patients who need a particular formulation of a drug are able to access it. These patients, however, must still overcome additional layers of restrictions that plans put in place to further manage utilization.

Additionally, the findings provide new evidence that health plans are employing a range of utilization management and other tools such as selective formularies, coinsurance, and prior authorization to maximize use of lower-costing medications for both brand and generic medications across the protected classes.

The Medicare population is comprised of individuals over age 65, who often have multiple chronic conditions, and individuals with significant disabilities. The protected classes policy is designed to reflect Medicare enrollees’ unique and challenging health characteristics. Limiting access to the most appropriate medications would drive higher costs in Medicare Part A and Part B and Medicaid by increasing admittance to in-patient care and emergency departments due to the destabilization of patients’ conditions. The costs associated with this care otherwise would not be incurred by Medicare or Medicaid.

# Part Five

## *Study Design*

### **COMPARISON OF PART D BENEFIT DESIGN AND FORMULARY PLACEMENT**

This study analyzes Part D benefit design and formulary data from 2016 to assess coverage and management of drugs under six protected classes. Specifically, for each protected class and in aggregate, Avalere used its proprietary database of formulary and benefit design data, PlanScape, to analyze:

- Drug tier placement
- Cost sharing type (copay vs coinsurance)
- Average cost sharing amounts
- Utilization management restrictions, especially prior authorization and step therapy requirements

### **ASSESSMENT OF UTILIZATION OF BRAND AND GENERIC DRUGS IN PART D PROTECTED CLASSES**

The study also is designed to provide a side-by-side comparison of brand and generic drug utilization for the six protected classes and insights to the classes where generic use is more prevalent. This analysis uses data from Inovalon's Medical Outcomes Research for Effectiveness and Economics Registry (the MORE2 Registry®), which includes access to comprehensive Medicare Fee-for-service (FFS) Parts A/B claims data, Part D prescription drug event (PDE) data, Medicare Advantage claims data, Medicaid managed care plan claims data, and commercial health plan claims data. The registry also includes some clinical data, such as laboratory results, for certain populations.

### **DATA ANALYSIS**

Across the Part D plans there is variation in the level of coverage within a category of drugs in the protected classes. Avalere looked across all Part D plans to calculate the average level of coverage. The findings presented for each class reflect enrollment-weighted averages across all Part D plans analyzed in the 50 states and DC. The results of the analysis are stratified by generic versus brand drugs.

The coverage, cost-sharing, and utilization management analysis was conducted using publicly available and proprietary databases to identify approximately 18,000 national drug codes (NDCs) on the market in 2016 for the six protected drug classes under Medicare Part D (Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals and Immune Suppressants). This database combines and analyzes the Centers for Medicare & Medicaid Services (CMS) 2016 Public Use Files (PUF) data on Part D enrollment, plan benefit and formulary design, and negotiated drug



prices. Avalere then identified a subset of approximately 1,200 NDCs on Part D plan formularies spanning individual months in 2016. Avalere excluded Cost plans, demonstration plans, and Programs of All-Inclusive Care for the Elderly (PACE) plans from the analysis due to the unique benefit design of those plans that would not be representative of the Part D market.

If an NDC of a drug was placed on different tiers across months for the same plan, Avalere captured the highest tier for that NDC in the analysis. In addition, among all drugs analyzed, Avalere identified a subset of 228 NDCs across all 6 protected classes (76 unique drugs) that were predominantly placed on high tiers (non-preferred or specialty) by plans in 2016 (i.e., at least 90% of Part D beneficiaries were enrolled in plans that placed those drugs on high tiers on their formularies).

To assess the utilization of brand and generic drugs in Part D protected classes Avalere analyzed the 2016 Part D prescription drug event (PDE) data from Inovalon's Medical Outcomes Research for Effectiveness and Economics Registry (MORE2 Registry®). For each protected class, Avalere calculated the volume of scripts overall and segmented by total brand versus generic drugs. The analysis of the generic and brand utilization used the subset of approximately 1,200 NDCs identified in the 2016 Part D plan formulary files to assess utilization using PDE data from 2016.

Per the data use agreement (DUA) with CMS, the final study cohort cannot comprise more than 20% of Medicare beneficiaries for any given year. The number of beneficiaries prescribed drugs from the antidepressants class exceeded the 20% threshold, so Avalere restricted the brand/generic analysis timeframe for this specific drug class. The restriction includes only beneficiaries with a prescription of interest in the 11 of 12 months of Part D coverage in 2016 which met the 20% threshold. Avalere also performed a utilization assessment specific to a subset of 228 NDCs identified as being predominately placed on high tiers by Part D plans in 2016.

## **TERMS AND DEFINITIONS**

For this analysis the Medicare definition of a covered drug was used.<sup>9</sup> The study uses the brand/generic indicator assigned to drugs in the formulary data as well as claims data.

Plans name and define their tiers in a variety of ways. For consistency this analysis aggregated different names into five tier categories: Brand, Generic, Preferred, Non-Preferred, and Specialty. In this context, "non-preferred tier" refers to instances where plans choose to place drugs for which they don't have agreements with manufacturers and/or the drug cost is high, and therefore cost-sharing on non-preferred tier is higher than on preferred tier. The specialty tier is designed for high-cost drugs whose prices exceed a certain threshold set by CMS: \$670 for a one-month supply at an in-network retail pharmacy.

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<sup>9</sup> See: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PartDDrugsPartDExcludedDrugs.pdf>