Impact of Protected Class Utilization Management in Medicare Part D

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Executive Summary

Health plans, including Medicare prescription drug plans (PDPs), commonly apply utilization management (UM) tools to manage spending on prescription drugs. While UM can reduce costs for plans and premiums for beneficiaries, it may also make it challenging for enrollees to access needed medications. In Medicare, UM is allowed in 5 of the 6 “protected classes,” for patients starting treatment for the first time (new starts), where plans must cover all unique products.

Avalere conducted an analysis to determine the relationship between the application of UM and prescription drug utilization in Medicare Part D across those 5 protected classes and 2 comparator non-protected classes. The results demonstrate that beneficiary utilization of prescription medications is substantially lower when the formulary applies UM to that product compared to when there is no UM. Specifically, in 2018, utilization was 75% lower for products in those classes when UM was applied than when those products were covered without UM. The findings also suggest applying UM in protected classes also leads to a larger reduction in utilization compared to when patients are required to go through the exceptions process to access products in the non-protected classes studied. While the impact varies by drug class and by year, the findings show a link between the application of UM and lower utilization of prescription drugs in the protected classes. Looking ahead, this finding has implications for any future potential changes to antiretrovials, the 1 remaining protected class for which the Centers for Medicare & Medicaid Services (CMS) does not permit UM.

Introduction

Background

UM refers to a variety of techniques that health plans and PBMs, including those in Medicare Part D (Part D), use to manage the utilization of specific prescription drugs. Plans can use UM to shift utilization between therapeutically equivalent products, to incent patients to use lower priced products, or to limit utilization of high priced, specialty medications. Generally, UM can be divided into 3 categories: quantity limits, step therapy, and prior authorization. Although these techniques are widely applied across all markets, they are each designed to lower costs for health plans and premiums for enrollees by driving patients towards therapies that are less expensive, more effective, or both.

Currently, Medicare prescription drug plans (PDPs) are permitted to implement UM and have increasingly relied on it to manage their formularies. The percentage of products with UM has grown since the early days of Part D, with PDPs placing UM on 24% of covered products in 2018.[1]

In 2018, CMS proposed a rule[2] allowing PDPs to expand use of UM—specifically, prior authorization and step therapy—for drugs in the protected classes. PDPs must cover “all, or substantially all” drugs in these protected classes, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. The final rule[3], which

significantly scaled back the initial proposal and codified what was already permitted in practice, allowed UM in 5 of the 6 protected classes for patients starting treatment for the first time (new starts)—or all protected classes except for antiretrovirals. Nonetheless, the rule continued a discussion about how to balance drug spending and plan affordability with patient access to needed treatments.

In 2019, the US Department of Health and Human Services (HHS) Office of the Inspector General (OIG) released a report[4] that found millions of prescriptions for Part D beneficiaries were rejected in 2017. Specifically, 23.8 million prescriptions were rejected due to prior authorization requirements, 14.5 million were rejected due to quantity limits, and 2.4 million were rejected due to step therapy requirements. Though beneficiaries can appeal rejections due to UM, OIG notes that these processes were only used 26% of the time, which could be due to the added patient and provider administrative burden. According to OIG, "73% of appeals result in rejections being overturned", a fact which they note means that some of those rejections were "avoidable or inappropriate."

In a separate 2019 report,[5] when the OIG interviewed drug manufacturers, Part D plan sponsors, and pharmacy benefit managers, manufacturers and most plan sponsors noted that, while UM can reduce certain costs, it may negatively impact beneficiaries' health overall, as it can prevent access to treatments that best suit their needs.

A 2019 OIG report found that 73% of appeals of an UM prescription drug coverage denial led to the denial being overturned.

Project Overview

Avalere was commissioned to determine the relationship between UM and product utilization in Medicare Part D between 2014 and 2018. The analysis was conducted on 7 drug classes, including 5 of the protected classes. Because nearly all drugs in the protected classes must be covered, these 5 classes acted as a controlled environment, allowing for comparisons over time and across categories. In addition to the protected classes, Avalere analyzed multiple sclerosis (MS) and rheumatoid arthritis (RA) classes for comparison and to determine utilization for those 3 classes where a coverage exception is required.

Avalere used Part D Prescription Drug Event (PDE) claims data under a Research Data Use Agreement with CMS to conduct the analysis. The analysis was conducted using multiple methodologies and segmentations to ensure validity of the results. The datasets allowed Avalere to determine differences in utilization (i.e., number of prescriptions filled) at the product and class level to determine the impact of UM.

Methodology

Avalere assessed the difference in utilization, or count of prescription drug scripts, in the 5 protected classes where UM is permitted, as well as in the MS and RA classes, from 2014 through 2018. Avalere identified claims for each of the products in the analysis and identified if they were subject to UM or not based on the coverage details from the formulary characteristics file. The results are presented as "weighted" amounts, which account for differences in the number of enrollees in each formulary. As part of the weighting process, the results are presented as "prescriptions per 10,000 enrollees." Each product is weighted equally relative to other products in the class.

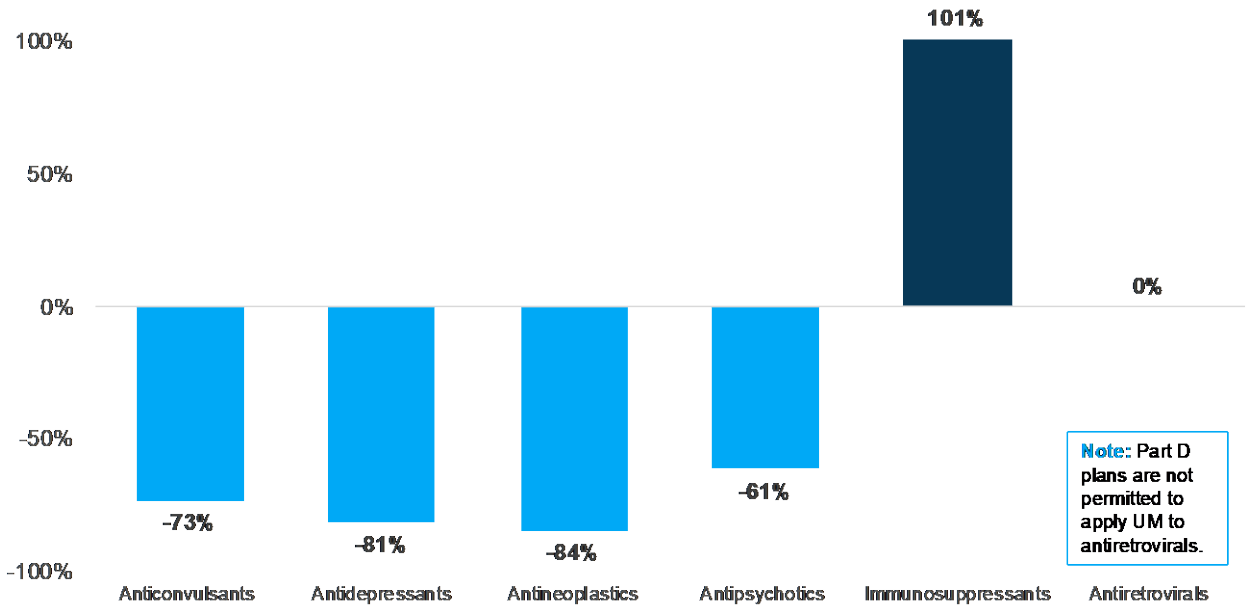
To conduct the analysis, Avalere extracted a 20% random sample of beneficiaries from the Medicare Beneficiary Summary File, which includes data about Medicare beneficiaries and enrollment in Medicare drug plans. Avalere then used the Formulary Characteristics File to analyze Part D claims for the products in the classes named above to determine whether those products were subject to UM. For all products in each class, Avalere calculated the enrollment-weighted average number of prescriptions per 10,000 enrollees in PDPs with specific formularies. Enrollment weighted averages are based on enrollment from December of each year.

Next, Avalere calculated a set ratio to assess differences in utilization associated with UM, providing the "weight" described above. Avalere defined products accessed through a coverage exceptions process as utilization of products that are not included on the Part D plan formulary in which that beneficiary is enrolled. In addition to conducting the analysis for all enrollees, Avalere calculated the analysis for four distinct segments: Beneficiaries who receive Medicare's low-income subsidy (LIS), beneficiaries who do not receive the LIS, beneficiaries who reached the catastrophic phase of the Part D benefit within the coverage year, and beneficiaries who did not reach the catastrophic phase within the coverage year. Avalere also re-tabulated the results to only include products where at least 10% of formularies apply UM (Table 7), and again to only include products where at least 20% of formularies apply UM (Table 8). These ratios were then converted to a percentage.

Results

As shown in Table 1 and Figure 1, the results demonstrate a correlation between UM and product utilization in the protected classes. In 4 of the 5 protected classes analyzed, anticonvulsants, antidepressants, antineoplastics, and antipsychotics, product utilization was substantially lower when UM was applied compared to when no UM was applied.

Figure 1. Percentage of Utilization with UM Compared to No UM Across 6 Protected Classes in Medicare Part D, 2014-2018 (Weighted)



In 2018, utilization when UM was applied averaged only about a quarter of utilization for anticonvulsant, antidepressant, antineoplastic, and antipsychotic products when UM was not applied. Expressed another way, utilization was about 75% lower for products in those classes when UM was applied than when those products were covered without UM. Across 4 of the 5 protected classes, the results are consistent, demonstrating that the effects of UM on decreasing product utilization are both substantial and evident from 2014 to 2018. For the 6th protected class, current regulations continue to prohibit UM for antiretrovirals. Therefore, there is no utilization impact for antiretrovirals.

Among the protected classes examined for which UM can be applied, 1 of the 5 classes, immunosuppressants, is an exception, with the results showing higher utilization when UM is applied than without. While the observed impact of UM has varied over the time period examined, ranging from 21% of utilization without UM to 201%, it does not fit the pattern of the other 4 protected classes examined. One potential explanation is that the low volume of scripts in the immunosuppressants protected class may lead to more inherent noise and variability than the other more heavily utilized protected classes.

Table 1. Percentage of Utilization with UM Compared to No UM Across 5 Protected Classes in Medicare Part D, 2014-2018 (Weighted)

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-49%	-52%	-59%	-63%	-73%
Antidepressants	-78%	-74%	-79%	-81%	-81%
Antineoplastics	-73%	-75%	-82%	-84%	-84%
Antipsychotics	-72%	-74%	-74%	-72%	-61%
Immunosuppressants[1]	-74%	-79%	-57%	68%	101%

In the non-protected comparator classes, MS and RA, utilization with UM compared to no UM varied between 2014 and 2018, as shown in Table 2. Utilization was higher in 2018 when UM was applied compared to when it was not applied, differing from the findings in the protected classes. Importantly, the variation may be attributable to Part D plans' ability to exclude products from these classes, providing an additional formulary management tool that is not available in the protected classes and lessening the impact of UM on patient utilization.

1 While immunosuppressants are an outlier among the results, the small number of products and users in this class may lead to volatility in the results than the other more heavily utilized protected classes.

Table 2. Percentage of Utilization with UM Compared to No UM Across Select Non-Protected Classes for All Formularies, 2014-2018 (Weighted)

Therapeutic Class	2014	2015	2016	2017	2018
Multiple Sclerosis	-17%	-13%	-6%	18%	24%
Rheumatoid Arthritis	12%	-12%	4%	28%	9%

Avalere also found that when a patient received a product through an exceptions process in the MS and RA classes, utilization was reduced to an average of 37% of utilization compared to that product being covered on formulary without UM, as shown in Table 3.

Effectively, the utilization of products in the two non-protected classes when received through an exceptions process was similar to the utilization of products in protected classes when UM was applied. As it relates to the UM findings in Table 1, this analysis suggests that applying UM in the protected classes produced a similar to greater reduction in utilization (compared to coverage with no UM) to receiving the product through a coverage exception in the non-protected classes examined.

Table 3. Percentage of Utilization When Accessed Through an Exception Compared to Covered with No UM Across Select Non-Protected Classes for All Formularies, 2014-2018 (Weighted)

Therapeutic Class	2014	2015	2016	2017	2018
Multiple Sclerosis	-56%	-58%	-65%	-59%	-57%
Rheumatoid Arthritis	-22%	3%	-69%	-63%	-70%

As previously noted, Medicare Part D plans are prohibited from applying any form of UM to antiretrovirals, unlike the other 5 protected classes. However, these findings—particularly those for the protected classes—can still inform decisions about coverage and access for antiretrovirals, given recent proposed rules that would have allowed UM into the antiretroviral

protected class. These results suggest that if UM were permitted for antiretrovirals, it would have a similar impact on utilization as is seen in most of the other protected classes.

As described above, and as shown in the Appendix, Avalere validated these results across multiple methodologies and segmentations. Specifically, the analysis was segmented by beneficiaries who are LIS (Table 5) and those who reach the catastrophic phase of the benefit (Table 6). These segmentations did not produce significant differences in findings. Similarly, additional methodologies that used minimum thresholds of 10% (Table 6) and 20% (Table 7) of formularies applying UM, as well as conducting the analysis without weighting by enrollment (Table 4), had similarly consistent results, confirming the overall findings that utilization was lower in the protected classes when UM was applied.

Conclusion

Given the public pressure to ensure stable premiums, Part D plan sponsors have relied on UM to manage Medicare's protected classes, especially as these drugs cannot be excluded from formularies. As the results indicate, even without exclusions, UM substantially may make it challenging for enrollees to access drugs under the protected classes—which, by definition, are in place to protect vulnerable patient populations. In addition, the findings demonstrate that UM in protected classes can have a similar reduction in utilization as an exception can have on the non-protected classes.

As policymakers consider additional flexibilities and expansions of UM in public programs, it is important to understand the implications on patient access to needed prescription drugs. As originally proposed, though not finalized, the 2018 MA/Part D rule would have extended UM permissions to antiretrovirals. This analysis indicates that expansion of UM to protected classes would likely lead to reductions in utilization for products on which it is applied. The magnitude of the effect, a decline in utilization of 75% in 2018 across 4 of the 5 protected classes, is an important consideration for future expansions of UM in Medicare Part D.

Appendix

Table 4. Percentage of Utilization with UM Compared to No UM in Medicare Part D (Unweighted), 2014-2018

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-57%	-50%	-52%	-46%	-51%
Antidepressants	-39%	64%	3%	-72%	-78%
Antineoplastic	11%	-36%	-42%	-48%	-48%
Antipsychotics	26%	65%	-25%	-34%	-2%
Immunosuppressants	-66%	-69%	-84%	-87%	-89%
Multiple Sclerosis	-5%	8%	-7%	7%	11%
Rheumatoid Arthritis	-8%	-1%	-5%	6%	-10%

Table 5. Percentage of Utilization with UM Compared to No UM for LIS Beneficiaries in Medicare Part D (Weighted), 2014-2018

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-52%	-61%	-68%	-68%	-75%
Antidepressants	-74%	-73%	-78%	-79%	-78%
Antineoplastic	-75%	-76%	-83%	-84%	-84%
Antipsychotics	-76%	-76%	-77%	-72%	-60%
Immunosuppressants	-68%	-72%	-37%	3%	-23%
Multiple Sclerosis	-33%	-19%	14%	14%	21%
Rheumatoid Arthritis	-21%	-32%	-9%	14%	14%

Table 6. Percentage of Utilization with UM Compared to No UM for Medicare Part D Beneficiaries Who Reach Catastrophic Threshold (Weighted), 2014-2018

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-50%	-49%	-52%	-54%	-69%
Antidepressants	-78%	-69%	-74%	-74%	-77%
Antineoplastic	3%	10%	-7%	-12%	-11%
Antipsychotics	-54%	-46%	-56%	-50%	-38%
Immunosuppressants	-52%	-69%	81%	435%	200%
Multiple Sclerosis	-14%	-7%	-1%	17%	24%
Rheumatoid Arthritis	34%	1%	27%	60%	45%

Table 7. Percentage of Utilization with UM Compared to No UM Including Only Products Where at Least 10% of Formularies Apply UM and No UM (Weighted), 2014-2018

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-62%	-61%	-66%	-69%	-70%
Antidepressants	4%	69%	2%	0%	-20%
Antineoplastic	-73%	-70%	-74%	-79%	-80%
Antipsychotics	-68%	-66%	-80%	-62%	-70%
Immunosuppressants	-26%	-82%	-93%	44%	-70%
Multiple Sclerosis	-15%	-13%	-4%	26%	30%
Rheumatoid Arthritis	678%	-	-22%	234%	-60%

Table 8. Percentage of Utilization with UM Compared to No UM Including Only Products Where at Least 20% of Formularies Apply UM and No UM (Weighted), 2014-2018

Therapeutic Class	2014	2015	2016	2017	2018
Anticonvulsants	-69%	-65%	-65%	-70%	-37%
Antidepressants	-21%	79%	0%	-1%	-21%
Antineoplastic	-69%	-65%	-76%	-79%	-78%
Antipsychotics	-69%	-57%	-62%	-49%	-48%
Immunosuppressants	-14%	-88%	-93%	161%	-49%
Multiple Sclerosis	-15%	-16%	-3%	33%	38%

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