

06.04.2025

Step therapy in Medicare Advantage: Insights from provider experiences

Funding for this research was provided by ASP Coalition. Avalere Health retained full editorial control.

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Executive summary

Step therapy (ST) is a form of utilization management (UM) increasingly used by health plans, including Medicare Advantage (MA) plans, with the stated intent to guide prescribing decisions toward cost-effective, evidence-based therapies. Under this approach, patients may be required to try a lower cost or plan-preferred treatment before accessing the originally prescribed option. While ST can serve as a valuable tool for managing costs and ensuring appropriate use of medical therapies, it also introduces new and potentially complex dynamics into the provider-patient relationship and care delivery process.

As MA continues to grow, now covering over 50% of the Medicare population, these plan-level decisions affect a growing share of Medicare beneficiaries. Since the Centers for Medicare and Medicaid Services (CMS) codified the use of ST for Medicare Part B drugs in 2019, questions have emerged about how these policies function in real-world practice. Avalere Health surveyed 300 healthcare providers to better understand their experiences with ST protocols, particularly as they apply to physician-administered therapies.

Survey results found that ST is widely used by MA plans and many providers report increased administrative demands and challenges in aligning treatment decisions with clinical judgment. Respondents identified delays in patient access and adjustments to practice operations as recurring issues. These findings indicate opportunity for further refinement of ST policy implementation to ensure a better balance of cost containment, clinical efficacy, and patient-centered care.

Introduction to step therapy in Medicare Advantage

Step therapy has long been used in commercial health plans as a mechanism intended to promote the use of safe, clinically effective, and lower cost treatment options. Health plans assert that requiring progression through therapeutically similar or guideline-endorsed alternatives before authorizing more expensive treatments promotes evidence-based care and reduces unnecessary spending. In the MA context, this tool has been selectively extended to physician-administered drugs covered under Medicare Part B. However, as with any UM tool, the effects of ST can vary depending on how protocols are designed, how exceptions are handled, and how clearly criteria are communicated. In specialties managing complex or high-cost conditions, such as oncology, rheumatology, or ophthalmology, providers often treat patients with time-sensitive therapeutic windows or highly individualized needs. In such cases, ST requirements may not align with physician's clinical decision making, elevating the importance of transparency and responsiveness in the appeals process.

MA has experienced steady enrollment growth over the past decade, driven by expanded benefit offerings, integrated care models, and premium stability. As of 2025, more than 30 million beneficiaries are enrolled in MA plans. These plans are administered by private insurers under contract with CMS and are allowed greater flexibility in designing benefits and implementing care management tools than would be permitted under Medicare fee for service.

In 2018, CMS reversed guidance from a 2012 memo that had prohibited ST in MA, issuing a new policy that allowed MA plans to apply ST protocols for beneficiaries beginning new courses of treatment with Part B drugs starting January 1, 2019. ¹ This policy was further clarified and expanded through a final rule published in May 2019, which took effect January 1, 2020. ² The rule permitted integration of ST policies across both Part B and Part D—for example, requiring a patient to try an oral medication under Part D before approving a physician-administered alternative under Part B, or vice versa.

Supporters of this policy argue that it promotes fiscal sustainability in Medicare and helps ensure clinical appropriateness. In the regulatory impact analysis accompanying the 2019 Part D and MA final rule, CMS estimated significant cost savings from broader use of ST in MA,³ but the agency has not evaluated whether these savings have materialized. Critics, meanwhile, caution that ST may delay access to needed care, particularly when protocols do not reflect specialty-specific guidelines or when appeals processes create lengthy administrative barriers.⁴ Thousands of appeals involving ST are filed annually with the Part C Independent Review Entity, and most are decided unfavorably for beneficiaries.^{5,6} These competing priorities make ST a focal point for broader discussions about transparency, patient choice, and accountability within MA. They also may create new burdens for providers that impact physician autonomy, care patterns, and practice operations in a way that warrants further consideration of the broader net impact of ST protocols in Part B.

¹ CMS, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage". 2018. Available <u>here.</u>

² Federal Register, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses". 2019. Available here.

³ CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses", 2019. Available here

⁴ The American Journal of Managed Care, "Medicare Advantage Coverage Restrictions for the Costliest Physician-Administered Drugs". 2022. Available here

Health Affairs, "Integrated Appeals Are Essential, But Challenges Remain, 2022. Available here.

⁶ CMS, Appeals Decision Search – Part C. Available here.

Methodology and survey demographics

Avalere Health conducted a national survey in early 2025 to understand provider experiences with MA Part B ST. The survey sample included 300 healthcare providers from private or community-based practices. All respondents reported direct experience prescribing or navigating ST protocols for physician-administered drugs under MA. The sample reflected a broad mix of specialties, including:

- General Practice/Family Practice (21%)
- Dermatology (17%)
- Ophthalmology (14%)
- Internal Medicine (10%)
- Cardiology (7%)
- Gastroenterology (7%)
- Immunology (6%)
- Oncology (5%)
- Rheumatology (5%)
- Neurology (5%)

An additional 3% identified with other specialties. Most surveyed providers saw over 80 patients per week, and over two-thirds had more than a decade of experience working with MA coverage policies. This sample allowed for a cross-specialty assessment of how providers are impacted by ST requirements for physician-administered drugs, providing insights that may inform future programmatic or regulatory refinements.

Survey findings: Practice perspectives on MA step therapy in Part B

Trends in Part B step therapy utilization

Among providers that had experience managing Part B ST protocols, a vast majority indicated that they felt prevalence of ST use is increasing:

- 84% of surveyed providers reported that Part B ST use has risen over the past five years (Figure 1).
- Nearly 40% said that more than half of their MA patients are subject to ST for one or more Part B therapies.

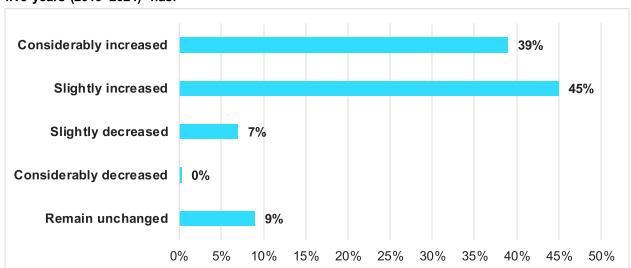


Figure 1. For patients who are prescribed a Part B product, the use of ST requirements in the last five years (2019–2024) has:

These findings suggest that ST for Part B drugs is now a standard element of coverage design in many MA contracts. For providers, this means that treatment plans often need to accommodate additional layers of approval and documentation, especially for newer or higher-cost therapies.

Clinical considerations and alignment

A recurring theme in survey responses was the degree to which Part B ST protocols align—or misalign—with clinical practice:

- 94% of respondents said that ST limits access to their preferred Part B treatments (Figure 2).
- 53% reported this interference occurred frequently ("often" or "always").
- 74% believed that ST protocols for Part B products were not consistently based on established clinical guidelines.

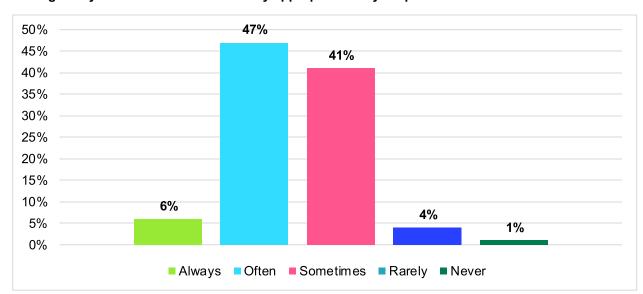


Figure 2. If you are a physician, how often do ST requirements limit your ability to prescribe a Part B drug that you deem the most clinically appropriate for your patient?

This misalignment may be particularly acute in therapeutic areas where treatment decisions rely on a nuanced understanding of disease progression, comorbidities, and prior treatment history. When ST requirements diverge from clinical judgment, providers face difficult trade-offs between adherence to plan policies and timely and effective patient care.

Still, some clinicians acknowledged that ST may have appropriate applications when implemented thoughtfully, particularly for conditions with multiple therapeutic options and well-supported prescribing pathways. The key concern shared by respondents centered on the variability of protocol design and the time required to pursue exceptions.

Patient experience and treatment access

Providers shared that ST requirements can have a negative impact on patient care, particularly when treatment delays affect disease progression or symptom control:

- Over 60% of providers described the burden on their patients of ST for Part B drugs as "high" or "extremely high" (Figure 3).
- Another 60% said that patients often wait weeks to receive their originally prescribed therapy.

Providers noted that while many patients ultimately gain access through exceptions or appeals, delays may contribute to anxiety or symptom exacerbation. These impacts are particularly concerning for patients with conditions that require early or aggressive intervention, or for those facing challenges navigating often complex administrative systems.

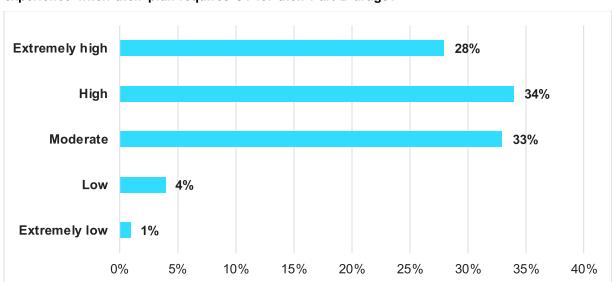


Figure 3. What level of burden or stress do you perceive that your patients with MA plans experience when their plan requires ST for their Part B drugs?

It is worth noting that some plans have sought to improve the patient experience by clarifying exception pathways and expanding support services. These efforts may help address barriers to access when implemented consistently.

Administrative and operational impacts

In addition to clinical concerns, many providers reported that ST policies for Part B drugs have altered the way their practice functions:

- 94% cited moderate to extremely high administrative burden associated with ST for Part B drugs (Figure 4).
- 56% said Part B ST policies affect drug stocking decisions—particularly when different MA plans require different step protocols.
- 67% of respondents reported dedicating staff solely to manage ST-related processes.

Survey respondents share that time spent on documentation, plan coordination, and workflow modifications averaged six to nine hours per week per activity. These operational adjustments have resource implications, particularly for smaller or community-based practices that lack dedicated administrative infrastructure.

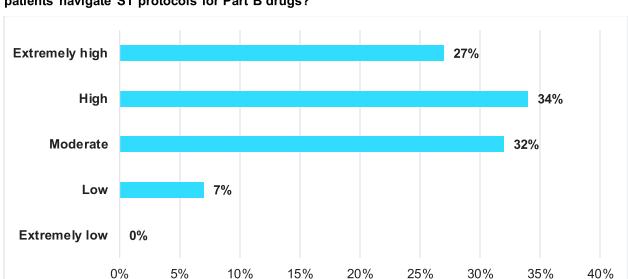


Figure 4. How would you assess the burden of documenting medical necessity, recordkeeping, financial impacts, patient monitoring, and communication with payers/PBMs to help your MA patients navigate ST protocols for Part B drugs?

While administrative burden is not a new challenge in healthcare delivery, ST may add complexity by requiring repeated justifications of treatment decisions that may already be well-supported clinically. Standardization, simplification, and improved plan-provider communication could help reduce some of these frictions.

Policy considerations

Step therapy, as a policy tool, sits at the intersection of clinical judgment, financial stewardship, and patient access. The survey findings point to several areas where stakeholders may consider adjustments to ensure that ST policies continue to evolve in a way that benefits all parties.

The Avalere Health survey highlights key themes that warrant further policy discussion:

- Clinical alignment: Many providers expressed concern that ST requirements often do not reflect specialty-specific guidelines, or the nuanced decision making needed in complex cases. Results emphasize the importance of aligning ST criteria more closely with clinical standards to preserve the integrity of evidence-based care and avoid unnecessary treatment delays.
- Patient access: Providers consistently cited treatment delays as a major consequence of ST,
 particularly when navigating appeals or waiting for exception approvals. These delays were
 reported to have negative impacts on patients' physical and mental wellness, especially among
 those with time-sensitive or rapidly progressing conditions.
- Streamlined ST processes: Nearly all providers described a significant administrative load associated with managing ST processes. Many reported dedicating staff time and resources specifically to handle ST documentation, appeals, and communication with plans. Smaller practices in particular reported operational strain posed by variation in plan processes.

• Transparency and communication: Respondents indicated variability in how clearly ST requirements, rationale, and exception pathways are communicated by MA plans. Inconsistent or opaque communications may contribute to confusion, delays, and provider frustration. Greater transparency was a recurring theme, particularly around plan-specific rules and expected response times.

ST policies in MA are designed to support the appropriate use of therapies and ensure the sustainability of the Medicare program. As these policies become more prevalent, however, their implementation must be carefully managed to preserve timely access to care and minimize unnecessary administrative burden.

This analysis provides a window into how providers are experiencing ST in practice. By using these insights to inform thoughtful policy adjustments, rooted in transparency and collaboration, stakeholders can better ensure that ST fulfills its promise as a constructive component of value-based care.