

Key Considerations for Medicare Advantage Plans Evaluating New Part B Step Therapy Flexibility /

Following its recent announcement to grant Medicare Advantage (MA) plans the flexibility to use step therapy techniques for Part B drugs beginning in January 2019, the Centers for Medicare & Medicaid Services (CMS) released an [FAQ](#) with additional guidance on its implementation. The document offers more clarity on the specific processes and requirements for plans interested in designing a step therapy program. However, operational considerations and broader environmental dynamics will shape MA sponsors' ability to institute major changes.

The new policy allows MA plans to require beneficiaries to begin treatment for a medical condition with the plan-preferred Part B drug therapy and progress to other therapies only if necessary. It also gives MA prescription drug plans (MA-PDs) the ability to require a beneficiary to use a Part D product before a Part B therapy, or vice versa. CMS has stated that any potential new step therapy requirements should be combined with drug management care coordination services with corresponding participation rewards incentives (described further below).

By allowing MA plans to use step therapy in Part B and cross-manage between Part B and Part D drugs, the administration anticipates plans will have more leverage in negotiations with manufacturers and more flexibility to lower costs. MA organizations will need to weigh these projected savings against the costs of compliance with CMS requirements. Key considerations include:

- **Calculating the Impact on Bids and Premiums:** CMS notes that cross-management of Part B and Part D drugs should not result in higher costs for beneficiaries, but it is unclear if or how CMS would enforce this. While MA plans may use step therapy in Part B starting in 2019, bids and premiums are already set for 2019. Plans will have to consider the implications of these new flexibilities for their bid and premium calculations going forward, as well as the feasibility of



implementing these policies for 2019 within the constraints of their existing calculations

- **Identifying Part B Drugs for Step Therapy:** CMS “strongly encourages” but does not require plans to use their Part D pharmacy and therapeutics (P&T) committees to determine coverage policies for Part B drugs. While plans must continue to cover all medically necessary Part B drugs for beneficiaries, they do not have to submit their Part B step therapy criteria to CMS for approval. MA plans will need to develop their own processes for identifying the Part B drugs to which they will apply step therapy
- **Designing Drug Management Care Coordination Services:** MA plans implementing step therapy must provide drug management care services that include, at a minimum, interactive medication review and medication reconciliation, educational materials, and medication adherence strategies for enrollees. As MA plans design these services, they will need to explore if and how they can be integrated with existing coordination and adherence programs (e.g., Medication Therapy Management (MTM) programs)
- **Developing a Rewards Program:** CMS expects that plans will generate savings through implementing step therapy policies and requires that MA plans pass on at least half of the amount saved per beneficiary to participating enrollees in the form of a reward (e.g., a gift card). In the FAQ, CMS states that MA plans “have flexibility in how they calculate and administer rewards” as long as they adhere to certain requirements (e.g., enrollees must complete a service/activity, the reward cannot be cash or a rebate, etc.). Plans will have to consider how to determine the amount saved, what rewards to offer, as well as other program requirements
- **Educating Providers:** MA plans will need to communicate with providers about new step therapy and care coordination protocols, as well as determine how these policies may impact shared risk arrangements. CMS has not stated if it will partner with MA plans to communicate the changes in policy, so MA plans may have to take the lead in developing outreach strategies

As MA plans evaluate the next steps of introducing step therapy into Part B, these and other considerations may shape both their implementation strategies and the beneficiary impact. It is not clear how many MA plans will be able to pursue major changes to utilization management in Part B for 2019, so the larger scale impact of this policy may be delayed.

Overall, CMS is rolling out a number of regulatory flexibilities around drug policy to further the administration’s goal of bringing down costs. Recent guidance on indication-based formularies, as well as Part B step therapy, are examples of this approach.



Operationalizing these flexibilities will need to happen within the constraints of the annual bidding and regulatory cycle, so MA plans should monitor these changes and plan ahead.

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