

# Medicare Part D's Six Protected Classes Policy

*Coverage Policies Create Access Challenges  
for Patients with Complex, Chronic  
Conditions*

**Partnership for Part D Access**

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





# EXECUTIVE SUMMARY

**A** new study from the Partnership for Part D Access confirms that the Medicare Part D protected classes policy is an essential pillar of protection for beneficiaries with complex health conditions. Yet, the research also highlights that Medicare prescription drug plans (PDPs) are increasingly limiting access to medications — even for patients with complex, chronic conditions. The study, performed by Avalere Health, a leading strategic advisory company, provides new insights into the various steps Medicare Part D plans are taking to manage utilization of medications covered under Medicare’s six protected classes policy. The protected classes policy is designed to ensure that Medicare beneficiaries with some of the most serious health conditions — cancer, HIV, epilepsy, mental illness, and those at risk of organ rejection, among others — have access to the full range of medicines recommended by their physician.

For Medicare beneficiaries who need a specific medication that their doctor believes is necessary and most appropriate, the six protected classes policy is intended to ensure they can get it. However, even with these protections, this new research demonstrates that patients must often overcome layers of restrictive financial and administrative barriers put in place by plans intended to inhibit access to these essential medications.

According to the Avalere analysis, Part D plans are leveraging formularies and utilization management tools for Medicare beneficiaries across drugs in the protected classes. For example, in 2019, the most recent year for which data is available, plans covered just 54% of drugs across the protected classes — a decrease of nearly 20% since 2016 when the coverage rate was 67%. For covered drugs, nearly two-thirds of all medications in the six protected classes were placed in a non-preferred or specialty category, with 89% of branded products categorized as non-preferred or specialty and 37% of generics also subject to placement on the higher tiers. In aggregate, Part D plans placed drugs from the protected classes on high tiers (non-preferred or specialty) 64% of the time.

These coverage limitations are particularly concerning because of the negative impact they have on patients and their quality of life. If a patient does not receive the best treatment option, it opens the door for complications resulting in emergency department visits, physician visits, hospitalization, or other types of care that increase overall Medicare costs. Moreover, because standalone Part D Prescription Drug Plans (PDPs) are not liable for the cost incurred under Medicare Part A and Part B

or Medicaid, research shows that they do not work as hard as commercial plans to ensure they offer a robust formulary. That is why Congress explicitly created fundamental patient protections — including the six protected classes policy — which are unique to Medicare and recognize the unique needs of seniors and persons with disabilities who rely on Medicare.

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# Part One

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

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) momentarily created the Medicare Part D drug program. During the debate, Senators committed to ensuring beneficiaries had protections to access critical medications in certain drug classes and the Centers for Medicare and Medicaid Services (CMS) responded. CMS issued sub-regulatory guidance directing prescription drug plans (PDPs) to cover “all or substantially all” medications within six classes:<sup>1</sup> anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants.<sup>2</sup>

Five years later in 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA). Section 176 of MIPPA created the Six Protected Classes of drugs under Medicare Part D,<sup>3</sup> codifying CMS' initial guidance and creating a standardized application of the Six Protected Classes among plans. Specifically, it dictated that Part D plan sponsors must grant formularies access to substantially all drugs in the Classes, including categories of priority. To consider additional classes for protection, MIPPA codified two statutory criteria with which CMS must comply: (1) the identified class would have major or life-threatening consequences should the class be restricted; and (2) the identified class contains multiple drugs needed to treat a disease or disorder.

The Affordable Care Act (ACA) reiterated MIPPA's two conditions for considering new classes.<sup>4</sup> It also reiterated the protection for coverage of the six existing classes and categories under the Protected Classes policy as well as expanded coverage to include all drugs in each class and category. Regulations stipulate that plans only need to cover one clinically equivalent drug per Protected Class.<sup>5</sup> In other words, should a Protected Class contain one brand name product and two generics, the plan sponsor can choose to cover one of the three drugs.

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<sup>1</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>2</sup> The Medicare protected classes policy applies to immunosuppressants when such products are used to lower the body's ability to reject a transplanted organ, at the time of the transplant and on an ongoing basis to prevent rejection. Additionally, if a transplant recipient has Medicare at the time of transplant, and if Medicare pays for the transplant, his/her immunosuppressant drugs are covered under Medicare Part B. If a transplant recipient has any other insurance at the time of transplant then later becomes eligible for Medicare, the immunosuppressant drugs are covered under Medicare Part D.

<sup>3</sup> Pub. L. No 110-275, 122 Stat. 2494, July 15, 2008

<sup>4</sup> Pub. L. 111-148, 124 Stat. 119, March 23, 2010

<sup>5</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

In early 2014, CMS suggested alterations that would have denied access to these critically protected medications due to concerns that plans could not manage the Protected Classes. The proposed changes would have removed protected status from antidepressants and immunosuppressants for the 2015 coverage year, followed by antipsychotics in 2016. After significant, bipartisan pushback from Congress and stakeholders, CMS chose not to finalize its proposed rule. However, the agency indicated at the time that it might circle back to the issue “in future years.”

Two years later in June 2016, concerns related to the potential erosion of the Protected Classes resurfaced when the Medicare Payment Advisory Committee (MedPAC) recommended that two Protected Classes be eliminated.<sup>6</sup> In May 2018, the Department of Health and Human Services (HHS) responded by publishing a Request for Information as it sought out more input on whether or not it should continue its efforts to change Protected Class policies.<sup>7</sup>

Most recently, on the last day of the Trump Administration, CMS announced plans to allow new flexibilities under the Part D Payment Modernization (PDM) Model.<sup>8</sup> The PDM Model was created under the Centers for Medicare and Medicaid Innovation’s (CMMI) authority and permits Medicare Part D plans to limit the drugs they cover. Specifically, beginning calendar year (CY) 2022, participating plans will be permitted to cover only one drug per therapeutic class and can treat five of Medicare’s six protected classes as if they are any other class of drug, no longer requiring coverage of “all or substantially all” of the drugs in those classes.<sup>9</sup> CMS stated that the sixth protected class — antiretrovirals — will also be treated as any other class for CY 2023. In exchange, plans will accept two-sided risk for the federal share of the catastrophic phase of the Part D benefit.

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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.

<sup>6</sup> Medicare Payment Advisory Commission (MedPAC) Report to the Congress: Medicare and the Health Care Delivery System, June 2016: <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf?sfvrsn=0>

<sup>7</sup> “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,” Federal Register, 83 FR 22692, May 16, 2018: <https://www.federalregister.gov/documents/2018/05/16/2018-10435/hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs>

<sup>8</sup> “Part D Payment Modernization Model Calendar Year 2022 Fact Sheet,” Jan. 19, 2021: <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet> (Accessed Jan. 19, 2021)

<sup>9</sup> Part D Payment Modernization Model Request for Applications for CY 2022: [Part D Payment Modernization Model Request for Applications for CY 2022 \(cms.gov\)](https://www.cms.gov/medicare/medicare-coverage-database/part-d-payment-modernization-model-request-for-applications-for-cy-2022) (Accessed, February 5, 2021)

# Part Two

## Key Findings

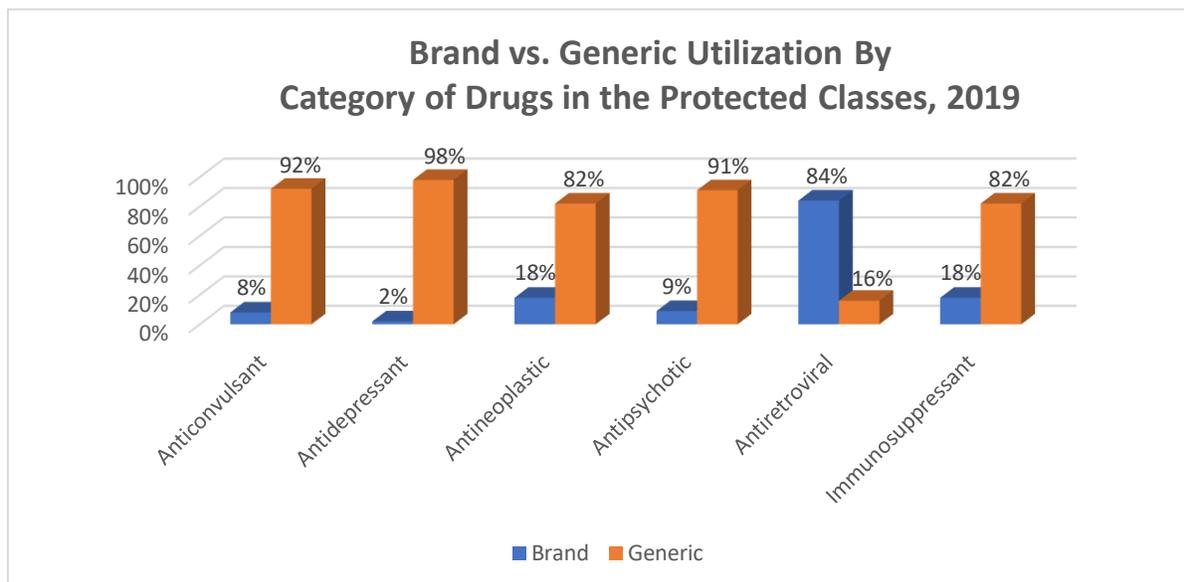
The following results from a new Avalere study demonstrate that, as currently implemented, Medicare’s protected classes policy remains an essential protection for patients who have specialized treatment needs while also providing plans with meaningful tools to manage front-end access as well as overall costs.

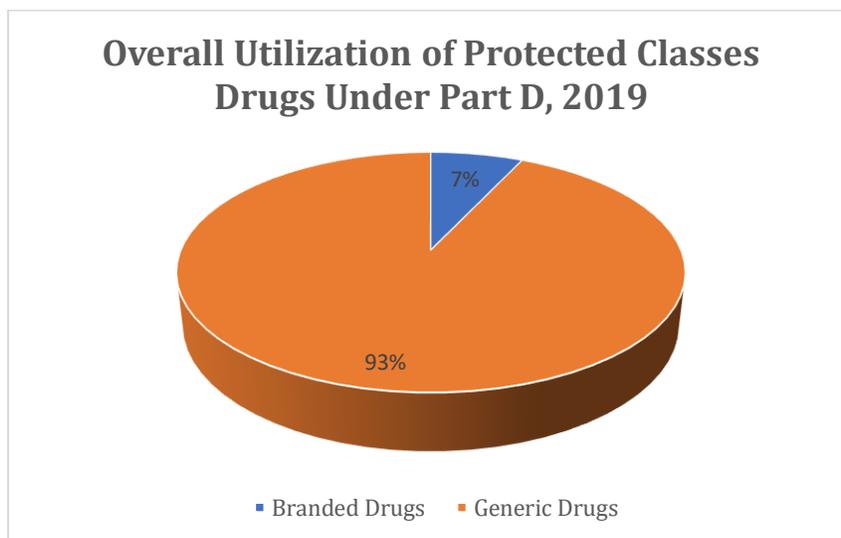
### Generics are an even greater share of the prescriptions filled for drugs in the protected classes in 2019 compared to 2016.

- Across all protected classes, 39% of covered drugs were generic, yet generic drugs represented 93% of prescriptions filled in 2019, up from 91% in 2016.
- Generics represented more than 90% of the prescriptions filled within each of the categories for anticonvulsants (92%), antidepressants (98%), and antipsychotics (91%).

### Tier placement by plans may hinder access to key medications.

- Only 4% of all the prescriptions filled in 2019 were for a subset of drugs that were nearly always placed on high tiers (non-preferred or specialty) by plans. This may indicate that placement of a drug on higher tiers, which have greater cost-sharing requirements and additional management processes, can discourage use of medications that could be more effective for the patient.



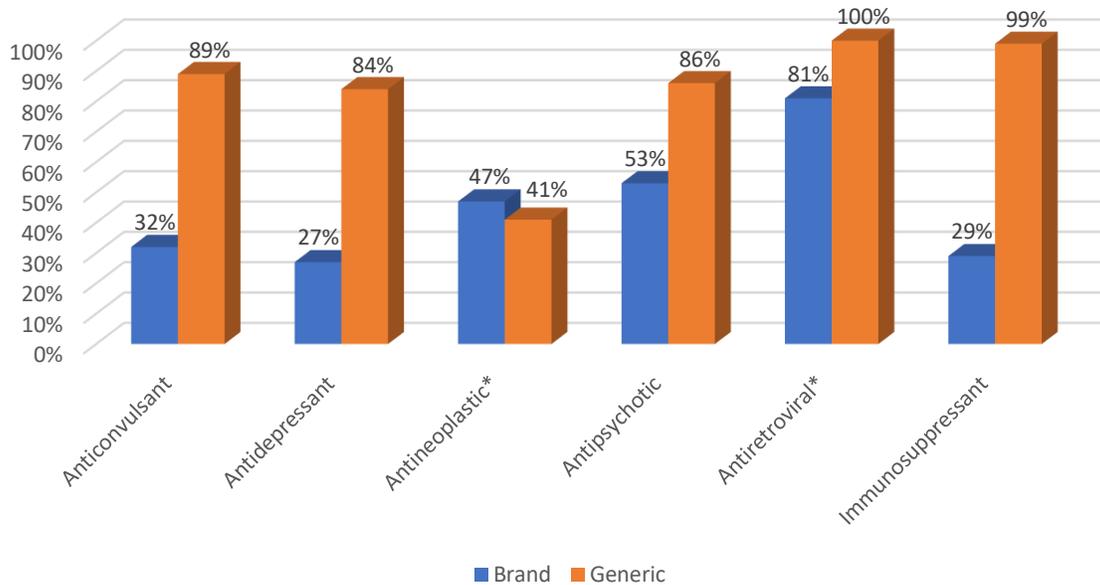


*Key takeaway: Part D plans use tier placement to manage Medicare beneficiary access to drugs, driving patients toward generic medications and the lowest cost options that the plan chooses, not necessarily the ones chosen by patients and their doctors.*

**Comparing 2019 to 2016, Part D plans were covering fewer drugs across all six of Medicare's protected classes, on average.**

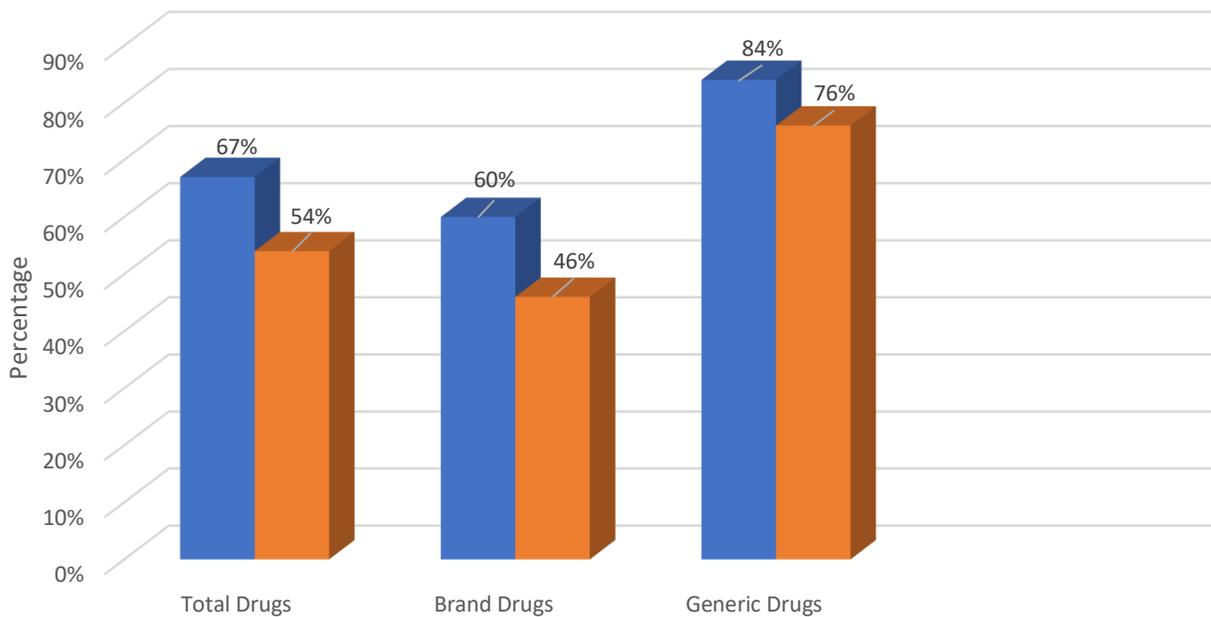
- Across all classes, plans covered fewer total drugs in 2019 compared to 2016 (285 versus 305).
- In 2019, beneficiaries were enrolled in Part D plans that covered less than 50% of drugs in several of the protected classes. It is worth noting that all beneficiaries were enrolled in plans that covered less than 50% of available antineoplastics. For immunosuppressants, 81% of beneficiaries were enrolled in plans that covered less than 50% of products, while nearly a quarter of beneficiaries (22%) were in plans with these coverage limits for antidepressants.
- Among the available brand name products, coverage fell to 46% in 2019 from 60% in 2016, on average.
- In the class for antidepressants, plans covered, on average, only 27% of brand name medications, for immunosuppressants they covered 29% of brand name products, and for anticonvulsants they covered 32%.

### Average Brand and Generic Coverage of Drugs in the Protected Classes, 2019



\* Plans may be limited in their ability to direct patients to generic alternatives for antineoplastics and antiretroviral since there are a limited number of alternatives available and treatments typically follow specific clinical protocols.

### Aggregate Coverage of Drugs in the Six Protected Classes, 2016 vs. 2019\*



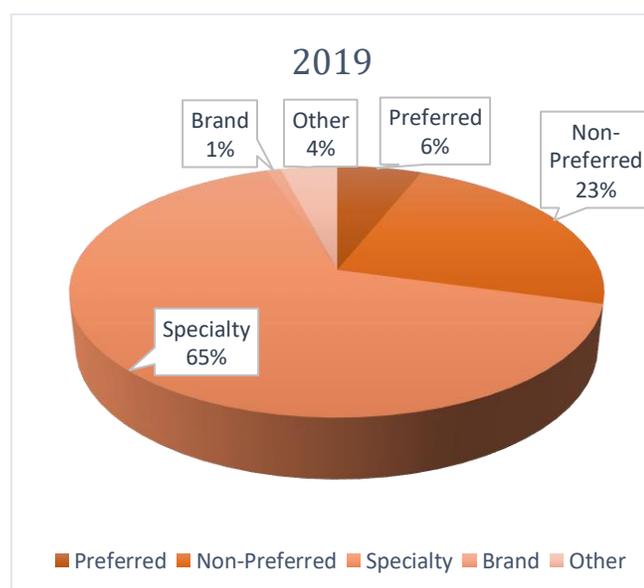
\*Drugs reflect a count of unique drugs.

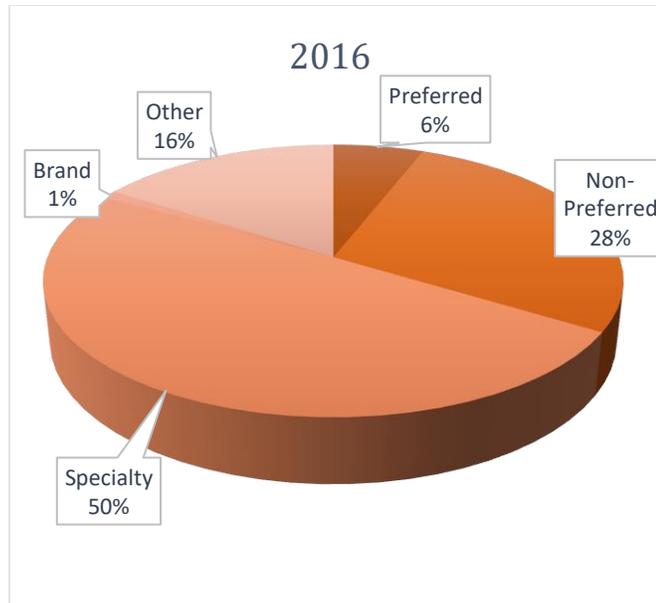
*Key takeaway: Part D plans are required by statute to cover all drugs in the protected classes. However, CMS has interpreted this to mean unique chemical entities, which typically does not result in coverage of all medications on the market for a class of medications. This may result in inadequate access to necessary medications.*

**Over time, Part D plans are placing more brand products on high tiers to restrict access and utilization in the six protected classes.**

- In 2019, 227 drugs from the protected classes were predominately placed on the highest tiers (non-preferred or specialty) compared to only 76 drugs (25%) in 2016. This means that 90% or more of beneficiaries were enrolled in Part D plans that placed 80% of drugs on high tiers.
- The average Part D beneficiary was enrolled in a plan that places drugs from the protected classes on high tiers (non-preferred or specialty) 64% of the time.
- Specifically, branded products were placed on high tiers 89% of the time and generics 37% of the time — meaning these drugs were subject to higher cost sharing and may have required additional authorization for coverage.

### **Tier Placement for Brand Drugs Within the Protected Classes\*\***





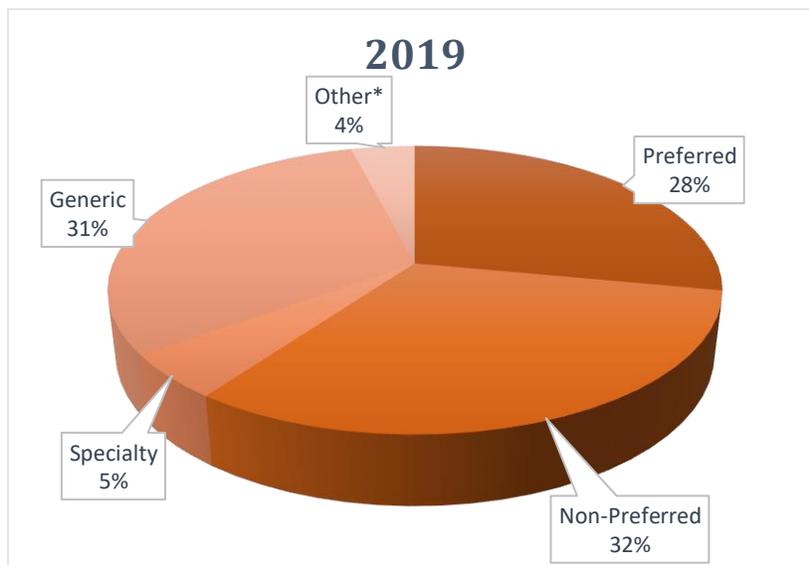
\*\* "Other" tier types reflect "Injectable" and "Non-Medicare"

*Key takeaway: Part D plans more frequently use high tiers for medications, which subjects patients to more barriers and higher cost sharing, potentially hindering access to life-saving medications.*

**Coverage of generic products in the six protected classes is trending downward, on average.**

- Only 76% of generic drugs in the protected classes, on average, were covered by plans in 2019 compared to 84% in 2016.
- Almost one third of generic drugs (31%), on average, were put on the generic tier while over a third (37%) were placed on high tiers (non-preferred or specialty tiers) in 2019.
- Within the class of antineoplastics, 41% of generic products were covered by plans, on average, and more than half of these covered products (56%) were placed on non-preferred or specialty tiers, which may limit patients access, depending on the drug price.

## Tier Placement for Generic Drugs Within the Protected Classes



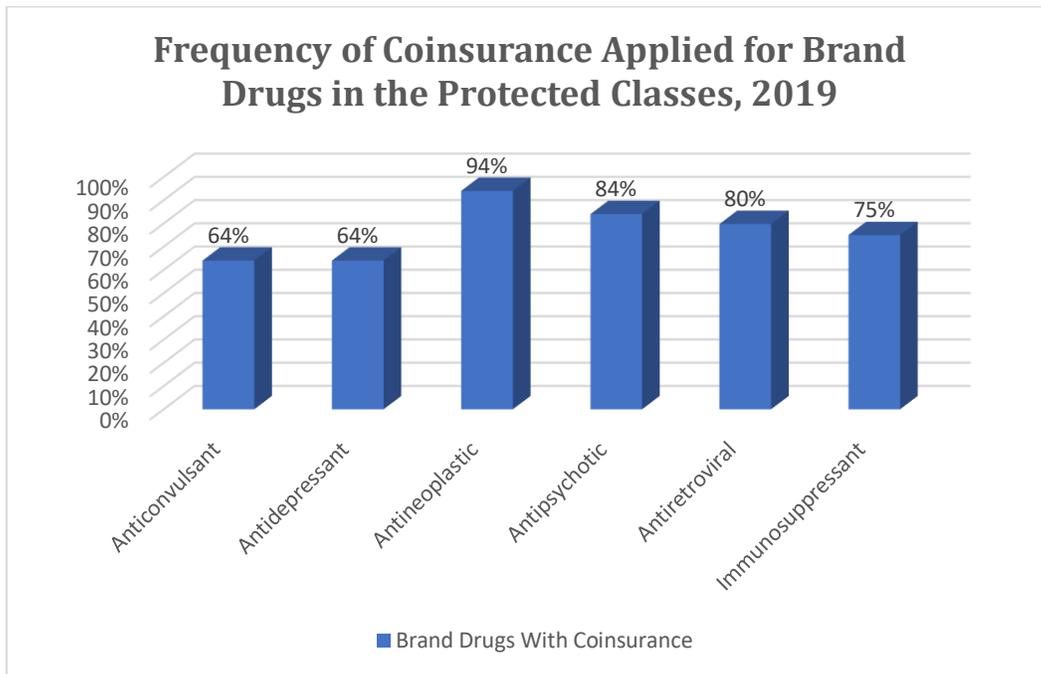
\*Other" refers to tier types that include "Injectable" and "Non-Medicare" products.

*Key takeaway: Given CMS' interpretation of the statutory requirement to cover all medications under the protected classes, drug coverage decisions and plan benefit design could result in limiting patient access to generic medications.*

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

- Beneficiaries were enrolled in plans where drugs in the protected classes required coinsurance nearly 60% of the time, on average. This was the same as 2016 despite plans covering fewer total drugs in the protected classes in 2019.
- For brand name products specifically, beneficiaries faced coinsurance 83% of the time.
- Plans applied a coinsurance 94% of the time for brand antineoplastics, 84% of the time for brand antipsychotics, 80% for brand antiretrovirals, 75% of the time for brand immunosuppressants, and 64% of the time for brand antidepressants and brand anticonvulsants.

- The average patient cost sharing amount for a brand name medication across the six protected classes was \$3,635 in 2019.<sup>10</sup>



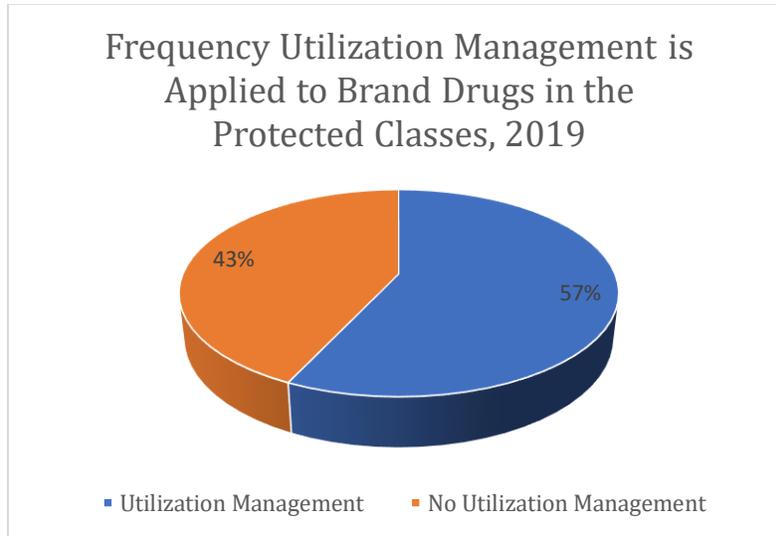
*Key takeaway: When beneficiaries are subjected to coinsurance, which requires them to pay a percent of total costs, it likely results in higher out-of-pocket expenses than when a copayment is assessed, depending on the benefit design, which may hinder access.*

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

- Similar to findings from 2016, plan sponsors in 2019 employed utilization management tools nearly 40% of the time across all drugs in the protected classes.
- Specifically, plans placed utilization management on branded drugs in the protected classes 57% of the time in 2019 compared to 54% in 2016.

<sup>10</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 2016 and 2019, prior authorization (PA) was the most frequent utilization management tool required for brand drugs in the protected classes (49% and 55% of the time, respectively).



*Key takeaway: Plans increasingly apply utilization management requirements on drugs in protected classes, which can create access barriers for Medicare Part D enrollees.*

# Part Three

## *Discussion*

**T**his study reinforces the fact that Medicare Part D plans are aggressively employing strategies to limit access to prescription drugs in the protected classes, and in some instances may be undermining one of Medicare’s fundamental patient protections. Plans have increased their use of product design and meaningful financial requirements over time, as well as administrative hurdles that could inhibit patient access to needed medications. Moreover, several economic analyses suggest that these coverage limitations may be the result of perverse incentives among Medicare PDPs, which do not pay for hospital or physician services and therefore may be less invested in preventing avoidable hospitalizations and other unnecessary medical care.

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

While Medicare’s protected classes policy precludes plans from entirely excluding a drug, plans have become more aggressive in using the latitude provided by CMS that permits exceptions to this coverage requirement.<sup>11,12,13,14</sup> In practice, this means plans are not covering all medications that fall within the protected classes and categories, which could lead to negative health outcomes for beneficiaries if they cannot obtain the medication that works best for them. The result of these practices is that plans are excluding some brand medications within the protected classes and they were doing so more frequently in 2019 compared to 2016.

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<sup>11</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>12</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>13</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>14</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.

## **TIER PLACEMENT**

Medicare Part D plan sponsors plans can — and do — place brand and generic drugs in the protected classes on high tiers, which can make it more difficult for beneficiaries to obtain their medication. Higher tiers generally require a greater out-of-pocket payment from the patient, and drugs placed on these tiers can be subject to additional layers of review by plan administrators. The analysis of Medicare Part D claims data demonstrates a lower rate of utilization for some products, which may be related to a higher tier placement. 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. This indicates, particularly for antipsychotics, that patients may not be accessing newer medications that have fewer side effects, which have been shown to improve drug adherence.

## **UTILIZATION MANAGEMENT TOOLS**

While the protected classes policy provides additional safeguards for Medicare patients with certain complex health conditions, health plans have the ability to structure their drug benefit using formulary design and a range of utilization management tools to encourage patients to use low cost, preferred medications. In particular, prior authorization remains the most frequent tool employed by health plans for patients that request brand medications, with plans using this tool more frequently than in 2016. This additional administrative 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 policies to direct patients to lower-cost alternatives. For the average Part D beneficiary, most drugs in the protected classes are placed on tiers that require coinsurance. Plans are particularly consistent in applying a significant coinsurance for brand medications across the protected classes, which presents another hurdle for patients who require higher-cost medications.

## **PERVERSE INCENTIVES AMONG PDPs**

The most popular type of Medicare drug coverage is through a stand-alone PDP. Stand-alone drug plans are focused solely on delivery of the drug benefit. They do not pay for hospital or physician visits — those services are covered by traditional Medicare — and PDPs do not bear any risk or financial responsibility for the costs incurred within Medicare Part A and Part B. Medicare Advantage (MA) plans offer another way to receive the Medicare drug benefit. MA plans are private insurance plans subsidized by the federal government to manage prescription drug benefits alongside all other covered benefits. Researchers have suggested that PDPs have less incentive than MA-PD plans to offer formularies that contribute to keeping Medicare beneficiaries healthy and avoid increased utilization of services paid for by Medicare Part A and Part B.

This phenomenon is brought to light in multiple economic analyses, which repeatedly highlight how PDPs are incentivized to limit covered medications or increase out-of-pocket costs because they are not responsible for costs incurred by other parts of the Medicare, such as increased physician visits or hospitalizations. A study issued by researchers at Northwestern University's Kellogg School of Management and the University of Texas at Austin concludes that in covering drugs less generously than MA plans, Part D plans end up costing traditional Medicare \$475 million per year.<sup>15</sup> Moreover, another study published by the National Bureau of Economic Research (NBER) determined that stand-alone drug plans charge enrollees about 13% more than MA plans in cost sharing for drugs that are highly likely to help patients avoid an adverse health event within two months.<sup>16</sup>

Part of the purpose of Medicare's drug benefit is to encourage enrollees to take prescription drugs that improve their health. This effect is illustrated by a recent study led by a Harvard economist that shows that seniors' increased use of medications to manage health conditions contributed to much slower growth in Medicare spending than had been expected.<sup>17</sup> By ensuring that Medicare beneficiaries with the most complicated conditions have access to the right combination of prescription drugs, the six protected classes policy helps hundreds of thousands of patients effectively manage their illness — keeping them out of the hospital and ultimately producing considerable savings in Medicare Parts A and B.

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<sup>15</sup> Starc, A., & Town, R. J. (2019). Externalities and benefit design in health insurance. *The Review of Economic Studies*, 87(6), 2827-2858. <https://doi.org/10.1093/restud/rdz052>

<sup>16</sup> Lavetti, K., & Simon, K. (2018). Strategic formulary design in Medicare part D plans. *American Economic Journal: Economic Policy*, 10(3), 154-192. <https://doi.org/10.1257/pol.20160248>

<sup>17</sup> Cutler, D. M., Ghosh, K., Messer, K. L., Raghunathan, T. E., Stewart, S. T., & Rosen, A. B. (2019). Explaining the slowdown in medical spending growth among the elderly, 1999–2012. *Health Affairs*, 38(2), 222-229. <https://doi.org/10.1377/hlthaff.2018.05372>

# Part Four

## *Conclusion*

**A**t a time when plans are increasingly trying to inhibit access to needed medications through reduced coverage and increased barriers, Medicare’s protected classes policy is more important than ever. The study results, which demonstrate greater limitations on patient access to drugs in the protected classes, reinforce the need for strong patient protections in Medicare’s prescription drug program — particularly for patients who rely heavily on medications to manage complex chronic conditions.

These findings provide new evidence that health plans are taking aggressive steps to apply a range of utilization management and other tools, such as selective formularies, coinsurance, step-therapy and prior authorization, which may have the effect of delaying patient access to medications, disrupting stable drug regimens, increasing out-of-pocket costs, or altogether restricting access to medications prescribed by their physician. In some instances, the data appears to demonstrate that plans are not meeting the intent of the statutory coverage requirements, which undermines one of Medicare’s fundamental patient protections — access to *all* medications within the protected classes.

The Medicare population is comprised of individuals over age 65 and individuals under 65 who have a permanent disability. Nearly a quarter of Medicare enrollees (22%) have five or more chronic conditions.<sup>18</sup> The protected classes policy is designed to recognize Medicare enrollees’ unique and challenging health characteristics. Many of the medications within the protected classes are not interchangeable. Limiting access to the most appropriate medications could drive higher costs in Medicare Part A and Part B and Medicaid by increasing admittance to inpatient 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. As a result, guardrails such as the protected classes are necessary to ensure that Medicare plans are providing access to an appropriate range of medications that keep people healthy.

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<sup>18</sup> Kaiser Family Foundation, “An Overview of Medicare,” February 13, 2019: [An Overview of Medicare | KFF](#) (Accessed, January 29, 2020)

# Part Five

## *Study Design*

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

This study analyzes Part D benefit design and formulary data from 2019 to assess coverage and management of drugs under six protected classes. Specifically, for each protected class and in aggregate, Avalere used its proprietary database, PlanScape® with the Centers for Medicare & Medicaid Services (CMS) Public Use Files (PUF) data on Part D plan benefit and formulary design, enrollment, and negotiated drug prices, to analyze:

- Drug tier placement
- Cost sharing type (copay vs coinsurance)
- Average cost sharing amounts
- Utilization management restrictions

### **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 Part D prescription drug event (PDE) data under the terms of a CMS research data use agreement (DUA).

### **DATA ANALYSIS**

Avalere looked across all Part D plans to calculate the average level of coverage, cost-sharing, and utilization management requirements for drugs in the protected classes.

Using publicly available and proprietary databases, Avalere identified approximately 22,000 national drug codes (NDCs) on the market in 2019 for the six protected drug classes (Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals and Immune Suppressants). Avalere then identified approximately 1,100 NDCs associated with drugs in protected classes and present on Part D plan formularies spanning individual months in 2019. 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 559 NDCs across all six protected classes (226 unique drugs) that were predominantly placed on high tiers (non-preferred or specialty) by plans in 2019 (i.e., at least 90% of Part D beneficiaries were enrolled in plans that placed those drugs on high tiers on their formularies).

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. 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.

To assess the utilization of brand and generic drugs in Part D protected classes Avalere analyzed the 2019 Part D PDE data. In compliance with the CMS DUA, no more than 20% of all Medicare beneficiaries were included in any particular protected class analysis. The number of beneficiaries prescribed drugs from the Antidepressants class exceeded the 20% threshold, so Avalere conducted a random sampling for this specific drug class. As a result, the Antidepressant scripts analyzed corresponded to 89% of all beneficiaries who received an Antidepressant script in 2019. 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 1,100 NDCs identified in the 2019 Part D plan formulary files.

Avalere also performed a utilization assessment specific to a subset of 559 NDCs identified as being predominately placed on high tiers by Part D plans in 2019.

## **TERMS AND DEFINITIONS**

For this analysis the Medicare definition of a covered drug was used.<sup>19</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: Generic, Preferred Brand, Non-Preferred, Specialty, and Other e.g. "Injectable" or "Non-Medicare".

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<sup>19</sup> See: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PartDDrugsPartDExcludedDrugs.pdf>