Utilization Management in Multiple Myeloma

Executive Summary

As drug costs in the United States rise, health insurance plans are implementing strategies to balance expenditures and utilization. Plans can employ utilization management (UM) tactics to mitigate prescription drug spending. Though UM is used to lower plan spending and premiums for beneficiaries, it can also jeopardize patient access to necessary prescriptions, especially higher cost specialty products, such as oncology drugs.

To better understand the application of UM for oncology drugs, the American Cancer Society Cancer Action Network (ACS CAN) engaged Avalere Health to conduct an analysis on the coverage and UM practices of a subset of oral brand drugs that treat multiple myeloma, including Ninlaro, Pomalyst, Revlimid, Thalomid, and Xpovio. The analysis focused on the pharmacy benefit within the Medicare Part D insurance market, including Medicare Advantage-Prescription Drug plans (MA-PDs) and standalone Prescription Drug Plans (PDPs), and the commercial insurance market, in 2025 and 2026. Results indicate similar coverage for multiple myeloma drugs across all plan types in both years (80-84% of the time). The share of drugs not covered by MA-PDs and PDPs is driven by Revlimid, which has a generic available that was not included in the analysis. Drug tiering varies within commercial plans, with roughly equal placement in the preferred and specialty tiers, while MA-PDs and PDPs most frequently place multiple myeloma drugs on the specialty tier.

All plan types were found to have similar UM requirements across both years, with commercial plans requiring prior authorization (PA) less frequently (73% of the time) than MA-PDs (94% of the time) and PDPs (100% of the time). Though plans did not explicitly indicate step therapy (ST) within formularies, Avalere Health evaluated whether ST requirements were embedded within PA requirements across all plan types. Among plans imposing UM restrictions, commercial plans had embedded ST 44% of the time in 2025 and 45% of the time in 2026. MA-PDs had embedded ST 54% of the time, which decreased in 2026 to 46% of the time, while PDPs had embedded ST 64% of the time, which increased to 67% of the time in 2026.

Introduction

As drug costs in the United States rise, health insurance plans are implementing strategies to balance expenditures and utilization. Plans can employ utilization management (UM) tactics to mitigate prescription drug spending. Though UM is used to lower plan spending and premiums for beneficiaries, it can also jeopardize patient access to necessary prescriptions, especially higher cost specialty products, such as oncology drugs.

In both Medicare Part D (including Medicare Advantage Part D Plans (MA-PDs) and standalone Prescription Drug Plans (PDPs)) and commercial markets, the intended use of prior authorization (PA) and step therapy (ST) protocols is to provide appropriate drugs to their beneficiaries based on clinical evidence. However, these policies may adversely impact beneficiary health when they limit or delay patient access to necessary and appropriate drugs and higher healthcare system burden.[1]

[1] American Medical Association. "2025 AMA prior authorization physician survey." May 2026. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

The implementation of the Inflation Reduction Act (IRA) includes changes to the Part D benefit design that require drug manufacturers and plans to pay an increased share of drug costs for Part D enrollees. Plans are taking on significantly more liability because of the IRA, particularly for beneficiaries receiving low-income subsidies and patients in the catastrophic phase of the benefit, which cancer patients are disproportionately more likely to reach compared to the average Part D beneficiary.[2] These changes in the benefit design give plans a greater incentive to control access to Part D-covered drugs through the use of UM.[3] Anticipated increase in UM and other formulary restrictions highlights the importance of the Centers for Medicare and Medicaid Services (CMS) and commercial regulators using detailed review processes to ensure UM is appropriate.

Background on UM

UM involves different methods that health plans and pharmacy benefit managers (PBMs) can use to facilitate beneficiary use of specific drugs or services. Use cases include shifting utilization among therapeutically equivalent treatment options or limiting utilization of high-priced, specialty medications. In theory, UM works by evaluating that a prescription is medically necessary and providing the lowest-cost, most effective option. In practice, growing evidence suggests that UM strategies thwart timely, efficient, and high-quality care and can lead to treatment delays, administrative burden, and adverse outcomes.[4,5,6] For purposes of this study, UM policies are categorized into two categories: ST and PA, although other UM types exist, such as quantity limits.

Prior Authorization

PA requires that a patient receive pre-approval from their health insurance company before a medical service or treatment can be covered or reimbursed. In a 2022 survey of American Society of Clinical Oncology members, nearly all respondents reported at least one of their patients has experienced harm because of PA processes. Respondents reported delays in treatment (96%), increased patient OOP costs (88%), denied therapy (87%), disease progression (80%), and even death (36%). Notably, 64% of respondents reported that a patient abandoned care.[7]

Step Therapy

ST requires patients to try and fail (or "step through") an insurer's preferred medication before the patient can access the medication originally prescribed by their health care provider. Step therapy can delay access to proper treatments, which can result in potentially irreversible disease progression or other adverse outcomes.[8]

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[2] Commonwealth Fund. "Catastrophic Coverage in the Medicare Part D Drug Benefit: Which Beneficiaries Need It and How Much Are They Spending?" September 2020. https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/catastrophic-coverage-medicare-part-d-drug-benefit.
[3] Hayden. "Inflation Reduction Act: Revisiting Price Negotiation & its Anticipated Impact on the Biopharma Landscape." January 2024. https://haydencg.com/wp-content/uploads/2024/01/IRA-Revisiting-Price-Negotiation-Paper.pdf.
[4] American Cancer Society Cancer Action Network. "New Survey: Utilization Management Delays Cancer Care; Leads to More Stress and Contributes to Worse Outcomes." March 2019. https://www.fightcancer.org/releases/new-survey-utilization-management-delays-cancer-care-leads-more-stress-and-contributes.
[5] Park, Yujin, Syed Raza, Aneesh George, Rumjhum Agrawal, and John Ko. "The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review." *Journal of Managed Care & Specialty Pharmacy* 23, no. 8 (2017): 893–901. https://doi.org/10.18553/jmcp.2017.23.8.893.
[6] Tharp, Louis, and Zoe Rothblatt. "Do Patients Benefit from Legislation Regulating Step Therapy?" *Health Economics, Policy and Law* 17, no. 3 (2022): 282-97. doi:10.1017/S1744133121000153.
[7] Association for Clinical Oncology. "ASCO Prior Authorization Survey Summary." November 2022. https://cdn.bfldr.com/KOIHB2Q3/as/wt2thjbxbj24ncwnwjwzvk9c/2022-ASCO-Prior-Auth-Survey-Summary.
[8] Ibid.

Embedded Step Therapy

Embedded ST requires patients to step through at least one drug within the PA requirements, even though the formulary lists the drug as requiring PA but not ST.[9] Embedded ST can further delay beneficiary access to treatment because it is not labeled explicitly on formularies and can only be found by referencing more detailed plan coverage policies.

Impact of UM on Beneficiary Access

The purpose of UM is to allow plans to manage costs for beneficiaries; however, research suggests that the policies may create barriers to access.[10,11] Plan enrollees that receive unfavorable determinations may appeal the decision through a process that involves the provider and potential additional levels of appeal. Determinations may be appealed if they are barriers to timely care or if the UM criteria itself is not clear. The long processing times and complex requirements of the appeal process can delay treatment plans, leading to treatment abandonment or adverse patient outcomes. Beneficiaries and physicians may elect to not appeal unfavorable determinations due to burdensome requirements and lack of success and previous appeals, which may lead to increased OOP costs to obtain necessary products[12,13,14]

Medicare Protected Classes

Beneficiaries with cancer or other similarly complex and progressive conditions need to be able to access all therapy options to address and prevent avoidable disease progression. To facilitate access to necessary treatment, CMS requires Part D plans to include "all or substantially all" drugs in each of the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants) on their formularies.[15] Though UM is still allowed for most protected drugs, this policy ensures that beneficiaries with specific conditions can receive essential treatment without worrying about coverage.[16]

There is no protected class equivalent in the commercial market. Under the Affordable Care Act's Essential Health Benefits requirement, individual and small-group health plans must cover at least one drug per class to ensure access to necessary care.[17] Covered drugs may still require PA or ST.

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[9] Avalere Health. "Part D Prior Authorization Policies May Include Step Therapy." April 15, 2025. https://advisory.avalerehealth.com/insights/part-d-prior-authorization-policies-may-include-step-therapy.
[10] US Government Accountability Office. Gordon, Leslie V. "Medicare Advantage: CMS Oversight of Prior Authorization Criteria Should Target Behavioral Health Services" May 29, 2025. https://www.gao.gov/products/gao-25-107342.
[11] American Medical Association. "2025 AMA prior authorization physician survey." May 13, 2026. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[12] Ibid.
[13] Centers for Medicare & Medicaid Services. "Analysis of Calendar Year 2017 Medicare Part D Reporting Requirements Data." https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.
[14] American Cancer Society Cancer Action Network. "The Medicare Appeals Process: Reforms Needed to Ensure Beneficiary Access." November 17, 2020. https://www.fightcancer.org/policy-resources/medicare-appeals-process-reforms-needed-ensure-beneficiary-access.
[15] Centers for Medicare and Medicaid Services. "Medicare Prescription Drug Benefit Manual Chapter 6-Part D Drugs and Formulary Requirements." https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.
[16] UM is permitted for beneficiaries initiating therapy in all protected classes except for antiretrovirals.
[17] Centers for Medicare and Medicaid Services. "Information on Essential Health Benefits (EHB) Benchmark Plans." March 2026. https://www.cms.gov/marketplace/resources/data/essential-health-benefits.

Project Overview

ACS CAN engaged Avalere Health to evaluate PlanScape® formulary data in commercial plans and Medicare Part D, including both standalone PDPs and MA-PDs for select oral multiple myeloma drugs to assess plan coverage and UM. PlanScape® is a database of comprehensive formulary data of major payer markets including commercial, Medicare Part D, Medicaid, and public insurance exchange plans. PlanScape® includes cross-benefit coverage and restrictions data for a holistic perspective across pharmacy and medical benefits. Avalere partners with Clarivate to obtain formulary and restrictions data for coverage analyses (i.e., coverage, tiering, and UM). Clarivate gathers data directly from health plans and PBMs, ensuring the accuracy and validity of the formulary data.

Methodology

Avalere Health evaluated 2025 and 2026 pharmacy UM policies for multiple myeloma products, which included the following oral brand drugs: Ninlaro (ixazomib), Pomalyst (pomalidomide), Revlimid (lenalidomide), Thalomid (thalidomide), and Xpovio (selinexor). Drug coverage analyses were based on top PDP, MA-PD, and commercial plans based on enrollment. UM information was analyzed at static points in December 2025 and February/March 2026, to understand how plans shifted UM requirements across plan years; UM changes beyond 2025 and 2026 plan formularies were outside the scope of the analysis

In the UM analysis, Avalere Health first identified the plans requiring PA. For these plans, Avalere then parsed the PA criteria text to identify whether ST was also required, either explicitly listed or embedded in PA criteria; whether the step edit was aligned with the FDA label or more stringent than the FDA label; and the number of steps required.

Throughout, results are reported as the "percent of the time." This measure accounts for differences in plan enrollment and represents the share of enrollees who would be subject to a given formulary feature (e.g., coverage, tier placement, UM requirements) when seeking access to therapies.

Results

Commercial, MA-PD, and PDP Multiple Myeloma Drug Coverage

In 2025, commercial plans covered the analyzed multiple myeloma drugs 84% of the time, MA-PDs 81% of the time, and PDPs 80% of the time (Tables 1, 2, and 3). Both MA-PDs and PDPs cover Ninlaro, Thalomid, Pomalyst, and Xpovio 100% of the time. MA-PD and PDP non-coverage is driven by Revlimid, which has a generic available that was not included in the analysis.

Commercial coverage of multiple myeloma drugs decreases to 81% in 2026 (Figure 1). Both MA-PDs and PDPs cover multiple myeloma drugs 80% of the time, similar to 2025 coverage levels. Both MA-PDs and PDPs cover Ninlaro, Pomalyst, Thalomid, and Xpovio 100% of the time.

In both 2025 and 2026, payers least frequently cover brand Revlimid, for which a generic is available, but frequently cover all other oral therapies for multiple myeloma. Since antineoplastics are a protected class under the pharmacy benefit, it is assumed that either Revlimid or its generic is covered 100% of the time in Medicare Part D. Non-coverage for commercial plans is also partially

driven by Xpovio in both years, which could be explained by its FDA approval as both a second- and fifth-line therapy.

In both 2025 and 2026, tiering varies for multiple myeloma drugs for commercial plans, with roughly equal placement in preferred and specialty tiers overall. Both MA-PDs and PDPs place multiple myeloma drugs on the specialty tier most frequently. Notably, PDPs place non-Revlimid drugs on the specialty tier 100% of the time in both years, whereas MA-PDs place non-Revlimid drugs on the specialty tier 86% of the time in 2025, increasing to 88% of the time in 2026. A majority of the plan lives (86% in 2025 and 70% in 2026) that can access non-Revlimid drugs on the preferred tier fall under one large MA special needs plan (SNP). Differences in drug tiering may result in differences in cost-sharing obligation for beneficiaries. Under the pharmacy benefit, plans classify drugs as not covered, preferred, non-preferred, or specialty, with specialty drug classification resulting in the highest OOP costs.

Figure 1: Multiple Myeloma Pharmacy Benefit Coverage by Drug Across All Commercial Plans, 2025-2026

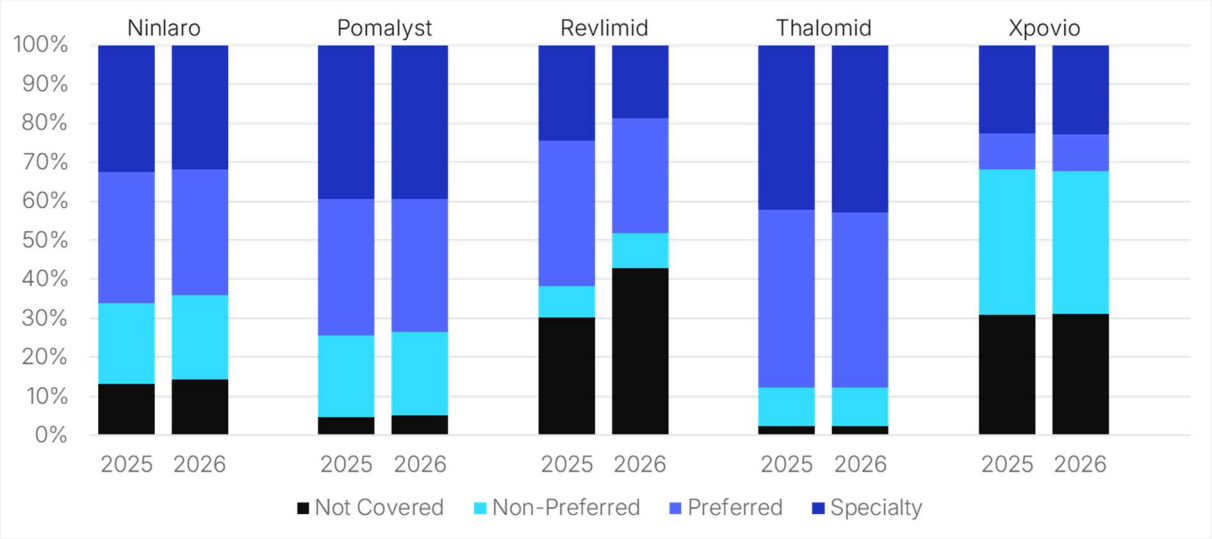


Table 1: Multiple Myeloma Pharmacy Benefit Coverage by Drug, Commercial Plans, 2025-2026

Drug Name	2025				2026			
	Not Covered	Non-Preferred	Preferred	Specialty	Not Covered	Non-Preferred	Preferred	Specialty
All MM Drugs	**16%**	**19%**	**32%**	**32%**	**19%**	**20%**	**30%**	**31%**
Ninlaro	13%	21%	34%	32%	14%	22%	32%	32%
Pomalyst	5%	21%	35%	39%	5%	22%	34%	39%
Revlimid	30%	8%	37%	24%	43%	9%	29%	19%
Thalomid	2%	10%	46%	42%	2%	10%	45%	43%
Xpovio	31%	37%	9%	23%	31%	37%	9%	23%

N=142M plan lives (2025), N=147M plan lives (2026); MM: Multiple Myeloma

Table 2: Multiple Myeloma Pharmacy Benefit Coverage by Drug, MA-PDs, 2025-2026

Drug Name	2025				2026			
	Not Covered	Non-Preferred	Preferred	Specialty	Not Covered	Non-Preferred	Preferred	Specialty
All MM Drugs	**19%**	**0%**	**11%**	**70%**	**20%**	**0%**	**9%**	**71%**
Ninlaro	0%	0%	14%	86%	0%	0%	12%	88%
Pomalyst	0%	0%	14%	86%	0%	0%	12%	88%
Revlimid	97%	0%	0%	3%	97%	0%	0%	3%
Thalomid	0%	0%	14%	86%	0%	0%	12%	88%
Xpovio	0%	0%	14%	86%	0%	0%	12%	88%

N=19M plan lives (2025), N=25M plan lives (2026); MM: Multiple Myeloma

Table 3: Multiple Myeloma Pharmacy Benefit Coverage by Drug, PDPs, 2025-2026

Drug Name	2025				2026			
	Not Covered	Non-Preferred	Preferred	Specialty	Not Covered	Non-Preferred	Preferred	Specialty
All MM Drugs	**20%**	**0%**	**0%**	**80%**	**20%**	**0%**	**0%**	**80%**
Ninlaro	0%	0%	0%	100%	0%	0%	0%	100%
Pomalyst	0%	0%	0%	100%	0%	0%	0%	100%
Revlimid	98%	0%	0%	2%	100%	0%	0%	0%
Thalomid	0%	0%	0%	100%	0%	0%	0%	100%
Xpovio	0%	0%	0%	100%	0%	0%	0%	100%

N=17M plan lives (2025), N=18M plan lives (2026); MM: Multiple Myeloma

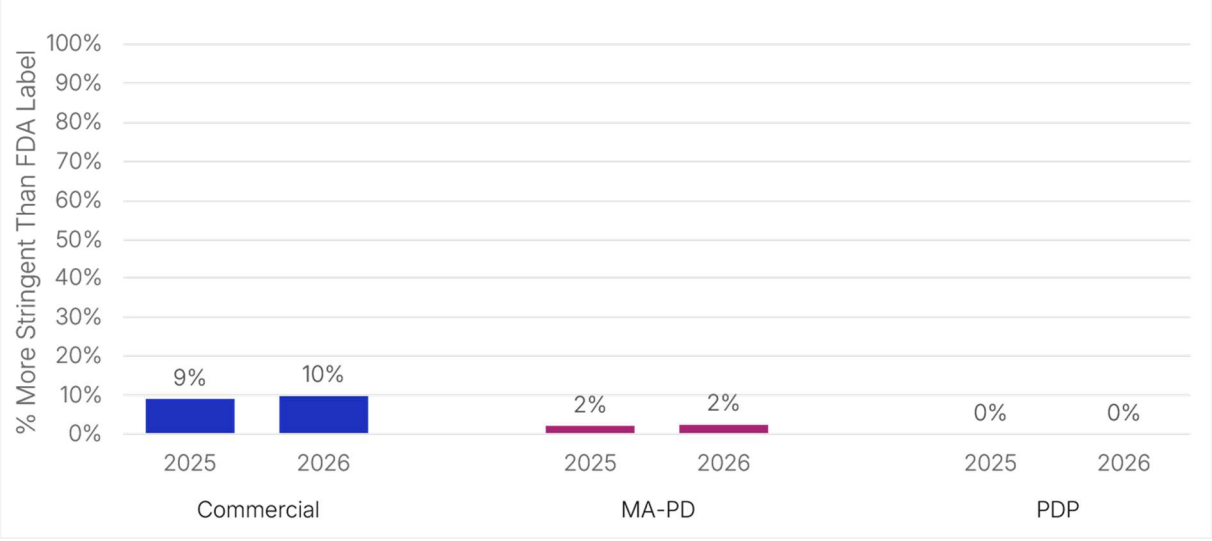
Commercial, MA-PD, and PDP Multiple Myeloma Pharmacy Benefit Utilization Management

All plan types have similar UM requirements as outlined by the formulary. Commercial plans require PA 73% of the time and ST less than 1% of the time. MA-PDs require PA 94% of the time and ST 0% of the time. PDPs require PA 100% of the time and ST 0% of the time. There is little variation in UM requirements across the multiple myeloma drugs in each plan type. All plan types experienced minimal changes in UM requirements from 2025 to 2026.

Though plans did not explicitly require ST in the formulary design, ST can be embedded into PA requirements. Among plans with UM in 2025, commercial plans had PA with embedded ST 44% of the time, MA-PDs had PA with embedded ST 54% of the time, and PDPs had PA with embedded ST 64% of the time. Commercial plans experienced minimal change from 2025 to 2026. MA-PDs with embedded ST decreased to 46% of the time, while PDPs with embedded ST increased to 67% of the time in 2026, driven largely by Pomalyst and Xpovio. The difference in embedded ST may be attributable to changes in plan contracting along with a greater relative increase of MA-PD plan lives.

ST is considered to be more stringent than the FDA label if the plan requires patients to try more products than indicated on the FDA label. For example, Ninlaro "is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy," so ST requiring beneficiaries to try two prior therapies would be more stringent than the FDA label.[18] Among plans covering drugs with ST or PA with embedded ST, step edits are more stringent than the FDA label 9% of the time for commercial plans, 2% of the time for MA-PDs, and 0% of the time for PDPs. There was minimal change from 2025 to 2026 for all plan types (Figure 2). Among commercial plans, Revlimid and Thalomid have embedded ST more stringent than the FDA label 100% of the time (Figure 3). On the other hand, MA-PDs do not have embedded ST for either drug (Figure 4). Across all plan types, step edits for Xpovio are always aligned with the FDA label. Since Xpovio has two FDA approvals, as both second- and fifth-line therapies, plans were considered to be aligned with the FDA label if one of the approval criteria (i.e., fifth-line) were met.

Figure 2: ST Requirements Compared to FDA Label for All Plans Covering Drugs with ST or PA, 2025-2026



[18] Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; 2024.

Figure 3: ST Requirements Compared to FDA Label for Commercial Plans Covering Drugs with ST or PA by Drug, 2025-2026

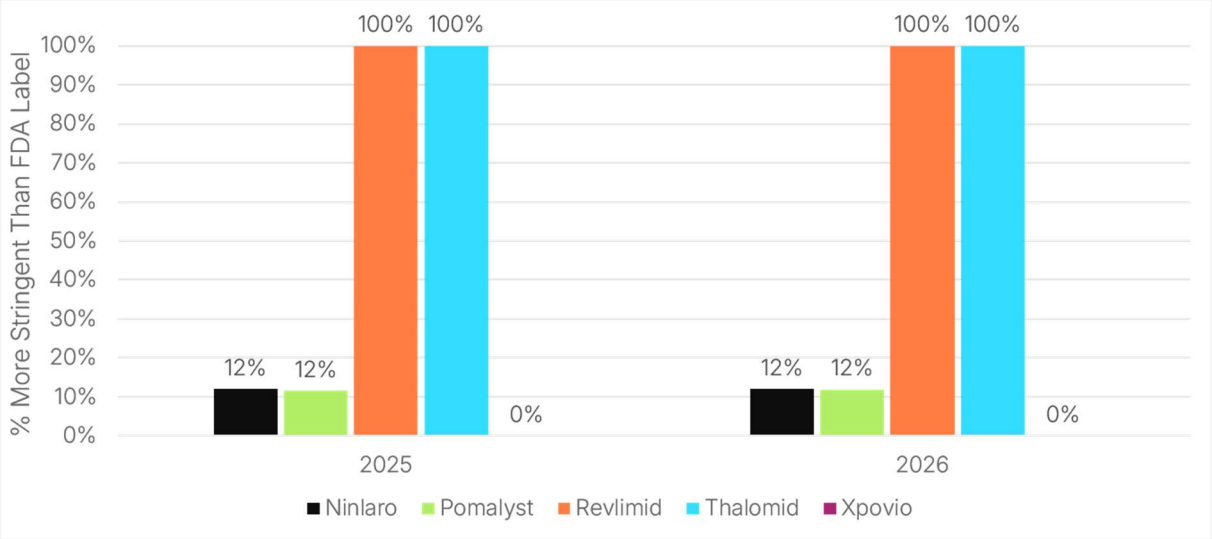
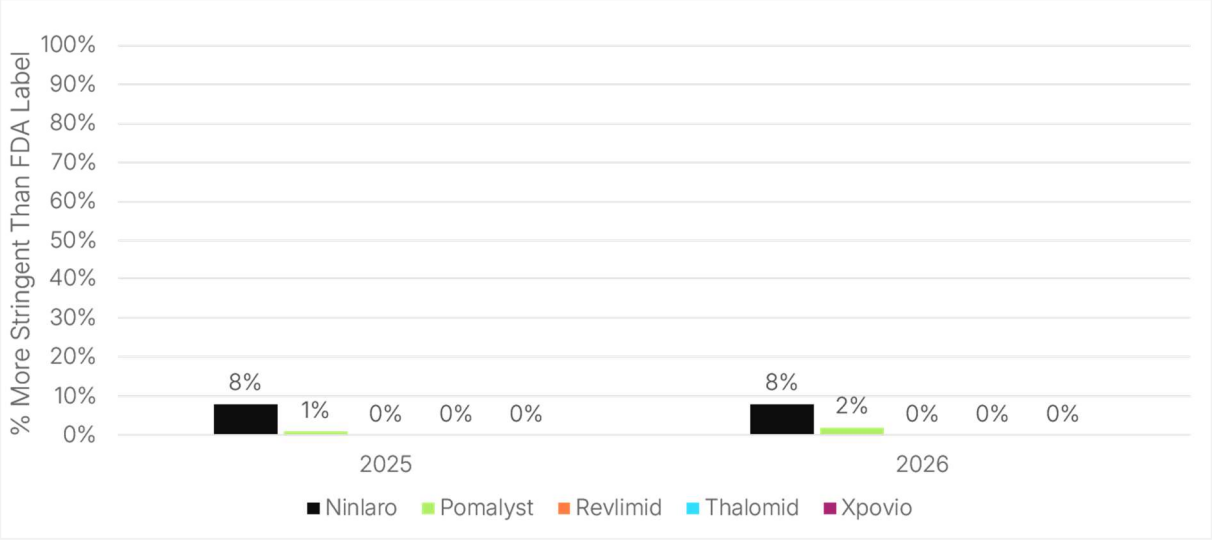


Figure 4: ST Requirements Compared to FDA Label for MA-PDs Covering Drugs with ST or PA by Drug, 2025-2026



When ST is present, the majority of plans across all payer types require beneficiaries to step through one or two drugs. A small number of commercial plans require three or more steps for Xpovio (Figure 5). ST was not found to be required for Revlimid and Thalomid among MA-PDs and PDPs in 2026. Minimal changes occur from 2025 to 2026 across all payer types.

Figure 5: ST Requirements Under the Commercial Pharmacy Benefit, 2025-2026

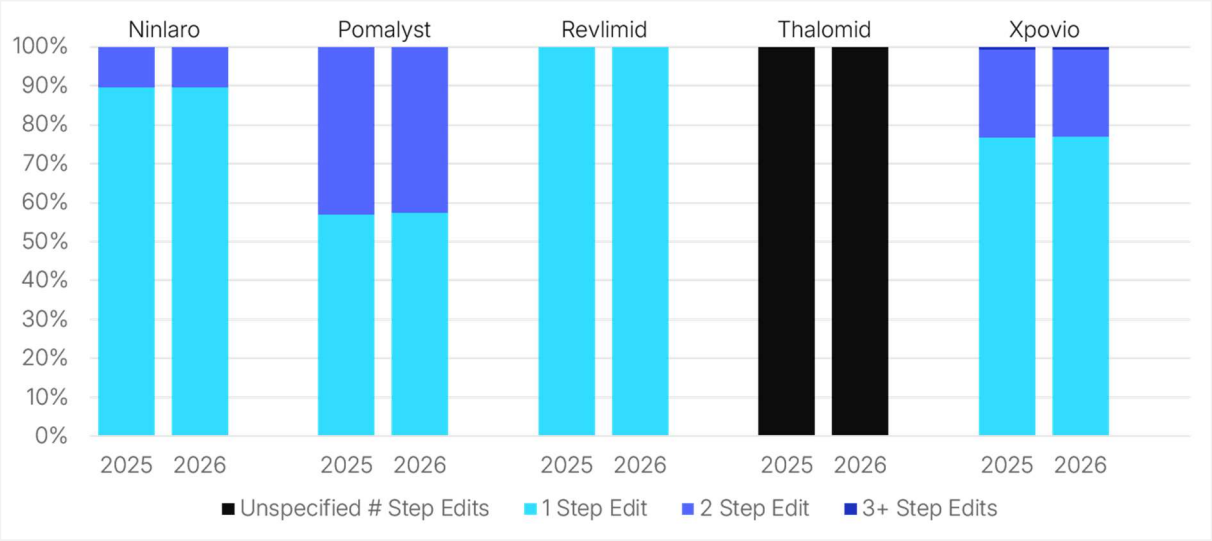


Figure 6: ST Requirements Under the MA-PD Pharmacy Benefit, 2025-2026

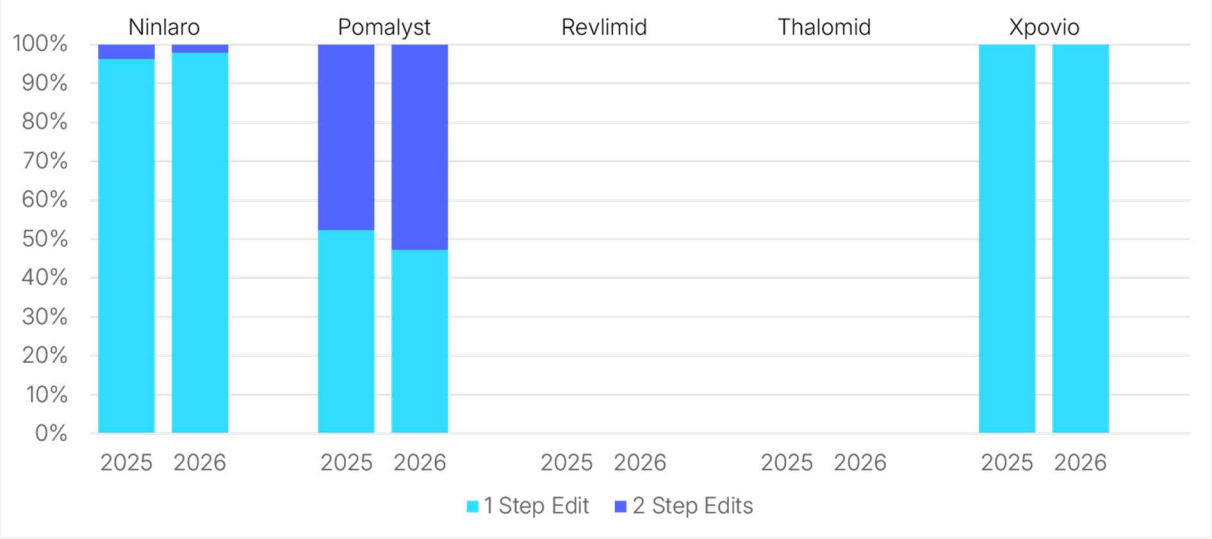
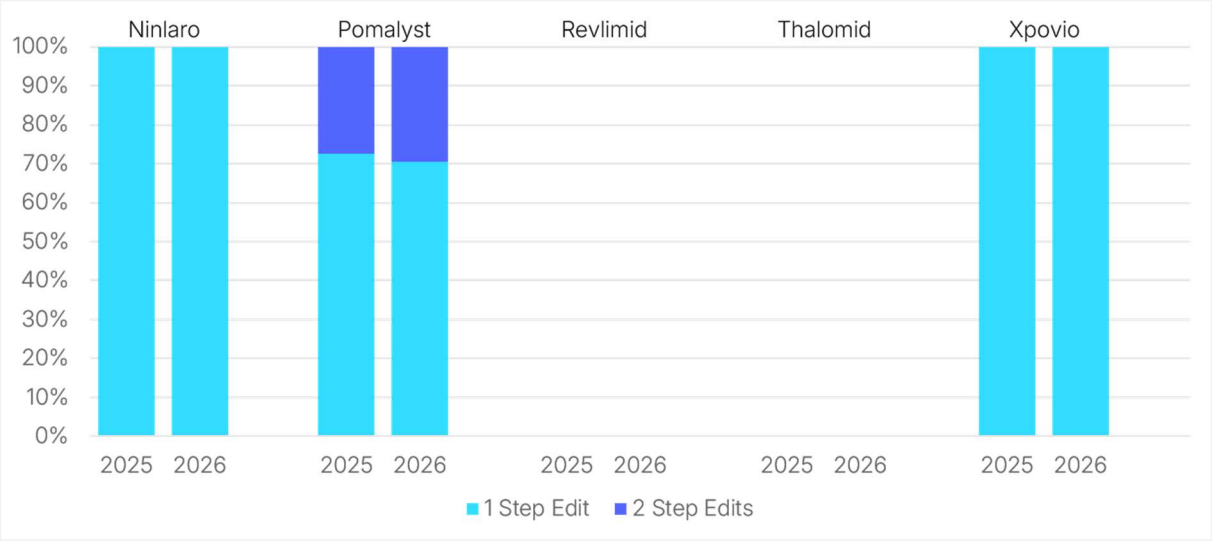


Figure 7: ST Requirements Under the PDP Pharmacy Benefit, 2025-2026



Conclusion

In general, commercial plans require UM less frequently compared to MA-PDs and PDPs. This may be attributed to differences in patient populations covered by each plan type, with Medicare plans covering older individuals. CMS should regularly monitor UM processes to ensure patients can access oncology care in a timely manner, which is especially important for an older population. While plans employ step therapy as a way to steer patients toward a lower cost drug, it is imperative that plans ensure that the use of step therapy (indeed, all utilization management tools) do not impede access to clinically appropriate care. In cancer care, guidelines developed by the National Comprehensive Cancer Network (NCCN) are recognized as the gold standard of oncology care and thus any utilization management tools should not counter guideline-indicated care. The NCCN recently clarified that "step therapy, within a line of therapy, is not clinically recommended within any NCCN Guideline."[19]

MA-PDs and PDPs are more likely to require PA with embedded ST than commercial plans, but 40-65% of all plan types are likely to have PA with embedded ST to access multiple myeloma drugs. In Medicare Part D, embedded steps may obscure CMS's formulary review process and pose additional barriers for patient access. CMS should monitor beneficiary access challenges stemming from UM through avenues such as rejected claims and appeals. CMS should be resourced and required to proactively conduct more in-depth formulary analysis, rather than relying on outlier analyses of UM practice information reported by plans. Commercial regulators should also conduct formulary analyses and monitor the appeals process to ensure that beneficiaries are receiving timely access to medication.

As a result of IRA implementation, beneficiary enrollment continues to shift toward MA-PDs. MA-PDs and PDPs had similar counts of enrollees in 2025, but MA-PD grows by 31% while PDP grows by 7% in 2026. The extent of UM among MA-PDs will consequently impact a higher share of

[19] National Comprehensive Cancer Network. (2026). https://www.nccn.org/.

beneficiaries. Though MA-PDs and PDPs require PA for multiple myeloma drugs a similar percent of the time, MA-PDs require more step edits for each drug. With increased enrollment in MA-PDs, more beneficiaries must step through multiple drugs, potentially leading to additional cost and impact on treatment access or outcomes. Additionally, the difference in multiple myeloma drug tiering between MA-PDs and PDPs raises concerns for the application of placement rules within the Part D benefit.

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