

# Navigating Medicare Part D:

## *Approaches to Addressing Beneficiary Affordability and Access Challenges*

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Medicare Access for Patients Rx™  
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## EXECUTIVE SUMMARY



With its launch in 2006, Medicare’s Prescription Drug Program (Part D) became an essential avenue for Medicare beneficiaries to access critical, life-saving oral and self-administered medications. Prior to Part D, beneficiaries had limited access to coverage of prescription drugs, either via select drugs under Part B or through a supplemental plan. Many had no coverage at all.

Over the years, Part D has been viewed as a success story due to its overall popularity among enrollees and lower-than-expected government expenditures. Despite its overall strength, current challenges remain around access to medications, key consumer purchasing information, and beneficiaries’ ability to pay for covered medications—and these issues loom large over the future of the program. Presently, the following challenges are inhibiting the program from being an even more successful resource for the healthcare needs of the country’s Medicare beneficiaries.

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**Increased cost-sharing requirements:** Part D plan sponsors are placing more of the cost burden on beneficiaries, especially through higher cost-sharing requirements for select innovative therapies.
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**Failure to pass along manufacturer rebates to beneficiaries at the point of sale (POS):** When Part D plans and pharmacy benefit managers (PBMs) do not apply manufacturer rebates to prices at the POS, beneficiaries who are in the deductible or who are paying coinsurance for a Part D drug may face significantly higher out-of-pocket (OOP) costs than if the plan or PBM had reduced prices via rebates.
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**Risk of the Centers for Medicare & Medicaid Services (CMS) allowing plans to exclude more medicines from formularies in the six protected classes.** CMS is now considering regulatory changes that would allow plans to walk away from the current protections and require stable patients to undergo prior authorization or step therapy to stay on their medicines and would also allow plans to exclude medicines from the six protected classes in some cases.
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**Adverse tiering for chronically ill beneficiaries:** Treatments within select therapeutic areas are typically placed on formulary tiers with high cost-sharing requirements, and sometimes, without access to an appeal for a lower cost-sharing amount. This leaves beneficiaries who are often the most ill in a position where they are unable to afford and access their medicines.
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**Upcoming OOP “cliff”:** The Part D OOP threshold is expected to grow by \$1,250 between 2019 and 2020, a significant year-to-year jump, which will cause an additional OOP burden for select beneficiaries.
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**Lack of an annual OOP maximum:** While the Part D benefit offers an OOP threshold, there is no true cap on OOP expenditures in Part D. This is unlike the experience most beneficiaries face with commercial coverage, where there is a single out-of-pocket cap for all covered services or in Medicare Part B, where they have other OOP protections (such as the ability to purchase supplemental coverage).
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**CMS-sanctioned erosion of beneficiary protections in favor of plan flexibility:** Patient advocates are concerned that CMS has favored preserving plans’ flexibility over ensuring patient access on key issues such as specialty tiers, protected classes, formulary tiering and composition, meaningful differences policy, and communication of plan materials.
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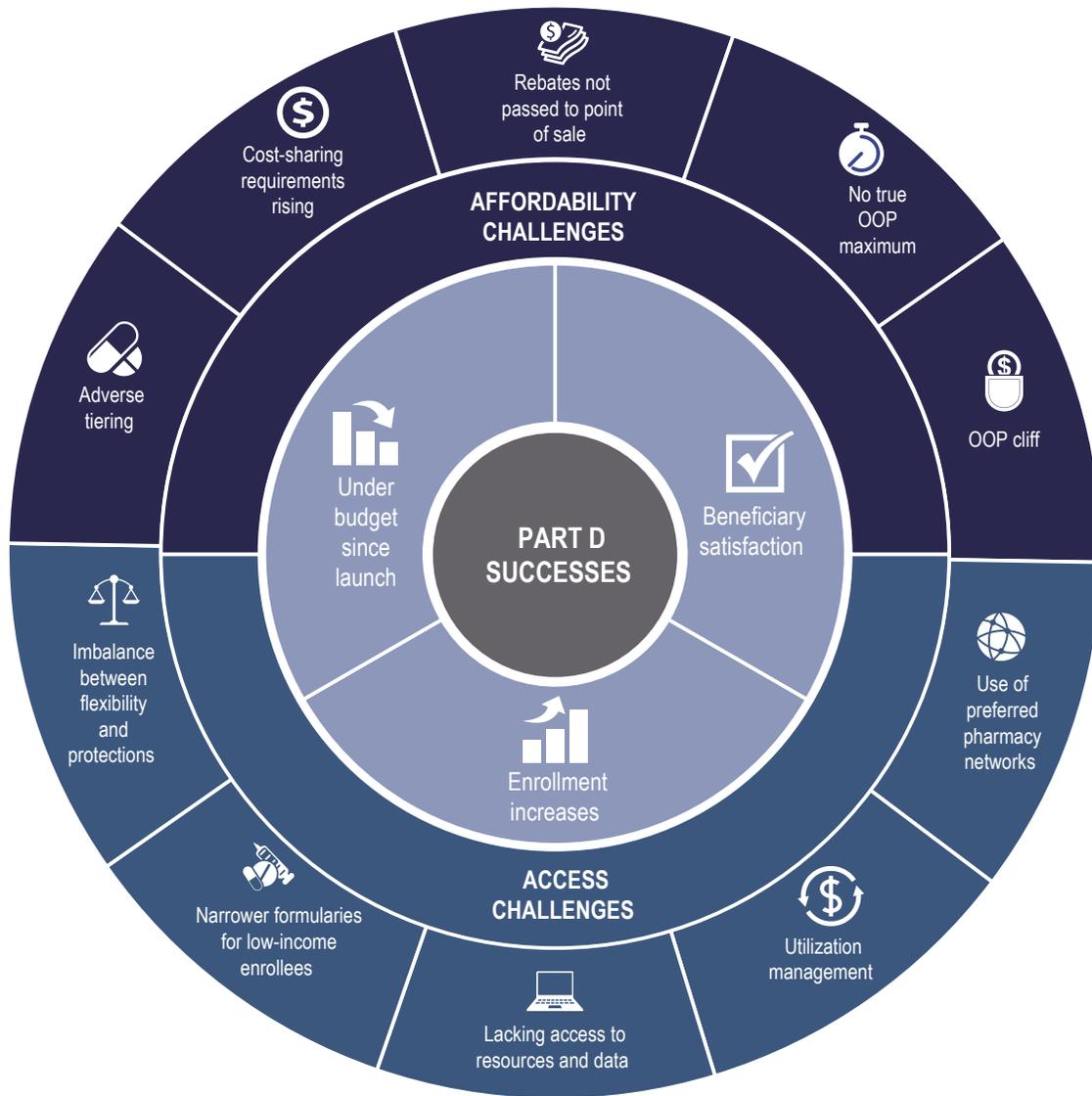
**Utilization management:** Part D plan use of utilization management is on the rise, and for many patients, these are steep barriers to accessing their needed prescribed medications.
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**Use of preferred pharmacy networks:** An overwhelming majority of Part D plans elect to offer preferred pharmacy networks, but concerns remain around adequate access to these pharmacies (with lower cost-sharing amounts compared to other network pharmacies).
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**Lack of easy-to-navigate resources that explain plan options, appeals, and exceptions:** The quality of information and number of resources (e.g. Medicare Plan Finder) to assist beneficiaries in enrollment choices should be improved.
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**Narrow formularies for low-income subsidy (LIS) benchmark plans:** Standalone prescription drug plans (PDPs) that are able to receive assigned LIS beneficiaries often have narrower formularies compared to other Part D plans, resulting in fewer medication choices for their members.

Figure 1. Part D Successes and Challenges



Key: OOP - out-of-pocket.

While significant challenges persist in the Part D program, policymakers stand well positioned to address the challenges facing beneficiaries.

*CMS should:*



**Conduct transparent scrutiny of plan benefit designs to ensure wide access to medications in key therapeutic areas and minimize OOP burdens.**

- Maintain the current coverage protections of Medicare Part D's six protected classes of drugs and consider adding additional classes where restricted access to those drugs would have significant health consequences.
- Prohibit the use of overly restrictive medical utilization management tools and enhance oversight of medication utilization management tools (such as medication substitution, step therapy, or quantity limits).
- Ensure that non-discrimination and actuarial value standards are being met.
- Place stringent restrictions on the number of generic drugs permitted to be covered on brand tiers.
- Provide greater and stricter scrutiny during the formulary review process to ensure that LIS beneficiaries have access to a wide range of therapies, even in high-cost therapeutic areas, and that the benefit is not discriminatory.



**Apply a specific percentage of rebates at the POS to reduce OOP expenses.**



**Allow cost-sharing exceptions for specialty tier drugs, and the specialty tier threshold should be increased annually at the same rate as the benefit parameters.**



**Explore and pursue innovative ways to communicate about the Part D benefit.**

- Enhance Medicare Plan Finder in order to provide beneficiaries with easy-to-access information and additional support if beneficiaries have issues or questions.
- Collect and share information on utilization of exceptions/appeals at the plan level and provide additional education on the entire exceptions/appeals process for different stakeholder audiences.
- Require greater transparency about covered drugs in advance of the Annual Enrollment Period. Plans should provide beneficiaries plan benefit package information 15 days prior to the Annual Enrollment Period, and hard copies should be provided with the ability for beneficiaries to opt out of receiving these materials.
- Provide greater oversight of Part D plan sponsor marketing materials.
  - Ensure that notice of non-coverage, appeals, and exceptions processes are simple and understandable. Encourage additional communication on the availability of tiering exceptions (outside the specialty tier) and require public information on the utilization data of tiering exceptions.
  - Require plans to provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.
  - Encourage plan sponsors to feature information on their pharmacy networks more prominently on their materials and websites.

*Congress must take action to:*



**Avoid the OOP cliff by revising current law to make the current OOP threshold permanent.**



**Establish a true cap on annual OOP expenses that would limit exposure to high OOP costs, even after beneficiaries met their deductible and coverage gap obligations and explore ways to spread OOP costs more evenly through the year.**

Both policymakers within Congress and CMS have varying authority to implement some of the potential solutions in order to ease the access and financial burdens on beneficiaries. With a renewed focus on beneficiary protections, policymakers can further solidify Part D's strong footing.

# INTRODUCTION

On what is now the 15<sup>th</sup> anniversary of the enactment of Medicare's outpatient prescription drug benefit, the Medicare Part D program is hailed as a success of public-private partnership. With robust plan options, the Part D benefit has offered eligible seniors and people with disabilities an avenue for accessing critical oral and self-administered medications. Part D is rated highly for beneficiary satisfaction, and enrollment has increased every year since its implementation in 2006.

Part D program expenditures have consistently beaten initial Congressional Budget Office projections. Part D is largely viewed as a model for a successful government healthcare program.

## Modernizing a 2003 Program to Meet 2020 Beneficiary Needs

When the Part D program launched, it was the first time a prescription-only benefit had been attempted at this scale—and there were many unknowns. Over time, the incentives and practices of stakeholders (e.g., manufacturers, Part D plans, PBMs) have evolved. The marketplace has adapted to meet the benefit, and medical innovation has moved toward outpatient treatment.

The Medicare program is constantly evolving because healthcare is always changing; in order to meet beneficiaries' prescription drug needs, the Part D benefit has to keep up, too. The program was enacted in 2003, but its design remains stuck in that decade rather than meeting the needs of today's beneficiaries.

Currently, there are a number of program features that hinder beneficiaries' ability to appropriately access their prescription drugs. These program features, listed below, are discussed in more detail in this paper.

- **Increased cost-sharing requirements**
  - Shift to coinsurance
  - Rising cost of generic drugs
- **Failure to pass along manufacturer rebates to beneficiaries at the POS**
- **Adverse tiering for chronically ill beneficiaries**
  - Utilization of specialty tiers and limitations in requesting exceptions
  - Use of non-preferred brand tiers
- **Upcoming OOP “cliff”**
- **Lack of an annual OOP maximum**
- **CMS-sanctioned erosion of beneficiary protections in favor of plan flexibility**
  - Specialty tiers
  - Tier labeling and composition
  - Meaningful differences
  - Communication of plan information
- **Utilization management, such as step therapy**
- **Use of preferred pharmacy networks**
- **Lack of easy-to-navigate resources explaining plan options and appeals and exceptions**
- **Narrow formularies for LIS benchmark plans**

On one hand, Part D plans do need to manage overall benefit costs with checks and balances to ensure appropriate utilization of prescription drugs, but on the other hand, plans can also be given too much flexibility, which can impede necessary access for beneficiaries. This white paper explores the affordability and access challenges facing beneficiaries and offers policy solutions to ensure the success of the program for years to come.

It should be noted that while many beneficiaries who are enrolled in the LIS program do not face the same affordability issues (cost-sharing for most is \$8.50 or less for brand drugs in 2019), they **do** face access issues.

## AFFORDABILITY CHALLENGES

While the Part D program was enacted as part of the Medicare Modernization Act of 2003 (MMA), it is not a static program. Each year, the Part D program evolves as legislation, regulation, market dynamics, beneficiaries' experience and drug utilization shape its path. For example, the standard benefit design's coverage gap (or "donut hole") will be largely eliminated in 2019 through legislative actions. When the Part D program began, beneficiaries had to pay the total cost of their medications in the coverage gap until they reached an OOP threshold, at which point they entered catastrophic coverage (paying 5% of the cost of the drugs for the remainder of the plan year).

Beginning in 2011, the Affordable Care Act (ACA) started to gradually close the donut hole, lowering the share of total drug costs patients owed in the coverage gap each year. The Bipartisan Budget Act of 2018 sped up that process and closed the coverage gap for brand drugs one year earlier, so that it will now close in 2019 instead of 2020. This has largely been done through contributions from pharmaceutical manufacturers for brand name drugs: the ACA required a 50% contribution during the coverage gap, but the contribution increased to 70% under the Bipartisan Budget Act of 2018.

Despite the closing of the coverage gap, a number of beneficiaries encounter financial challenges when paying for their prescriptions under the Part D benefit. This inability to access drugs due to financial constraints hinders health outcomes and imposes costs on other parts of Medicare. For all beneficiaries, changes in plan design and the lack of discounts and rebates reflected in the price can affect affordability. This often leaves the most critically ill beneficiaries caught in a web of affordability and access issues because of high cost-sharing requirements for their necessary medications and a lack of an annual OOP maximum.

### Rise in Cost-Sharing Requirements

#### *Shift from copayments to coinsurance:*

Cost-sharing requirements can be either copayments or coinsurance, and while plans are required to be actuarially equivalent to the standard benefit design with 25% cost-sharing, that represents an average and not a per-prescription cost-sharing amount. When the program started, most plans had cost-sharing based on copayments (i.e., a set, fixed-dollar amount based on the tier that the drug was in). Plans create formularies for covered prescription drugs and typically divide these formularies into tiers, each with its own cost-sharing requirements. For example, a generic drug might have been on tier 1 and had a \$10 copayment for a 30-day fill, while a branded product might have been on tier 3 with a \$60 copayment.

Over time, plans have shifted patients' OOP payment from a copayment approach for select branded and generic drugs to a coinsurance model. According to the 2018 Medicare Payment Advisory Commission (MedPAC) Report to Congress, increasingly Part D plans have utilized coinsurance more than copayments for select formulary tiers, particularly for non-preferred tiers.<sup>1</sup> With coinsurance, beneficiaries are responsible for a set percentage of the list price of their prescription. For example, a prescription drug may have a list price of \$225 but a coinsurance of 25%, so the OOP cost for the patient would be \$56.25. The coinsurance amount can vary by location and month, depending on the pharmacy and the medication's current list price. Medicare beneficiaries face the reality of OOP costs with their wallet in hand at the pharmacy when they pick up their prescription. So, as cost-sharing requirements have changed, affordability concerns have become more acute.

Xcenda research has shown that in 2019, 51% of drugs on PDP formularies are subject to coinsurance amounts rather than copayments—this is compared to 40% in 2015.



#### **Deductible:**

*The amount beneficiaries pay for covered healthcare services from their own pocket before the plan starts to pay.*



#### **Copayment:**

*A fixed-dollar amount beneficiaries pay for a covered service after they pay the deductible.*



#### **Coinsurance:**

*A percentage of costs beneficiaries pay for a covered service after they pay the deductible.*

### Increased cost-sharing for generic drugs:

The wide availability of generics and their relatively lower costs have increased generic utilization rates dramatically (87% in 2015 compared to 67% in 2007), thus lowering OOP drug costs for many, but certainly not all, beneficiaries.<sup>1</sup>

While there is considerable attention paid to the rising cost of branded prescription drugs, the cost of a number of generics has risen considerably over time. To address the growing costs of generic medications, Part D plan sponsors began differentiating cost-sharing requirements between lower-cost generic medications (preferred) and more expensive generic medications (non-preferred).<sup>2</sup> These non-preferred generic copayments (which were broadly implemented in plan year 2012) are still relatively affordable, averaging over \$8 in 2018.<sup>3</sup> A more impactful move by Part D sponsors has been including select higher-cost generic medications on non-preferred formulary tiers, which may be subject to a coinsurance rate. For example, SilverScript Choice, one of the most popular PDPs, puts many of the generic antiretroviral drugs that treat HIV in tier 4 with 50% cost-sharing requirements, requiring beneficiaries to pay thousands of dollars over the course of the year.<sup>4</sup>

## Rebates Are Not Passed Along at the POS

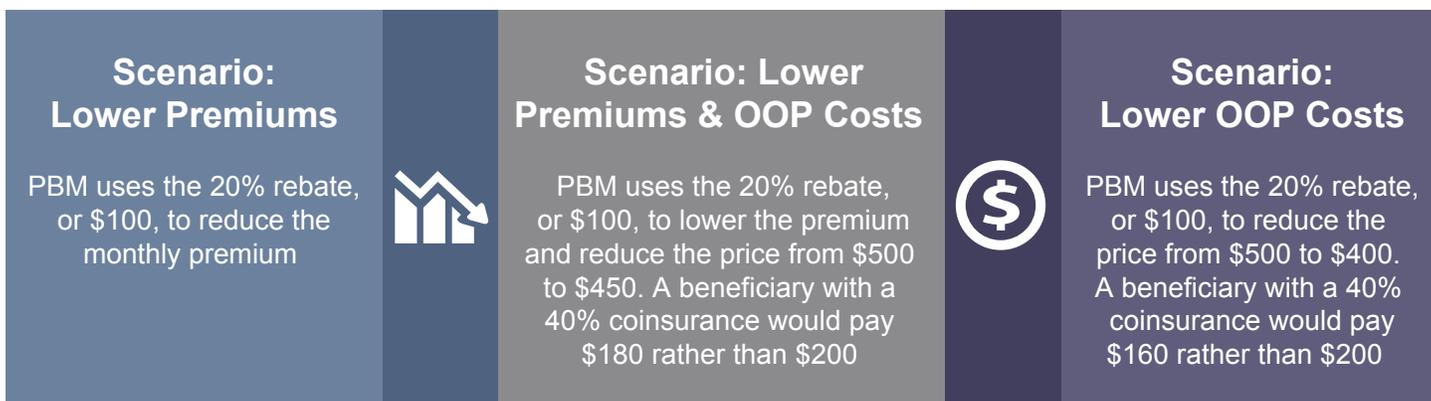
In Medicare Part D, as in the rest of the commercial market, plan sponsors and/or PBMs, acting on behalf of plans sponsors, negotiate with pharmaceutical manufacturers for formulary placement. Manufacturers generally offer rebates and discounts to get their products placed on formulary and/or to obtain a favorable formulary position for the product compared to a competitor product (i.e., lower tier with less cost-sharing).

Between 2010 and 2015, the combined dollar value of all forms of price concessions (discounts, rebates, and fees) received by Part D sponsors and their PBMs increased nearly 24% per year, about twice as fast as total Part D gross drug costs.<sup>5</sup> Manufacturer rebates account for most of this growth, but pharmacy price concessions have also grown. Pharmacies are often required to “pay to play” through performance-based price concessions. Part D sponsors rarely elect to include rebates and other price concessions in the negotiated price at the POS. Sponsors have typically utilized the rebates and price concessions to lower monthly premiums for beneficiaries; however, there is no requirement that the price at the POS reflect these discounts and rebates. Plans are thus able to keep these discounts and rebates while continuing to charge cost-sharing based on the list price.

### Figure 2. Part D Plan Application of Manufacturer Rebates

Three Scenarios Outlining the PBM Options to Apply the Rebate

Example: A manufacturer pays a PBM a 20% rebate on a product with a monthly price of \$500



Key: OOP - out-of-pocket; PBM - pharmacy benefit manager.

This dynamic presents a policy conundrum. While lower monthly premiums do help all beneficiaries, higher prices affect many beneficiaries, too—and the beneficiaries who have chronic conditions bear the burden of high monthly OOP costs. This is particularly problematic for beneficiaries who are paying the deductible or facing a coinsurance, as their OOP requirements are directly linked to the list price rather than the PBM-negotiated price. Further, as Part D plans have moved to requiring coinsurance for select branded and specialty drugs, this problem has only been exacerbated. Some beneficiaries, particularly those who have no therapeutic alternative to branded medicines, may end up paying a larger share of the drug's actual cost.

Recent research shows that beneficiaries taking products with large rebates do not receive any financial relief; however, if a portion of those rebates were used to reduce prices, these beneficiaries would realize significant OOP savings. A November 2016 Milliman report concluded that Part D plans have a financial incentive to cover drugs with higher list prices and larger rebates as a means of driving down premiums.<sup>6</sup> Moreover, because benefit designs have shifted more to the coinsurance model—which bases the OOP costs on the list price—beneficiaries who take medications with larger rebates are penalized, since plans are not applying the rebates to the list prices. Milliman concluded that these embedded incentives increase costs to the government and beneficiaries.<sup>6</sup>

In 2018, Milliman released another report on the topic, finding that applying rebates to the list prices would result in total beneficiary savings of up to \$28 billion over 10 years. Furthermore, monthly plan premiums would increase only slightly if plans applied rebates to the POS. Average costs to the federal government do increase, by roughly \$6 billion—or the equivalent of \$1 per member per month.<sup>7</sup>

## Adverse Tiering That Affects Chronically Ill Patients

Since the implementation of the Part D benefit in 2006, a primary concern among patient advocates has been “adverse tiering,” defined as placing all or nearly all products in a therapeutic area on a higher, thus more unfavorable, formulary tier with increased OOP requirements. And, as just discussed, these beneficiaries are often paying their OOP requirements based on a list price that does not account for discounts and rebates paid by the manufacturer.

While generic utilization in the Part D benefit is higher than ever at close to 90%, Part D enrollee utilization of branded medicines without generic therapeutic equivalents has also increased. These medicines are often costly, and plans place these products in tiers with higher cost-sharing requirements. So, while the plans make these treatments “available,” the cost-share can be prohibitively expensive for many beneficiaries, particularly those who are chronically ill and therefore face high OOP expenses each month, and not just a one-time treatment expense.

While plan sponsors have a fiscal responsibility to balance access to medicines with steering beneficiaries to lower-cost alternatives, sometimes there simply aren't any low-cost alternatives available. Beneficiaries with chronic conditions are subject to high costs in Part D every month, where the lack of supplemental coverage, compared to Part B, makes the adverse tiering even more of a financial challenge.

### *Utilization of specialty tiers and limitations in requesting tiering exceptions:*

While there is no standard agreed-upon definition of specialty drugs in the Medicare Part D context, they are typically self-administered biologics (although they can be orals) that are more costly than other Part D drugs. Each year, CMS announces the minimum dollar amount that qualifies a drug for the specialty tier (\$670 for a 1-month supply at an in-network pharmacy for 2019). Part D plans may require a 25% coinsurance for specialty tier drugs under the standard design and can increase it to a 33% coinsurance if the plan lowers the annual deductible. While cost-sharing for specialty drugs is capped at 33%, these limits do not apply for other tiers of drugs, such as the branded non-preferred drug tier. Beneficiaries are unable to file tiering exception requests for drugs that are in the specialty tiers. This means that patients taking prescription medicines on the specialty tier increased OOP costs (often above the standard benefit design of 25%) and no opportunity to appeal for a lower cost-sharing tier.

For example, a beneficiary with rheumatoid arthritis may likely be taking a drug that has a negotiated price of roughly \$5,000 a month. In their first month of filling this prescription, they will pay over \$1,600 and in the second month, over \$1,300, before landing in catastrophic coverage during the third month, where they will pay \$250 a month for the rest of the plan year.

With the proliferation of specialty drug launches in recent years, more and more innovative therapies have become candidates for inclusion on specialty tiers.<sup>8</sup> Xcenda analysis shows that the percentage of drugs covered on the specialty tier grew for both PDPs and Medicare Advantage prescription drug (MA-PD) plans between 2015 and 2019. For PDPs, in 2015, 13% of all drugs on formulary were placed in specialty tiers; for 2019, it will be 16% of all formulary drugs in specialty tiers. For MA-PD plans, it has gone from 12% to 17%.

For drugs covered on the specialty tiers, the coinsurance amounts can range from 25% to 33%, leaving beneficiaries paying thousands of dollars in OOP costs for drugs and biologics used to treat cancer, multiple sclerosis, rheumatoid arthritis, lupus, and other conditions. As a result, many beneficiaries are denied access to the most clinically appropriate medication because it is out of reach financially. Beneficiaries have no recourse to obtain expensive specialty drugs at a lower OOP cost when no therapeutic alternatives exist—hence adverse tiering concerns. These are chronically ill beneficiaries who are left with no options but to either pay the high OOP cost or not take the prescriptions.

For example, as illustrated in **Table 1**, in 2018, nearly all products in 3 different therapeutic areas (multiple sclerosis, rheumatoid arthritis, and multiple myeloma) were placed by Part D plans on specialty tiers when covered on formulary.<sup>3</sup> Only Extavia (multiple sclerosis), Revlimid (multiple myeloma), and Velcade (multiple myeloma) are covered on anything other than a specialty tier. Even then, the overwhelming majority of treatments are still placed on specialty tiers.<sup>3</sup>



**A tiering exception is used when a medication is on a plan's formulary but is placed in a non-preferred tier with a higher copayment or coinsurance. Beneficiaries may request plans to make a tier exception when the drug is demonstrated to be medically necessary. If the request is approved, the plan makes it available at a lower copayment that is usually reserved for preferred drugs. However, tiering exceptions are not available for drugs on specialty tiers.**

In terms of cost-sharing for these products, most of the negotiated prices for these products are substantial.

*For a patient with multiple sclerosis, the drugs may be on formulary on the specialty tier with negotiated prices around \$8,000 which translates to a 33% cost-share of*

**\$2,640**

*For a patient with multiple myeloma, the price of the drugs in the class varies, but for a drug with negotiated price of \$13,000, the cost sharing of 33% would be around*

**\$4,300**

*For a patient with rheumatoid arthritis, many of the product options are around \$5,000 a month, which translates to a 33% cost-share of*

**\$1,650<sup>9</sup>**

As nearly all Part D plans place the select products within these therapeutic areas on specialty tiers, the average coinsurance ranges from 25% to 30% for PDPs and 30% to 31% for MA-PD plans.<sup>3</sup> With these coinsurance rates, non-LIS beneficiaries may face significant OOP costs for just 1 monthly fill of a drug. With the additional limitation on employing tiering exceptions, the impact on beneficiaries prescribed one of these Part D medications is that they have no ability to select a product with a lower cost-sharing amount, raising the specter of discrimination against beneficiaries who require treatment in these therapeutic areas. Patient advocates have urged CMS to reform the specialty tier policy in order to alleviate the OOP burden and increase the availability of other products outside of the specialty tier. However, the agency has consistently stated that it will allow Part D sponsors flexibility in managing the benefit packages, thus preserving the status quo and stacking the deck against the most ill beneficiaries.

**Table 1. Percentage of Plans Covering Select Products on Specialty Tiers<sup>3</sup>**

Therapeutic Area	Brand Drug	MA-PD Plans			PDPs		
		On Formulary	On Specialty Tier	Average Coinsurance	On Formulary	On Specialty Tier	Average Coinsurance
Multiple sclerosis	Aubagio	32%	100%	30%	13%	100%	29%
	Avonex	75%	100%	30%	24%	100%	30%
	Betaseron	96%	100%	30%	90%	100%	29%
	Copaxone	87%	100%	30%	94%	100%	28%
	Extavia	13%	93%	31%	7%	100%	25%
	Gilenya	91%	100%	30%	93%	100%	29%
	Plegridy	36%	100%	31%	4%	100%	29%
	Rebif	61%	100%	30%	24%	100%	30%
	Tecfidera	43%	100%	30%	31%	100%	27%
Multiple myeloma	Farydak	100%	100%	30%	100%	100%	28%
	Ninlaro	100%	100%	30%	100%	100%	28%
	Pomalyst	100%	100%	30%	100%	100%	28%
	Revlimid	100%	100%	30%	100%	98%	28%
	Thalomid	100%	100%	30%	100%	100%	28%
	Velcade	99%	97%	30%	87%	99%	28%
Rheumatoid arthritis	Actemra	24%	100%	31%	31%	100%	27%
	Cimzia	22%	100%	31%	1%	100%	29%
	Enbrel	81%	100%	30%	55%	100%	28%
	Humira	100%	100%	30%	100%	100%	28%
	Kevzara	12%	100%	31%	0.3%	100%	29%
	Kineret	32%	100%	30%	12%	100%	29%
	Orencia	32%	100%	31%	19%	100%	26%
	Simponi	51%	100%	30%	18%	100%	27%
	Xeljanz	87%	100%	30%	53%	100%	29%

Key: MA-PD – Medicare Advantage prescription drug; PDP – prescription drug plan.

## Increased availability of innovative medicines and shift to non-preferred tiers

Non-preferred tiers have affordability and access concerns similar to the specialty tiers. These are tiers of products that are on the formulary but subject to significant cost-sharing and utilization management.

Like other parts of the benefit design, the non-preferred tiers—tiers of drugs that have higher cost-shares—have increasingly shifted to a coinsurance payment structure. As seen in Table 2, in 2019, 626 of the 629 PDPs analyzed (99.4%) now require a coinsurance for non-preferred tiers, while MA-PD plans still mostly offer copayments, with 89.2% of beneficiaries enrolled in MA-PD plans (Percent of Lives) having copayments in the non-preferred tiers.<sup>3</sup>

**Table 2. Cost-Sharing Trends for Non-Preferred Tiers, 2016–2019<sup>3</sup>**

Plan Year	Plan Type	Percentage of Plans		Percentage of Lives Covered by These Plans		Average Cost-Sharing Amount	
		Copay	Co-insurance	Copay	Co-insurance	Copay	Co-insurance
2015	MA-PD plan	88.6%	11.4%	90.1%	9.9%	\$88	47%
	PDP	27.4%	72.6%	36.6%	63.4%	\$67	41%
2016	MA-PD plan	85.9%	14.1%	88.1%	11.9%	\$93	46%
	PDP	9.2%	90.8%	4.0%	96.0%	\$93	41%
2017	MA-PD plan	87.8%	12.2%	90.6%	9.4%	\$95	37%
	PDP	2.9%	97.1%	2.5%	97.5%	\$85	40%
2018	MA-PD plan	84.1%	15.9%	89.3%	10.7%	\$95	44%
	PDP	0.4%	99.6%	0.1%	99.9%	\$84	40%
2019	MA-PD plan	80.9%	19.1%	<b>89.2%</b>	10.8%	\$95	44%
	PDP	0.6%	<b>99.4%</b>	0.2%	99.8%	\$86	40%

Key: MA-PD – Medicare Advantage prescription drug; PDP – prescription drug plan.

Unlike the specialty tiers, beneficiaries are allowed to request a tiering exception in order to reduce their cost-sharing—but beneficiaries may not know of their ability to request a tiering exception and/or the plan may not approve it. When MedPAC researched the exceptions and appeals process, they found there was insufficient data to evaluate how well the process is working for beneficiaries to gain access to needed medications.<sup>10</sup> In subsequent evaluations, the data from CMS had caveats that made the reliability of the information questionable.

### An Upcoming Medicare Cliff

In 2020, Part D beneficiaries may face another affordability issue related to the current OOP threshold: the phenomenon often referred to as the “OOP cliff.” As background, the OOP threshold is the amount that a beneficiary must spend out of their own pocket before they enter catastrophic coverage; this amount includes the 70% manufacturer contribution for brand name products during the coverage gap. For 2019, the OOP threshold is \$5,100. The OOP threshold is expected to grow by \$1,250 between 2019 and 2020, hence the “cliff”.<sup>11</sup> If Congress does not take action by early 2019, beneficiaries already facing high OOP expenses will see their costs increase further in 2020.

The OOP cliff is caused by a little-noticed provision in the ACA, where the growth rate of the OOP threshold was slowed from 2014 through 2019. Normally, the OOP threshold would grow just like the deductible and the initial coverage limit at the rate of beneficiary per-capita spending. But under the ACA, the OOP threshold grew in 2014 and 2015 at the rate of per-capita beneficiary spending less 0.25%, and then in 2016, 2017, 2018, and 2019, it grew at the Consumer Price Index rate + 2%. In 2020, the OOP threshold is set as if the growth had never been slowed down in the first place, causing the cliff.

Figure 3. The OOP “Cliff”

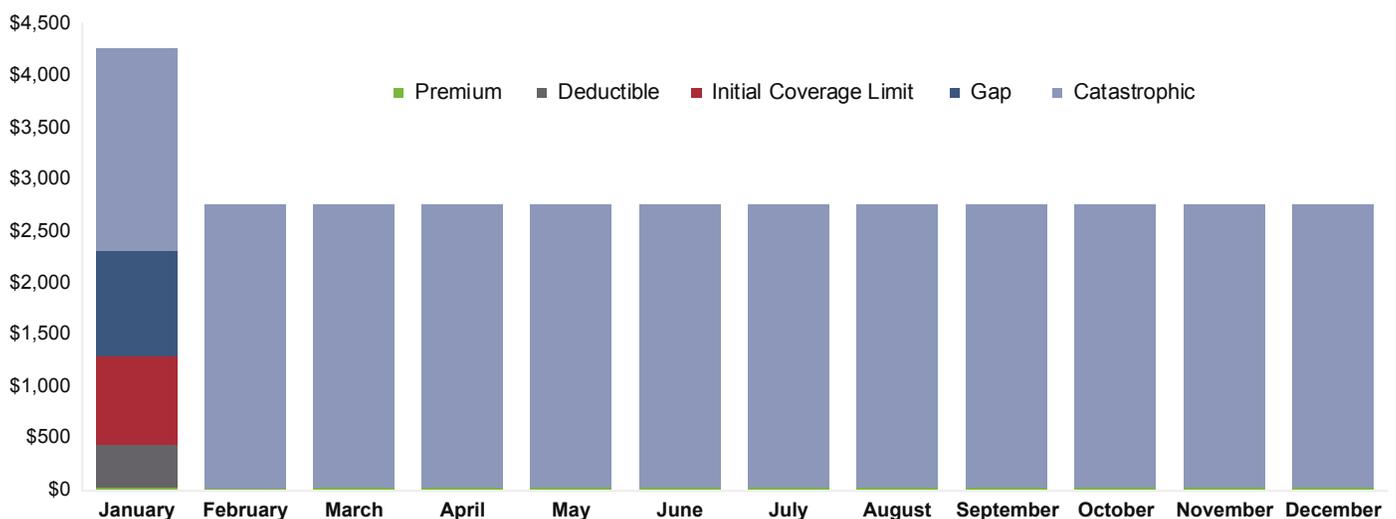


### No True OOP Maximum

Compounding affordability issues is that after non-LIS beneficiaries get through the coverage gap and into catastrophic coverage, they must pay 5% coinsurance until the next calendar year, when the cycle starts anew. This is unlike the experience for patients with commercial coverage, who have an out-of-pocket cap for all covered medical care, and most Medicare beneficiaries when using the Medicare Part B benefit (outpatient services), since most have some type of supplemental coverage that assists with OOP expenses and/or offers an annual OOP maximum.

Given the high cost of specialty products per year, the catastrophic coverage phase 5% cost-share requirement can impose a material financial burden on beneficiaries. For example, as seen in **Figure 4**, a product that costs over \$50,000 per fill could result in OOP expenses of almost \$35,000 annually. Assuming a beneficiary starts therapy at the beginning of the plan year in January and has a standard benefit design, they may pay over \$4,000 for the first month, effectively moving to catastrophic coverage. For the rest of the year, the patient may still pay \$2,700 monthly just for this 1 treatment.

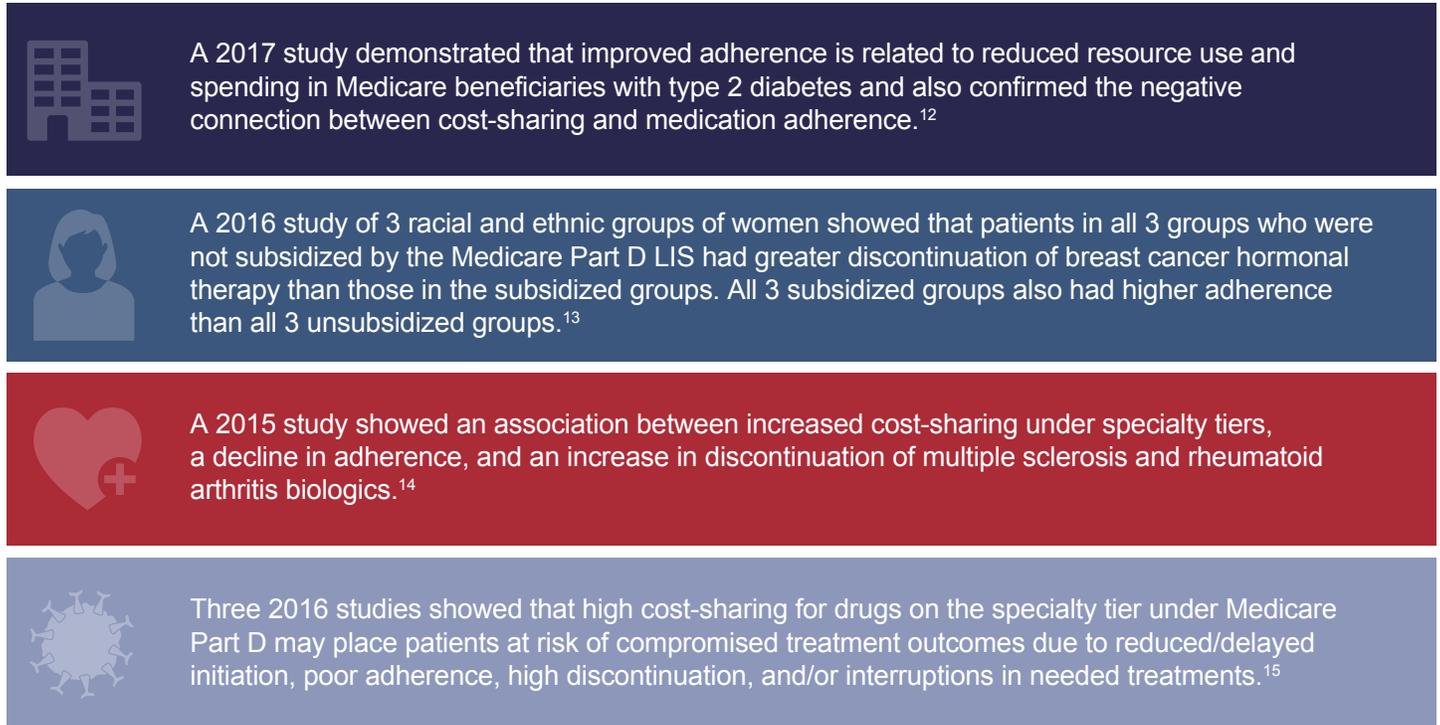
Figure 4. OOP for a ~\$55k/month Prescription Drug



These high OOP costs can deter beneficiaries from filling their prescriptions and, thus, remaining adherent to their therapy. Discontinuation of pharmaceutical therapy, in turn, can worsen patients' health. Total healthcare costs increase if their condition(s) decline to the point that they require hospitalization or other medical services.

Recent research on nonadherence with medication therapy due to higher OOP costs bears this out. **Figure 5** lists studies documenting that adherence to pharmaceutical therapy under the Part D program declines as OOP costs increase across a variety of different disease states, genders, and racial/ethnic groups.

### Figure 5. Highlights of Research on the Impact of Prescription Drugs Access on Adherence



Key: LIS – low-income subsidy.

In addition to the findings above, the Congressional Budget Office in 2012 found that a “1% increase in the number of prescriptions filled by beneficiaries would cause Medicare’s spending on medical services to fall by roughly one-fifth of 1%.”<sup>16</sup> This connection between prescription drugs and reductions in the use of other medical services (and thus reductions in Medicare A and B spending) highlights the value of the benefit and, as utilization of medical services and prescription drugs evolves, the link may even be stronger.

## ACCESS CHALLENGES

While the affordability issues discussed have impacted beneficiary access, there are other barriers affecting beneficiaries' ability to obtain their prescriptions, too. Access challenges include an erosion of beneficiary protections, utilization management, use of preferred pharmacy networks, lack of easy-to-navigate resources explaining plan options and the exceptions and appeals processes, and narrow formularies for LIS benchmark plans.

### Erosion of Beneficiary Protections in Favor of Plan Flexibility

Since the enactment of the MMA, CMS has been tasked with striking a delicate balance between two often-competing dynamics: protecting beneficiary access to medications and giving Part D plans the flexibility to manage benefits. From the program's launch, Part D plans have been required to cover a wide range of drugs across different therapeutic areas. The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class, although most cover many more.<sup>17</sup>

In addition, to ensure patient access to medications within certain key classes, Medicare implemented a policy in which Part D plans must cover "all or substantially all" drugs within 6 classes of clinical concern. These classes include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. The antineoplastics category includes many oral chemotherapy drugs. And finally, CMS implemented regulations to ensure wide access to preferred pharmacies, which potentially can offer lower cost-sharing for certain formulary drugs.

Even with these current requirements, beneficiaries *still* face access challenges within the Part D program. And in recent years, there has been a growing sense among patient advocates that CMS has favored preserving plans' flexibility over ensuring patient access.

As shown in **Table 3**, CMS has implemented regulatory and subregulatory guidance that could jeopardize protections in formulary design, meaningful differences,<sup>a</sup> and communication of plan benefit designs. Even in a recent proposed rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," released on November 26, 2018, CMS favors plan flexibility over patient protections, despite repeated statements by the Administration that these changes will benefit beneficiaries.<sup>18</sup> In particular, this proposed rule would make changes to the six protected classes that would allow plans to require patients stable on a medicine to try another medicine before getting coverage for the medicine that has been working for them. The proposed rule would make other changes that would make it easier for plans to take medicines in the six protected classes of the formulary—restricting access for patients.

When considered independently, these regulations and guidances may not appear as significant as other potential changes (e.g., removing a certain class from protected status), but together, they represent a significant policy shift toward expanding plan flexibility at the expense of beneficiary protections. As the cost burden continues to climb for patients, CMS should emphasize beneficiary protections to properly address the existing challenges around affordability and access.

<sup>a</sup> "Meaningful differences" is the CMS policy requiring that available PDPs offered by a plan sponsor in a select region have meaningful differences to help ensure that beneficiaries are presented with a clear and understandable array of choices. Previous CMS policy required sponsors to have 1 basic PDP and no more than 2 enhanced PDPs in a region.

**Table 3. Impact on Beneficiaries of CMS Regulatory Guidance Favoring Plan Flexibility Over Beneficiary Protection**

Issue Area	Regulatory Guidance/When It Started	Time Frame for Guidance	Effect(s) of Regulatory Guidance	Impact on Beneficiaries
<b>Specialty tier</b>	<ul style="list-style-type: none"> <li>• Maintains specialty tier threshold</li> <li>• Prohibits cost-sharing exceptions for specialty tier products</li> </ul>	Initiated in 2007 (ongoing)	<ul style="list-style-type: none"> <li>• Fails to consider the effects of inflation on drug prices and the growing number of high-cost specialty drugs that are reshaping the nature of the Part D benefit</li> <li>• Part D enrollees who are prescribed specialty medications have the most burdensome cost-sharing requirements, without any ability to seek a lower requirement (an option available for drugs on other tiers)</li> </ul>	<ul style="list-style-type: none"> <li>• Part D beneficiaries prescribed a specialty tier product are likely to face a significant OOP expense for the medication</li> <li>• With a high OOP cost, beneficiaries have no option for a lower cost-sharing amount, potentially resulting in therapy abandonment or inconsistent adherence</li> </ul>
<b>Tiering label and composition</b>	<ul style="list-style-type: none"> <li>• Allows plans to use a non-preferred tier option for both branded and generic drugs in which these 2 distinct tiers have the same maximum cost-sharing amounts</li> </ul>	Initiated in 2017 (ongoing)	<ul style="list-style-type: none"> <li>• Allows a shift toward coverage for generic drugs that is not distinguished from brand drug coverage, thereby leading to higher OOP costs for generic drugs for beneficiaries</li> </ul>	<ul style="list-style-type: none"> <li>• Beneficiaries may not only face relatively high cost-sharing amounts for branded medications, but given the potential makeup of a non-preferred tier, many may also face significant OOP costs for generic medications, too</li> </ul>
<b>Meaningful differences</b>	<ul style="list-style-type: none"> <li>• Eliminates the meaningful differences requirement between two enhanced PDPs offered by a PDP sponsor in one region</li> </ul>	Effective for plan year 2019	<ul style="list-style-type: none"> <li>• Creates potential confusion among prospective beneficiaries about the differences in benefit and formulary designs between 2 enhanced plans offered by the same sponsor</li> </ul>	<ul style="list-style-type: none"> <li>• Without the meaningful differences policy in place for enhanced plans, beneficiaries may have difficulty differentiating between enhanced plan options</li> </ul>
<b>Communication of plan materials</b>	<ul style="list-style-type: none"> <li>• Requires Part D sponsors to deliver certain plan materials at the start of the Annual Election Period (i.e., the day that beneficiaries can start enrolling) (rather than 15 days before)</li> <li>• Allows Part D plans to send only certain materials as hard copies through the mail, upon request</li> </ul>	Effective for plan year 2019	<ul style="list-style-type: none"> <li>• Removes an important step in communicating benefit design, formulary, and provider network changes in advance of the upcoming plan year that could lead to confusion for beneficiaries in making enrollment decisions</li> </ul>	<ul style="list-style-type: none"> <li>• It is critical for beneficiaries to be as informed as possible <b>before</b> making their plan selections</li> <li>• Requiring beneficiaries to request information, rather than sending it to them directly, is a hurdle to better communication</li> </ul>

Key: CMS – Centers for Medicare & Medicaid Services; OOP – out-of-pocket; PDP – prescription drug plan.

## Utilization Management

For many patients, there are steep barriers to accessing their needed prescribed medications. Part D is administered by private plans with extensive experience managing drug costs through advanced formulary and utilization management techniques in other market segments. For example, a “fail-first” policy requires that beneficiaries must first try a medicine preferred by their insurer before they can use the one their physician identified as being the most appropriate for the patient. These policies place unnecessary barriers between patients and their access to the medications recommended by their physicians. For many health conditions—particularly those treated by the drugs in the protected classes—such policies threaten patients’ lives, safety, and medical stability.

In recent years, Part D plan sponsor use of utilization management tools has increased.<sup>1</sup> For the therapies within the 3 therapeutic classes (multiple sclerosis, multiple myeloma, and rheumatoid arthritis) analyzed in **Table 1**, prior authorization requirements are commonplace. For example, the percentage of plans covering the analyzed drugs that require prior authorization ranges from 82% to 100% of plans for the multiple myeloma products, 96% to 100% for the rheumatoid arthritis products, and 24% to 97% for the multiple sclerosis products.<sup>3</sup>

## Increased Use of Preferred Pharmacies

Over the years, plans have increasingly offered reduced cost-sharing at in-network “preferred pharmacies.” In 2018, nearly all PDPs have a preferred pharmacy network.<sup>19</sup> Beneficiaries enrolled in plans with harder-to-access network pharmacies can find it difficult to fill their prescriptions at an in-network pharmacy and potentially have to pay more OOP for their medications at a non-network pharmacy. This dynamic may be especially problematic for beneficiaries in rural locations with a dearth of robust pharmacy options.

## Lack of Easy-to-Navigate Part D Resources

Beneficiaries have a limited amount of time each year to make a decision on which plan to enroll in for the upcoming plan year. For 2018, open enrollment is from October 15 to December 7. Beneficiaries are not able to change plans mid-year, so making an informed decision is critical.

### *Medicare Plan Finder*

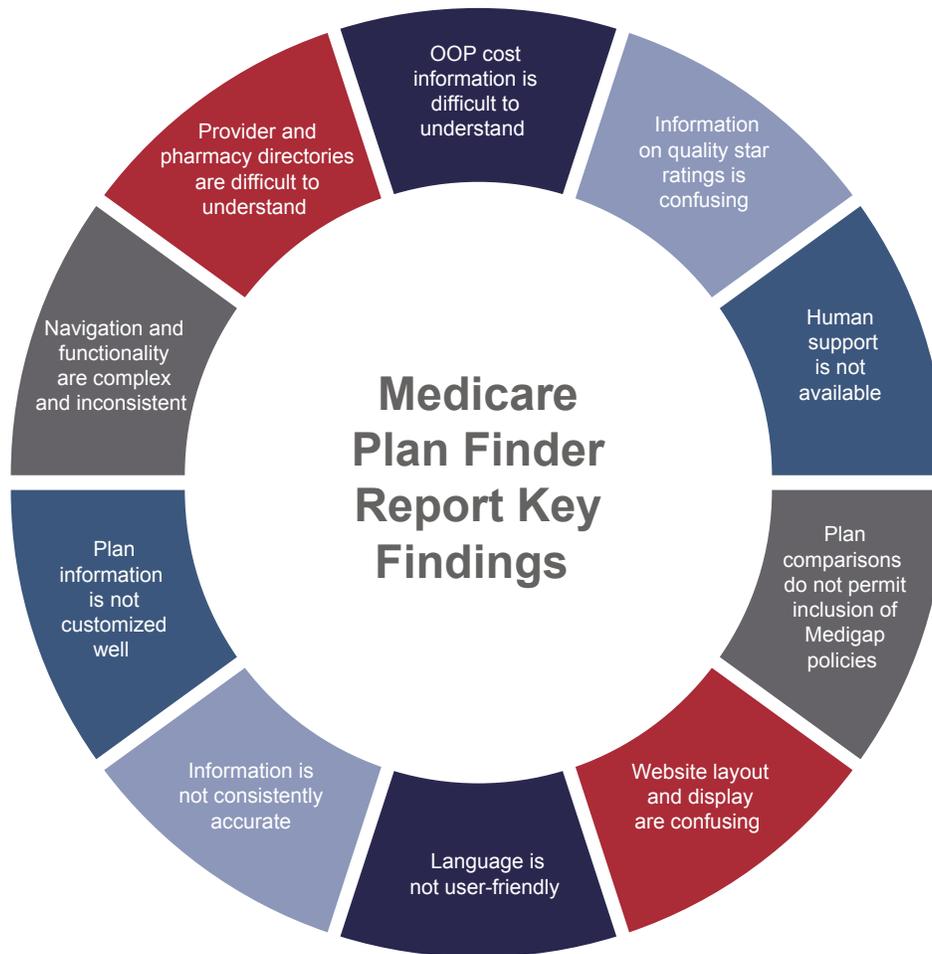
The quality of information resources to assist beneficiaries in enrollment choices is lacking. Resources such as the Medicare Plan Finder tool may be difficult to navigate and sometimes lack critical information, such as an easy way to determine which pharmacies are in the preferred network.

On the Medicare Plan Finder, maintained by CMS, prospective plan enrollees can review the available benefit designs and drug coverage of various PDPs and MA-PD plans. Beneficiaries are able to enter their medication and pharmacy information to project annual costs. Following this step, Medicare Plan Finder will list the available plans in the specific region or county. Beneficiaries can sort through the plan options via a number of parameters, such as the projected OOP costs for medications, plan premiums, plan names, off-formulary drugs, and star ratings, among others.

While the Medicare Plan Finder offers an online resource to help inform enrollment decisions, according to beneficiary advocates and experts, the tool has flaws. The resource can be cumbersome due to the large number of steps, difficult-to-navigate options, and confusing nomenclature. In April 2018, the National Council on Aging released a detailed report of the current flaws with the Medicare Plan Finder tool (**Figure 6**) including difficulty in understanding the OOP cost projections, challenges navigating the provider and pharmacy networks, and difficulty using the tool’s functionality effectively.<sup>20</sup>

Outside of the Medicare Plan Finder tool, there is no one-stop uniform resource. Beneficiaries may access information from a plan sponsor’s website; however, the ease of use varies widely by sponsor. Brokers may assist beneficiaries with enrollment information as well, but brokers may be representing a plan sponsor. Beneficiaries have access to State Health Insurance Assistance Programs, but they need to know these resources exist in order to access them.

Figure 6. Medicare Plan Finder Tool Report Key Findings



### *Exceptions and Appeals*

In addition to lacking resources to help inform enrollment decisions, other information—particularly surrounding the exceptions and appeals process—is generally difficult to obtain. Part D policy affords beneficiaries the avenue to seek a determination about coverage of a drug or its cost-sharing amount. Specifically, formulary exceptions seek access to non-covered drugs, while tiering exceptions seek a lower cost-sharing amount. If a beneficiary receives an adverse determination from the Part D plan, the policy offers the ability to seek a redetermination and an additional four other steps within the appeals process. Prospective enrollees could utilize information around the exceptions and appeals data to help them find the best plan for their needs. To date, CMS and MedPAC have sporadically released some data related to exceptions and appeals; however, only market-wide data have been presented and not plan-specific information related to appeals.

## Narrower Formularies for LIS Benchmark Plans

The Part D benefit provides prescription drug coverage and premium and cost-sharing assistance for the over 12 million beneficiaries who qualify for the LIS. Some beneficiaries, like those who qualify for both Medicare and Medicaid (i.e., dual-eligibles), are automatically enrolled, while others must apply and are subject to both an income and asset test. For example, in 2018, the resource limits are \$7,560 (\$11,340 if married) for the full LIS and \$12,600 (\$25,150 if married) for other LIS.<sup>21</sup>

While LIS beneficiaries may choose to enroll in any Part D plan, subsidies are available up to the cost of the average premium for the basic plan (benchmark plan). Over time, there have been fewer options available to choose from. For example, in 2018, there was a 6% decrease in available plans; about 3 in 10 PDPs are benchmark plans for LIS, and thus premium-free.<sup>22</sup> This reduces beneficiaries' ability to find plans that include their drugs on formulary.

While LIS beneficiaries face \$0 or nominal cost-sharing (at or below \$8.35) for Part D products, they can face other access challenges related to their medications. For example, PDPs with monthly premiums at or below a regional benchmark may receive assigned LIS beneficiaries. However, these plans may also have narrower formularies compared to alternatives with even modest premiums that other non-LIS subsidized beneficiaries might select, resulting in fewer medication choices for their members.

According to the Xcenda 2018 analysis seen in **Table 4**, LIS beneficiaries in benchmark plans generally have less access to select products within two specialty therapeutic areas, multiple sclerosis and rheumatoid arthritis, compared to other basic and enhanced PDPs.<sup>3</sup> The basic and enhanced PDPs provided far greater access, on average, than the benchmark PDPs for selected multiple sclerosis and rheumatoid arthritis treatments. Enhanced plans can offer a lower deductible or reduced cost-sharing, but often have a higher premium. For example, over 30% of benchmark PDPs cover Tecfidera (an oral medication treating MS) on formulary; however, other basic PDPs—without benchmark status—and enhanced PDPs cover Tecfidera at higher percentages (90% and 42%, respectively), implying that LIS beneficiaries may have greater access to Tecfidera outside of the designated benchmark PDPs. In the rheumatoid arthritis space, LIS beneficiaries prescribed Enbrel may face a similar scenario, as roughly 40% benchmark PDPs cover the product while other basic PDPs (59%) and enhanced (69%) PDPs appear to cover it more frequently.

**Table 4. Comparison of Benchmark, Basic, and Enhanced PDP Coverage of Select Treatments for Multiple Sclerosis and Rheumatoid Arthritis<sup>3</sup>**

Therapeutic Area	Drug Name	Benchmark PDPs	Other Basic PDPs		Enhanced PDPs	
		On Formulary	On Specialty Tier	Average Coinsurance	On Formulary	On Specialty Tier
Multiple sclerosis	Aubagio	5%	26%	More	10%	More
	Avonex	13%	44%	More	47%	More
	Betaseron	77%	51%	Less	92%	More
	Copaxone	86%	93%	More	91%	More
	Extavia	17%	39%	More	1%	Less
	Gilenya	92%	74%	Less	78%	Less
	Plegridy	4%	20%	More	10%	More
	Rebif	6%	20%	More	55%	More
	Tecfidera	34%	90%	More	42%	More
Rheumatoid arthritis	Actemra	30%	51%	More	25%	Less
	Cimzia	0%	3%	More	1%	More
	Enbrel	39%	69%	More	59%	More
	Humira	100%	100%	Same	100%	Same
	Kevzara	0%	2%	More	1%	More
	Kineret	8%	21%	More	12%	More
	Orencia	10%	33%	More	20%	More
	Simponi	14%	4%	Less	25%	More
Xeljanz	62%	33%	Less	56%	Less	

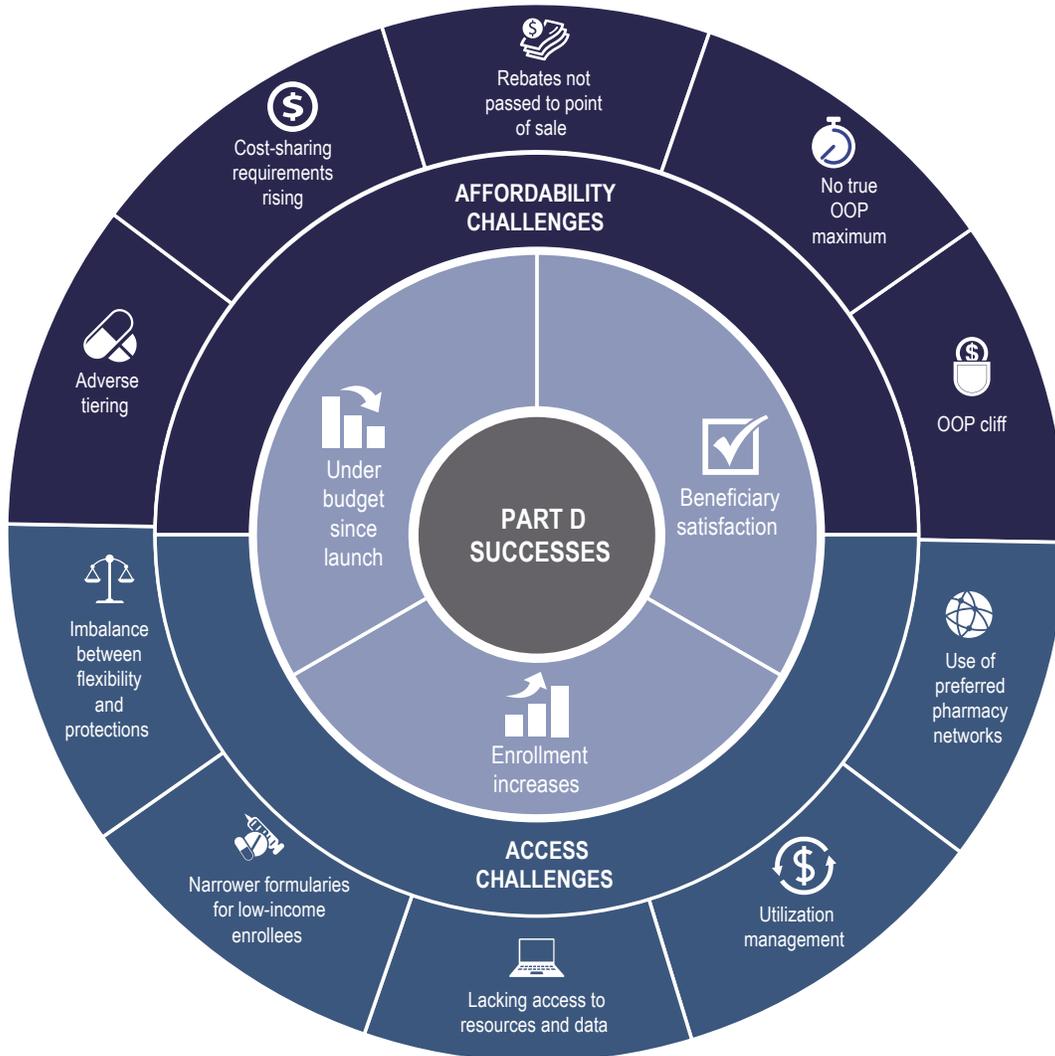
Key: PDP – prescription drug plan.

While enhanced PDPs are expected to offer a higher percentage of drugs compared to basic PDPs, as this helps achieve an actuarial standard above the basic design, those basic PDPs generally cover more drugs than their LIS benchmark counterparts. An important caveat to this analysis is that by covering fewer products, particularly specialty products, PDPs may be able to offer premiums below the regional benchmark. While this may enable PDPs to lower premiums, which can be beneficial, it is also important to continue building access protections for LIS beneficiaries and beneficiaries with chronic conditions to ensure their access to critical medications.

# CALL TO ACTION

The Part D story has largely been one of success, but current challenges around affordability and access still present barriers for beneficiaries. While balancing plan flexibility and beneficiary protections with affordability and access is a daunting task for policymakers and other stakeholders, a coalition of stakeholders—focused on the best interests of beneficiaries and exploring innovative policy solutions—can help address the current challenges and solidify an already strong foundation for all Part D beneficiaries over the next 15 years.

**Figure 7. Part D Successes and Challenges**



## PROPOSED SOLUTIONS

Problem	Potential Solution	Who Can Enact Solution
<b>Increased cost-sharing requirements</b>	<ul style="list-style-type: none"> <li>Little is known about how CMS does formulary reviews and testing for non-discrimination; CMS should make it easy for patients and advocacy groups to flag formularies for additional CMS review when formularies appear to be discriminatory.</li> <li>Plans should be required to provide clarity and transparency on coverage and consumers' OOP costs. A mix of copayments and coinsurance can cause significant confusion, especially for individuals on multiple and/or expensive medications who are trying to navigate the system and compare plans.</li> <li>Put stringent restrictions on the number of generic drugs permitted to be covered on brand tiers. Including large numbers of generic drugs on non-preferred tiers is misleading. It increases generic drug cost-sharing and artificially lowers average cost-sharing for the tier, allowing plans to achieve higher cost-sharing for high-cost brand drugs.</li> </ul>	CMS
<b>Prices not reflecting rebates/discounts at POS</b>	<ul style="list-style-type: none"> <li>While CMS has proposed including pharmacy-provided price concessions paid to the plan as a discount to beneficiaries at the POS, that is only a fraction of the discounts and rebates plans receive. Discounts and rebates from manufacturers should also be woven into the POS price.</li> <li>Apply a specific percentage of rebates at the POS to reduce OOP expenses.</li> </ul>	CMS
<b>Adverse tiering</b>	<ul style="list-style-type: none"> <li>Allow cost-sharing exceptions for specialty tier drugs.</li> <li>Conduct rigorous monitoring to ensure non-discrimination and actuarial value standards are being met</li> </ul>	CMS
<b>OOP "cliff"</b>	<ul style="list-style-type: none"> <li>Change the current law to make the current out-of-pocket threshold permanent</li> </ul>	Congress
<b>Lack of an annual OOP maximum</b>	<ul style="list-style-type: none"> <li>Establish a true cap on annual OOP expenses that would limit exposure to high OOP costs, even after beneficiaries met their deductible and coverage gap obligations.</li> </ul>	Congress
<b>Plan flexibility: Specialty tiers</b>	<ul style="list-style-type: none"> <li>The specialty tier threshold should be increased annually at the same rate as the benefit parameters in order to mitigate the number of drugs eligible for the specialty tier category.</li> </ul>	CMS
<b>Plan flexibility: Tier labeling and composition</b>	<ul style="list-style-type: none"> <li>Conduct enhanced rigor and scrutiny of plan formulary designs to ensure wide access to medications in key therapeutic areas and minimize OOP burdens.</li> <li>Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences. While CMS has proposed additional exceptions to the protected classes, these changes would come at the expense of patient access to needed therapies.</li> </ul>	CMS
<b>Plan flexibility: Meaningful differences and communication of plan information</b>	<ul style="list-style-type: none"> <li>Look for innovative ways to communicate plan options so that beneficiaries can find the plan that best meets their individual needs.</li> <li>Plan sponsors should provide plan benefit package information 15 days prior to the Annual Enrollment Period, and hard copies should be provided with the ability for beneficiaries to opt out of receiving these materials.</li> </ul>	CMS

Key: CMS – Centers for Medicare & Medicaid Services; LIS – low-income subsidy; OOP – out-of-pocket; POS – point of sale.

Note: While CMS has the authority to implement many of these proposed solutions, Congress can enact legislation that would require action by CMS.

Problem	Potential Solution	Who Can Enact Solution
<b>Utilization management</b>	<ul style="list-style-type: none"> <li>• Prohibit the use of overly restrictive medical utilization management tools. Insurers should not be allowed to override a healthcare provider’s practice of medicine by forcing utilization of certain medications or therapies that may be inappropriate to the care of their patients.</li> <li>• Conduct rigorous oversight of medication utilization management tools (such as medication substitution, step therapy, or quantity limits) to ensure use of these tools meets practice guidelines. Plans should provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.</li> <li>• Plans should provide clear, relevant patient information on the use of utilization management tools prior to enrollment.</li> </ul>	CMS
<b>Use of preferred pharmacy networks</b>	<ul style="list-style-type: none"> <li>• Provide greater oversight of Part D plan sponsor marketing materials and encourage plan sponsors to feature information on their pharmacy networks more prominently on their materials and websites. This information could also be available on the Medicare.gov Plan Finder tool.</li> </ul>	CMS
<b>Lack of easy-to-navigate resources</b>	<ul style="list-style-type: none"> <li>• Enhance the Medicare Plan Finder tool in order to provide beneficiaries with easy-to-access information and additional support if beneficiaries have issues or questions.</li> <li>• Notice of non-coverage, appeals, and exceptions processes should be simple and understandable.</li> <li>• Collect and share information on utilization of exceptions/appeals at the plan level and provide additional education on the entire exceptions/appeals process for different stakeholder audiences.</li> <li>• Encourage additional communication on the availability of tiering exceptions (outside the specialty tier) and require public information on the utilization data of tiering exceptions.</li> </ul>	CMS

Key: CMS – Centers for Medicare & Medicaid Services; LIS – low-income subsidy; OOP – out-of-pocket; POS – point of sale.  
Note: While CMS has the authority to implement many of these proposed solutions, Congress can enact legislation that would require action by CMS.

While significant challenges persist in the Part D program, policymakers stand well positioned to address the challenges facing beneficiaries. Both policymakers within Congress and staff at CMS have varying authority to implement some of the potential solutions that can ease the access and financial burdens on beneficiaries. With a renewed focus on beneficiary protections, policymakers can further solidify the program’s footing and build a program that is modernized for today—and tomorrow’s—drug utilization.

## ACRONYMNS

**ACA** – Affordable Care Act

**CMS** – Centers for Medicare & Medicaid Services

**LIS** – low-income subsidy

**MA-PD** – Medicare Advantage prescription drug (plan)

**MedPAC** – Medicare Payment Advisory Commission

**MMA** – Medicare Modernization Act of 2003

**OOP** – out-of-pocket

**PBM** – pharmacy benefit manager

**PDP** – standalone prescription drug plan

**POS** – point of sale

## DEFINITIONS

**Coinsurance:** Coinsurance is a percentage of costs beneficiaries pay for a covered service after they pay the deductible.

**Copayment:** Copayments are fixed-dollar amounts beneficiaries pay for a covered service after they pay the deductible.

**Deductible:** Deductibles are the amount beneficiaries pay for covered healthcare services from their own pocket before the plan starts to pay.

**Low-income subsidy (LIS):** Under Medicare Part D, some Medicare beneficiaries will qualify for additional help with their prescription drug costs depending on income. Beneficiaries can qualify for either a full subsidy or a partial subsidy under the LIS program.

**Medicare Advantage prescription drug (MA-PD) plan:**

An MA-PD plan is a Medicare Advantage plan that includes Medicare Part D prescription drug coverage. Medicare Advantage is an alternative to Original Medicare, and it combines Medicare Part A and Part B into 1 privately offered plan. An MA-PD plan also includes Part D coverage, so a person who selects an MA-PD plan would have Parts A, B, and D coverage, all under 1 plan.

**Medicare's prescription drug program (Part D):** Part D is Medicare's insurance coverage to help people with Medicare pay for their prescription drugs. People may have Part D coverage through either a standalone prescription drug plan (PDP) if they have Original Medicare or a Medicare supplement plan, or a Medicare Advantage prescription drug (MA-PD) plan.

**Out-of-pocket (OOP) costs:** OOP costs are expenses for medical care that aren't reimbursed by insurance. OOP costs include deductibles, coinsurance, and copayments for covered services plus all costs for services that aren't covered.

**Pharmacy benefit managers (PBMs):** PBMs are companies that contract with insurers and employers to manage the prescription drug benefit for enrollees or employees. PBMs negotiate prices with pharmaceutical manufacturers and process claims for drugs.

**Prior authorization:** Prior authorization is a prescription drug utilization management technique where, before a health plan will cover a particular drug, the patient's doctor must first show that the patient has a medically necessary need for that particular drug and/or has met the prior authorization requirements for the drug. Plans may require prior authorization to be sure that drugs are prescribed and used correctly.

**Standalone prescription drug plans (PDPs):** A PDP is a Medicare Part D plan that only covers prescription drugs.

**Step therapy:** Step therapy is a type of prescription drug utilization management. In most cases, the patient must first try a less expensive drug on the health plan's formulary (also called a drug list) that has been proven effective for most people with that condition before a patient can move up a "step" to a more expensive drug.

**Tiering exception:** A tiering exception is used when a medication is on a plan's formulary but is placed in a non-preferred tier with a higher copayment or coinsurance. Beneficiaries may request plans to make a tier exception when the drug is demonstrated to be medically necessary. If the request is approved, the plan makes it available at a lower copayment that is usually reserved for preferred drugs. Tiering exceptions are not available for drugs on specialty tiers.

**Utilization management:** Utilization management refers to special rules that restrict how and when the plan will cover prescription drugs. Utilization management occurs for 2 primary reasons: To help patients use drugs in the most effective ways and to help control overall drug costs. Common utilization management techniques are prior authorization and step therapy.

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## ABOUT MAPRx

Medicare Access for Patients Rx (MAPRx) is a coalition of patient, family caregiver, and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities who rely on Medicare's prescription drug coverage, Medicare Part D.

The Lupus Foundation of America founded MAPRx in 2005 after Part D was created by the passage of the Medicare Modernization Act. Prior to the launch and implementation of Part D in 2006, MAPRx brought the patient advocacy community together to ensure the program met the needs of their constituents and all Americans. MAPRx members represent every segment of Medicare beneficiaries and join together to advocate for their behalf and collaborate with national and state policymakers to ensure all beneficiaries have access to the medications they need.

Since its inception, the Coalition has worked with Congress, the Centers for Medicare & Medicaid Services, MedPAC, and every other relevant stakeholder to strengthen Part D and continue to improve the program. MAPRx activities include hosting educational briefings for lawmakers on Capitol Hill, conducting trainings for organizations working with Part D enrollees, and producing an annual open enrollment guide to help beneficiaries understand the benefit and pick the plan that best suits their needs.

## MAPRx PRINCIPLES

MAPRx is guided by the idea that every Medicare Part D beneficiary should have timely, affordable access to the medications they need to live a healthy life. To that end, MAPRx has established the following principles for all of our activities to strengthen and improve Part D:

- I. Plans should be required to have a robust formulary and provide coverage for a variety of medications in each drug class or category.
- II. Medicare Part D's six protected classes are a critical patient protection and coverage should be required for the protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.
- III. Oversight of a prescription drug benefit should include monitoring of:
  - Plan operations with an emphasis on key performance measures such as frequency and types of complaints, timeliness and resolution of appeals, completeness of enrollment information accessible to pharmacists, and availability of changes to drug pricing;
  - Formulary design to determine that appropriate access is afforded to physician prescribed treatments and to ensure that the formulary does not discriminate or discourage enrollment by certain beneficiaries;
  - Plans' use of utilization management tools such as prior authorization, quantity limits and step therapy (where a lower cost drug is tried first before a higher cost drug may be used), should be required to meet best practice standards and appropriate treatment guidelines;
  - Quality measures should be meaningful to help beneficiaries make an informed drug plan choice and provide CMS necessary information in its oversight role. Measures should include customer service, access to needed drugs, appeal and denial rates, beneficiary protections and overall satisfaction; and,
  - Pharmacy and therapeutic (P&T) committee membership, including robust consumer representation, as well as process and procedural requirements should ensure access to medically necessary medications. These requirements should include procedural safeguards and timely review of every newly FDA-approved drug so that beneficiaries do not encounter barriers, such as potentially long and unnecessary delays, that hinder their access to medication therapies.
- IV. Plans should be required to provide clarity and transparency on coverage and on consumer's out-of-pocket costs. A mix of co-payments and coinsurance can cause significant confusion especially for individuals on multiple and/or expensive medications trying to navigate the system and compare plans. The ability to understand the benefits provided in a plan, along with coverage levels and out-of-pocket costs is an important factor for consumers when making a determination of which plan best meets their needs.
- V. Notice of non-coverage, appeals and exceptions process should be simple and understandable. Enrollees should be given timely notice of the reasons for the denial of drug coverage and their appeal rights, including the right to an expedited review. Regulatory oversight should ensure sufficient consistency in exceptions processes among all plans so that providers can assist beneficiaries in an efficient and effective manner.
- VI. Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limit(s) is critical.
  - Insurers should not be allowed to override a health care provider's practice of medicine by forcing utilization of certain medications or therapies that may be inappropriate to the care of their patients.
  - Plans should provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.
  - Plans should provide clear, relevant patient information on the use of utilization management tools prior to enrollment.