Utilization Management in Non-Small Cell Lung Cancer

Executive Summary

Growing drug costs in the United States are placing pressure on health plans to implement strategies to balance drug expenditures and utilization. Utilization management (UM) tactics are frequently used across public and private insurance plan types to control prescription drug spending. Though UM aims to lower costs for beneficiaries by evaluating different treatment options, it can also complicate the process for patients to obtain necessary medication, especially high-cost 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 provider-administered drugs that treat non-small cell lung cancer (NSCLC), including Imfinzi, Keytruda, Libtayo, Opdivo, and Tecentriq. The analysis focused on the medical benefit within the Medicare Advantage (MA) and commercial insurance markets in 2025 and 2026.

Both commercial and MA plans covered the analyzed NSCLC drugs 100% of the time across both years. MA plans placed NSCLC drugs in the non-preferred tier 30% of the time and in the preferred tier 7% of the time.

The analysis focused on step therapy (ST) requirements. All analyzed drugs are approved for first-line treatment, so 100% of ST policies were more stringent than the Food and Drug Administration (FDA) label. Commercial plans shifted from one to two step edits across all NSCLC drugs with ST, generally, though the total number of plan lives affected is small. MA plans only required one step edit across all drugs with ST for both years.

Introduction

Growing drug costs in the United States are placing pressure on health plans to implement strategies to balance drug expenditures and utilization. Utilization management (UM) can be used to ensure patients are receiving the appropriate medication and shift utilization between therapeutically equivalent drugs to facilitate utilization and cost.

In the commercial market, the Affordable Care Act requires individual and small-group health plans to cover at least one drug per class to ensure access to necessary care.[1] Covered drugs may still require prior authorization (PA) or step therapy (ST). For beneficiaries enrolled in traditional Medicare, drugs administered by a provider (i.e., in an office or hospital outpatient setting) are covered under the medical benefit through Medicare Part B. Medicare beneficiaries have the option of receiving benefits from private plans through Medicare Advantage (MA) rather than from the traditional Medicare program (i.e., Medicare Part A and Part B). MA plans can apply ST to provider-administered drugs for patients initiating treatment, which may require patients to step through another provider-administered drug. While beneficiaries are rarely required to obtain PA under traditional Medicare Part B almost all MA plans (99%) required PA for some services in 2024,

[1] 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.

including the use of provider-administered drugs under the medical benefit.[2] As a result, product access considerations in MA are now more like those in the commercial market.

In the broader drug policy landscape, the renewed Most Favored Nation (MFN) policy aims to align US drug prices with those of comparable nations. In 2025, the Centers for Medicare and Medicaid Services (CMS) Innovation Center proposed the Global Benchmark for Efficient Drug Pricing (GLOBE) Model to implement MFN pricing for provider-administered drugs covered by Medicare Part B and potentially generate savings for patients.[3] Preliminary analyses indicate that model impacts on patient out-of-pocket (OOP) costs could be variable,[4] and the rollout of policies over time could lead to changes in UM as plans adjust to shifts in cost burdens. In addition, there is widespread industry concern for the implications of GLOBE on novel drug research, which could disproportionately affect treatment options for serious diseases like cancer.

Additionally, with the increased use of artificial intelligence (AI) to expedite administrative processes, stakeholders have weighed in on the growing presence of AI in making coverage determinations. For example, CMS has noted that MA organizations may only use an algorithm or software tool in ways that are consistent with publicly available coverage criteria, and that the criteria should not be shifted over time.[5] In cooperation, MA plans themselves established Utilization Management Committees to annually review UM policies and ensure consistency with traditional Medicare's national and local coverage decisions and guidelines.[6] As the landscape of UM evolves with technological innovations, the need to ground becomes increasingly emphasized.[7]

Background on UM

UM refers to a variety of practices that health plans use to manage the utilization of specific drugs or services. Plans can use UM to shift utilization between treatment options or to limit utilization of high-priced, specialty medications by ensuring that a prescribed drug or service is medically necessary. In practice, growing evidence suggests that UM strategies impede the delivery of timely, efficient, and high-quality care and can lead to delays in care, administrative burden, and worse

[2] Kaiser Family Foundation. "Medicare Advantage in 2024: Premiums, OOP Limits, Cost Sharing, Supplemental Benefits, Prior Authorization and Star Ratings." 2024. https://www.kff.org/medicare/medicare-advantage-in-2024-premiums-out-of-pocket-limits-supplemental-benefits-and-prior-authorization/.
[3] Centers for Medicare and Medicaid Services. "GLOBE (Global Benchmark for Efficient Drug Pricing) Model." December 2025. https://www.cms.gov/priorities/innovation/innovation-models/globe.
[4] Avalere Health. "How MFN Pricing in Part B May Affect Beneficiary OOP Costs." January 2026. https://advisory.avalerehealth.com/insights/how-mfn-pricing-in-part-b-may-affect-beneficiary-oop-costs.
[5] Centers for Medicare and Medicaid Services. "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)" February 6, 2024. https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf.
[6] Centers for Medicare and Medicaid Services. "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." 2023. https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
[7] American Medical Association. "AMA adds more to its game plan to fix prior authorization." June 2026. https://www.ama-assn.org/practice-management/prior-authorization/ama-adds-more-its-game-plan-fix-prior-authorization.

outcomes.[8,9,10] Under the medical benefit, UM policies focus on ST, although other UM types exist, such as PA and quantity limits.

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.[11] Stakeholders have requested that ST and drug switching policies be sufficiently grounded in clinical evidence and physician oversight for drug safety and efficacy.[12]

Impact of UM on Beneficiary Access

Although plans use UM to reduce costs and premiums for beneficiaries, reports suggest that UM policies create multiple potential access barriers for beneficiaries.[13,14] If an enrollee receives an unfavorable determination from the plan, they may work together with their provider to request reconsideration from the plan, usually due to the physician determining that the medication is essential in a treatment plan or because the UM criteria are unclear. Since the appeal process is complex and involves multiple layers of review, compounded delays in treatment can lead to treatment abandonment or adverse patient events. In some cases, physicians and beneficiaries may forgo the appeal process due to an urgency in treatment timeline or lack of success in previous appeal attempts, leading to patients paying OOP for necessary medication.[15,16,17]

To address some of these concerns, CMS proposed an expansion of interoperability and PA standards to drugs covered under the medical benefit by MA plans, including new reporting requirements, though data on adherence and enforcement are unavailable since the final rule has not yet been released.[18]

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[8] 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.

[9] 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.

[10] 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.

[11] Ibid.

[12] American College of Physicians. *Mitigating the Negative Impact of Step Therapy Policies and Nonmedical Switching of Prescription Drugs on Patient Safety.* 2020. https://www.acponline.org/sites/default/files/acp-policy-library/policies/step_therapy_nonmedical_switching_prescription_drugs_policy_2020.pdf

[13] US Government Accountability Office. *Medicare Advantage: CMS Oversight of Prior Authorization Criteria Should Target Behavioral Health Services*, by Leslie V. Gordon. Washington, DC, May 2025. https://www.gao.gov/assets/gao-25-107342.pdf.

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

[15] Ibid.

[16] 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.

[17] 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.

[18] Centers for Medicare & Medicaid Services, "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges," *Federal Register* 91 (April 14, 2026): 19890.

Project Overview

ACS CAN engaged Avalere Health to evaluate PlanScape® formulary data in MA plans, as well as commercial plans for select provider-administered NSCLC drugs to assess plan coverage and UM of the drugs. PlanScape® is a database of comprehensive formulary data of major payer markets including commercial, Medicare Part D, Medicaid, and public insurance exchange. 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 pharmacy benefit managers, ensuring the accuracy and validity of the formulary data.

Methodology

Avalere Health evaluated 2025 and 2026 medical UM policies for NSCLC, which included the following brand drugs: Imfinzi (durvalumab), Keytruda (pembrolizumab), Libtayo (cemiplimab-rwlc), Opdivo (nivolumab), and Tecentriq (atezolizumab). Coverage analyses were based on top MA and commercial plans by enrollment. Restrictions information was analyzed at static points in December 2025 and March 2026; formulary changes over time were outside the scope of the analysis.

Plans do not list the presence of UM for medical benefit like they do for pharmacy benefit formularies, so the analysis was unable to study plan-indicated PA and ST. However, Clarivate does review medical benefit policies to identify the use of ST and the step edits required. Avalere used Clarivate-indicated information to evaluate the number of steps required and whether the step edit was aligned with the FDA label or more stringent than the FDA label. The UM analysis only considers ST and not clinical PA (e.g., required diagnosis) as indicated by Clarivate.

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 feature (e.g., coverage, UM requirements) when seeking access to therapies. Large plans are defined as those with 100,000 enrollees or more.

Results

Commercial and MA Plan NSCLC Drug Coverage

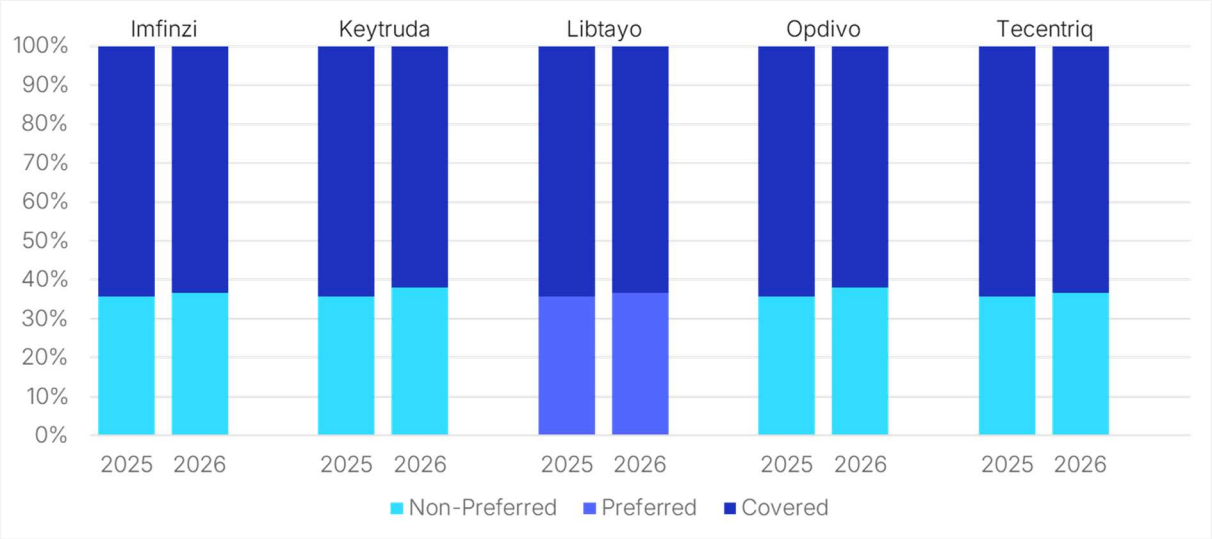
Differences in drug tiering may result in differences in cost-sharing obligation for beneficiaries. Under the medical benefit, plan coverage and tiering were classified as preferred, non-preferred, or covered, with non-preferred drugs generally requiring higher OOP costs (i.e., coinsurance). In both 2025 and 2026, commercial plans covered the analyzed NSCLC drugs 100% of the time. In 2025, plans placed NSCLC drugs in the preferred tier less than 1% of the time and in the covered tier almost 100% of the time. There was no variation between drugs.

MA plans covered the analyzed NSCLC drugs 100% of the time, with 29% placed in the non-preferred tier and 7% placed in the preferred tier (Figure 1). At the drug level, plans are placing Imfinzi, Keytruda, Opdivo, and Tecentriq on the non-preferred tier and Libtayo on the preferred tier. Little change occurred from 2025 to 2026. Libtayo has been placed on the preferred tier by two

large plan sponsors, potentially due to favorable cost-effectiveness compared to other NSCLC drugs when combined with chemotherapy.[19]

The difference between commercial and MA tiering may be attributed to the difference in populations covered by each plan type. Since the majority of NSCLC patients are diagnosed at or over age 65, MA plans are likely to cover more individuals with NSCLC than commercial plans do, which may explain the variation in contracting.

Figure 1: NSCLC Medical Benefit Coverage by Drug Across All MA Plans, 2025-2026



Note: The "Covered" category represents plan lives that do not indicate the coverage status (i.e., preferred, non-preferred) in the coverage data.

Commercial and MA NSCLC Medical Benefit Utilization Management

All analyzed NSCLC drugs are approved by the FDA as first line treatments, so all step edits are more stringent than the FDA label. At the drug level, Imfinzi and Opdivo had large increases in ST across both payer types, while Tecentriq had a large decrease in ST in commercial plans from 2025 to 2026 (Figure 2, 3). The change in commercial lives with ST for Tecentriq is driven by one large plan sponsor, which eliminated ST requirements for all its plans in 2026. The lives with ST for Tecentriq seen in 2026 can be attributed to a new commercial plan that was not present in the 2025 data. The increase from zero to 20 million commercial plan lives subject to ST for Imfinzi is driven by select plans from large sponsors.

[19] Xue, Xiangzhong, Surachat Ngorsuraches, Brandon Johnson, Jingyi Zheng, and Jingjing Qian. "Cost-effectiveness of cemiplimab plus chemotherapy vs pembrolizumab plus chemotherapy as first-line treatment for advanced non-small cell lung cancer." *Journal of Managed Care & Specialty Pharmacy* 31, no. 2 (February 2025). https://doi.org/10.18553/jmcp.2025.31.2.137

Figure 2: NSCLC Commercial Plan Lives with ST, 2025-2026

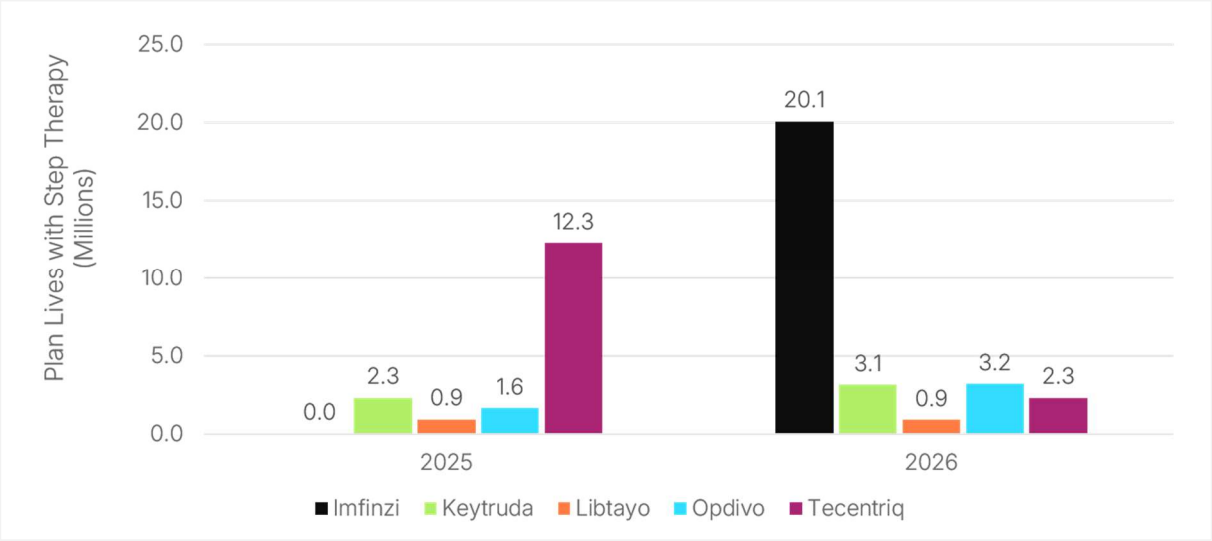
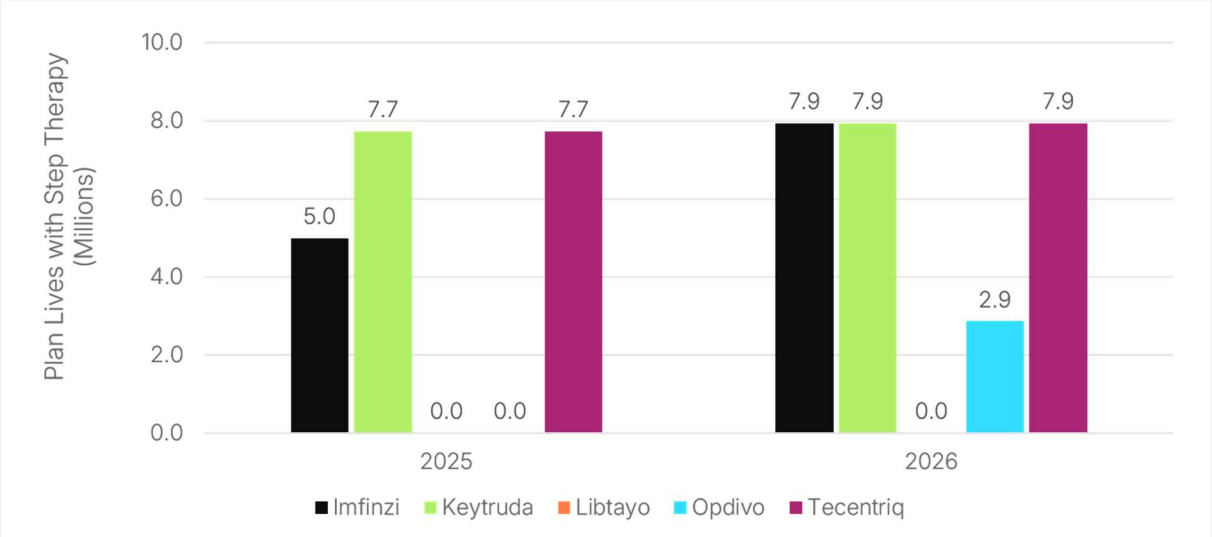


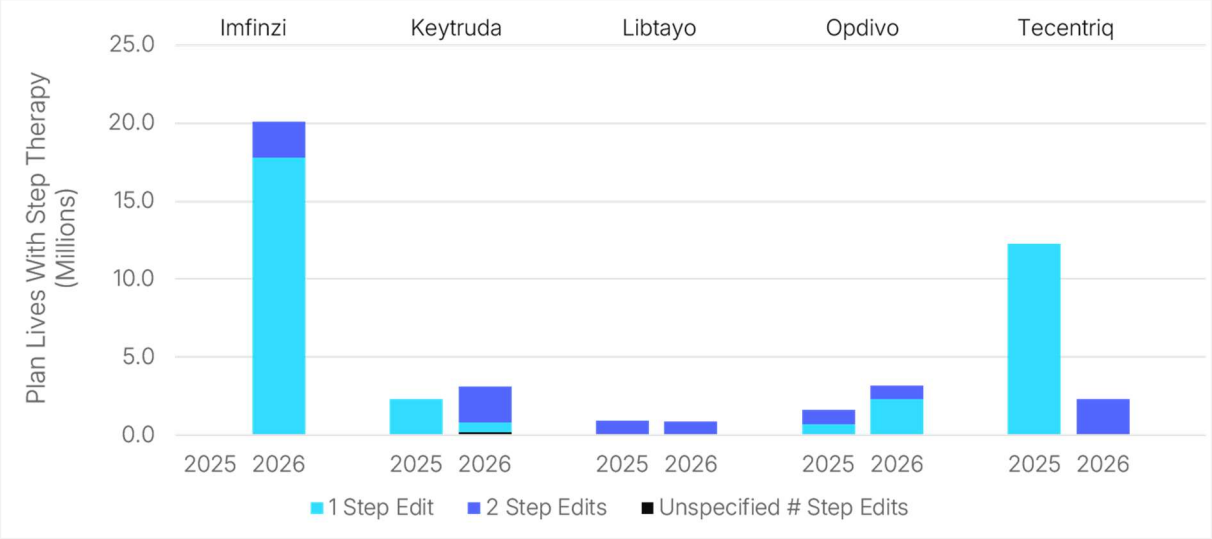
Figure 3: NSCLC MA Plan Lives with ST, 2025-2026



From 2025 to 2026, commercial plans using ST for NSCLC drugs shifted from requiring beneficiaries to step through one drug to two drugs across NSCLC drugs generally (Figure 4). The majority of commercial plans using ST require beneficiaries to step through two drugs to obtain Keytruda and Tecentriq in 2026 compared to just one drug in 2025. The majority of commercial plans using ST require beneficiaries to step through one drug to obtain Opdivo in 2026, whereas the majority required stepping through two drugs in 2025. The total number of plan lives affected is small, and the difference in step edits can likely be attributed to changes in plan contracting, as there are no known clinical reasons.

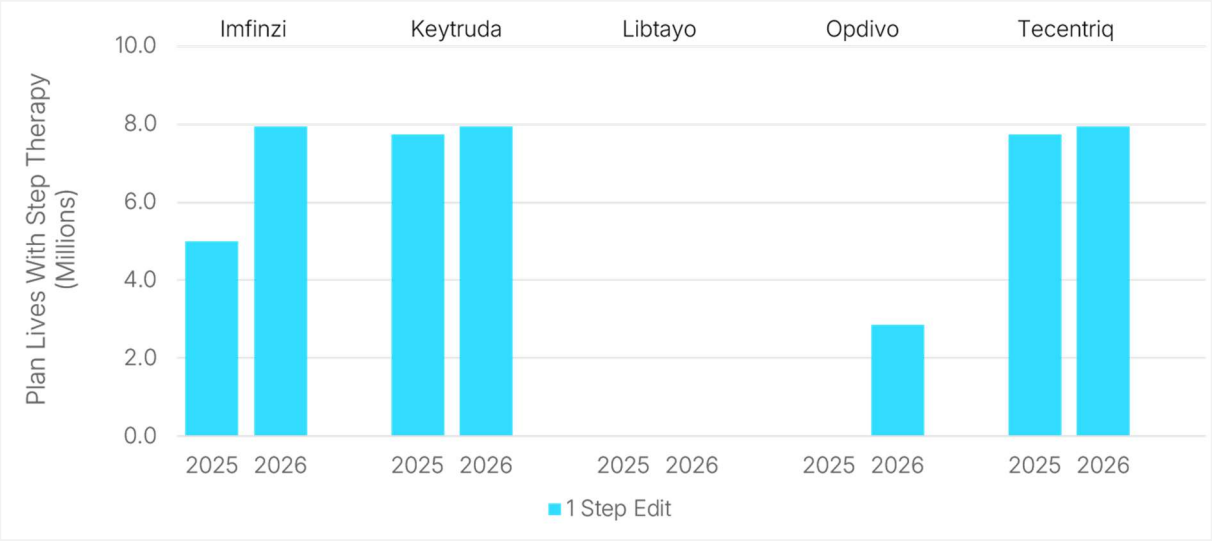
MA plans only require beneficiaries to step through one drug for NSCLC drugs when ST is present (Figure 5). Libtayo did not have ST because of its placement on the preferred tier among MA plans. The difference in number of step edits between commercial and MA plans may be driven by differences in patient populations between the two plan types.

Figure 4: NSCLC ST Requirements Under the Commercial Medical Benefit, 2025-2026



N=176M plan lives (2025), N=175M plan lives (2026)

Figure 5: NSCLC ST Requirements Under the MA Medical Benefit, 2025-2026



N=19M plan lives (2025), N=20M plan lives (2026)

Conclusion

The pronounced difference between commercial and MA plans for both NSCLC drug tiering and number of step edits shows that patients may have different ease of accessibility to drugs solely on the basis of plan type. Drugs with multiple FDA-approved indications may also be more susceptible to step edits as ST is applied according to the specific indication while plan contracting is more general. As CMS reviews drug coverage and formularies for MA plans, it should review step therapy requirements at the indication level as well as holistically; regulators for commercial plans should do the same. Plans aim to use step therapy to steer patients towards the lowest cost drug option, it is imperative that plans ensure that UM policies do not impede access to clinically appropriate care. Within oncology, National Comprehensive Cancer Network (NCCN) guidelines are regarded as the gold standard for care. As such, UM tools should operate within NCCN guidelines. The NCCN recently clarified that "step therapy, within a line of therapy, is not clinically recommended within any NCCN Guideline."[20]

Because all analyzed drugs are first-line drugs, 100% of plans that have ST requirements are more stringent than the FDA label for both years. Within commercial plans, the number of step edits increased for select drugs for a small number of plan lives from 2025 to 2026. The restrictiveness of UM policies, beyond what the FDA requires, for plans covering NSCLC drugs can further complicate and delay treatment for beneficiaries whose survival depends on timely surgery and care.[21]

In the coming years, the rollout of the MFN and its related models, such as the GLOBE Model set to launch late 2026, may increase patient OOP costs and shift UM requirements as plans adjust to new policies. Amidst the changing policy landscape, plans must balance increasing costs of care with maintaining appropriate and efficient access to medications. This balance is particularly important in oncology, where disease progression changes in a matter of weeks.

CMS should enforce regulations like the 2026 Interoperability Standards and Prior Authorization for Drugs to ensure transparency surrounding UM practices within MA. Stakeholders and policymakers should closely monitor UM practices and newly available metrics to ensure appropriate application of policies. Additionally, both CMS and commercial regulators should monitor beneficiary access challenges resulting from UM, including rejected claims and appeals. CMS and commercial regulators alike should prioritize conducting detailed formulary analyses on a regular basis, rather than relying on outlier analyses conducted by plans.

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[20] National Comprehensive Cancer Network. (2026). https://www.nccn.org/.
[21] Valderrama, Adrian, Kenneth Williams, Amanda Soe, and Jeffrey B. Velotta. "Timely Surgery for Early Stage Lung Cancer Matters." *Bulletin of the American College of Surgeons* 111, no. 4 (April 1, 2026). https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2026/april-2026-volume-111-issue-4/timely-surgery-for-early-stage-lung-cancer-matters/.