The Centers for Medicare & Medicaid Services (CMS) recently released a memorandum that reverses longstanding policy in the Medicare Part B program, allowing Medicare Advantage (MA) plans to implement step therapy requirements for Part B drugs.

**Step therapy in Medicare Advantage places vulnerable patients at risk without transparency, oversight, and patient protections:** CMS’ memo and the follow up “Q&A” document on the policy lack appropriate details around oversight of the use of step therapy, transparency for beneficiaries about their MA plan’s use of step therapy, a timely appeals and exceptions process, protections for those on existing therapy, and detail around ensuring patient out-of-pocket costs are not increased under the policy.

**Medicare provides critical beneficiary protections, transparency, and oversight in other parts of the benefit that are absent from the MA step therapy policy:** Medicare beneficiaries include the elderly and individuals with high healthcare needs. For these reasons, elements of the Medicare program have historically included patient protections to ensure plan design does not adversely affect patient health by being overly restrictive, and that beneficiaries are able to understand how their drugs are covered. ***Safeguards equivalent to those in the Part D prescription drug benefit are absent for the new MA step therapy Part B policy:***

**Medicare Part D**

**MA Part B Step Therapy**

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During open enrollment, will the beneficiary be able to go to Plan Finder at Medicare.gov and find out if their drug is covered and if step therapy applies?

Are plans required to submit their step therapy and prior authorization requirements to CMS?

Are plan step therapy requirements reviewed for clinical appropriateness?

Are MA plans required to ensure beneficiaries are able to stay on their therapy for the first 60 days they are on their plan (e.g., policy to prevent bait and switch)?

Do plans have to adhere to specific requirements for appeals and exceptions, including 24 hour review of an emergency appeal for a drug?

CMS can collect and incorporate the following information into Medicare plan finder.

CMS can develop guidance that requires plans to allow beneficiaries to stay on existing therapy through requiring a new transition benefit.

CMS can collect information on a plan’s step therapy activities, similar to the collection of formulary information in Part D, through updates to the Health Plan Management System (HPMS).

CMS can review information submitted through HPMS to ensure step therapy edits are clinically appropriate.

CMS can require plans to have an appropriate appeals and exceptions process in place, as is done for Part D.

***Potential Guidance Solutions***

**Further, CMS won’t be able to understand if the new policy has harmed access or required the beneficiary to use an inappropriate therapy:** Without any requirements for plans to share information with the Agency on activities in regard to step therapy, it will be very difficult to track these types of issues.

**It is critical that CMS issue requirements specific to this policy, and update their systems appropriately to ensure step therapy does not harm patient access and health outcomes.**