DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

**DATE:** August 7, 2018

**TO:** Medicare Advantage Organizations

**FROM:** Seema Verma
Administrator

**SUBJECT:** Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

CMS is hereby rescinding our September 17, 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," and issuing new guidance that recognizes Medicare Advantage (MA) plans may use step therapy for Part B drugs, beginning January 1, 2019, as part of a patient-centered care coordination program.

In the September 17, 2012 guidance, CMS stated that plans were precluded from imposing additional requirements for access to certain Part B drugs or services, such as step therapy requirements. That 2012 guidance did not affect other methods of prior authorization, which has been and continues to be allowed for Part B drugs. Section 1852 of the Social Security Act expressly anticipates a plan's application of utilization management tools, like prior authorization, and other "procedures used by the organization to control utilization of services and expenditures."[1] In this guidance, CMS is acknowledging that the use of step therapy is a recognized utilization management tool. The allowance of step therapy practices for Part B drugs will help achieve the goal of lower drug prices while maintaining access to covered services and drugs for beneficiaries.

Step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. This new guidance recognizes that MA plans may apply step therapy to control the utilization of services in a manner that does not create an undue access barrier for beneficiaries.[2] Specifically, CMS believes that appropriate patient engagement and care coordination services support appropriate pathways to access to Part B drugs such as step therapy.

In addition, CMS will consider rulemaking related to step therapy that might be appropriate for 2020 and future years. We remind MA organizations that the regulatory requirement to properly disclose policies and procedures to enrollees in accordance with 42 CFR § 422.111 remains. We also remind MA organizations of their statutory obligations to furnish and provide access to benefits that are available under Parts A and B. As such, CMS intends to treat step therapy for

[1] *See* section 1852(c)(1)(G), (c)(2)(B).
[2] Prior authorization cannot be required for emergency services. *See* section 1852(d)(1)(E) of the Act and 42 CFR 422.111(b)(5)(ii).

Part B drugs in a manner similar to our other requirements around prior authorization of Part C benefits and services.

Accordingly, MA organizations remain subject to regulations at 42 CFR § 422.101(b) to comply with national and, in some cases, local coverage determinations. An MA plan may implement its own step therapy policies and procedures as part of utilization management where an applicable national and/or local coverage determination is silent on the matter. However, an MA plan remains subject to FFS Medicare's step therapy policies and procedures when they are specified in a national and/or local coverage determination.

CMS strongly encourages that MAPD plans use their qualified Part D pharmacy and therapeutics (P&T) committees to determine when it is medically appropriate to use step therapy for selected drugs in Part B. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (also known as "MAPD plans") may use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy. MAPD plans may also apply step therapy to require a Part B drug therapy prior to allowing a Part D drug therapy. However, in these latter cases, MAPD plans must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs. For the 2019 annual election period, CMS will provide a special 8/17-8/21 window for MA submissions of Part B step therapy PA. The Part D drug must have a prior authorization edit submitted to CMS during this formulary update window. If the MAPD plan's P&T committee is unable to develop and approve PA criteria prior to this formulary submission window, placeholder PA criteria may be submitted with the submission by indicating "Criteria Pending" in the required PA submission fields. The standard Part D utilization management criteria review processes will provide MAPD plans an opportunity to finalize the criteria for the affected Part D drugs. If an MAPD plan chooses to implement criteria during the 2019 plan year, the addition of PA to a Part D drug can be requested as a negative change via the standard negative formulary change request timeframes.

If an MA plan decides to adopt and apply step therapy to Part B drugs, the MA plan must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under "Medicare Part B prescription drugs." If these documents are already in production, plans may send out an addendum to the ANOC and EOC to appropriately inform enrollees of the change. MA plans must provide benefits consistent with the coverage rules and benefits listed in these documents. For MA plans that choose to apply step therapy to Part B drugs in 2019, including this information in the ANOC and EOC prior to this year's annual election period satisfies that obligation. No changes to 2019 Plan Benefit Packages in the Bid Pricing Tool are needed in conjunction with adding a step therapy program for Part B drugs in 2019 based on this memo.

CMS believes that in order to maintain access to necessary drugs, step therapy should be coupled with drug management care coordination services and, importantly, rewards that incentivize beneficiary participation. In other words, under CMS's interpretation of its regulations, it is necessary for an MA plan opting to apply step therapy to Part B drugs to offer beneficiaries an

opportunity to participate in drug management care coordination activities. Patient-centered care coordination is an essential element to improved health outcomes, lower costs and providing access to drugs in the context of step therapy. It is an integral part of MA plans to coordinate and manage care in order to achieve quality care outcomes for enrollees. *See* 42 CFR §§ 422.112(b) and 422.152. Care coordination activities are truly effective when they reflect an enrollee's individual needs. In this context, CMS understands drug management care coordination activities to include, at a minimum:

- Interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up when necessary;
- Providing educational materials and information to enrollees about drugs within the drug management care coordination program; and
- Implementing medication adherence strategies to help enrollees with their medication regimen.

Patient engagement is essential to a successful care coordination program. To ensure adequate access to Part B drugs, it is necessary, under CMS's interpretation of its regulations, that MA plans opting to apply step therapy encourage enrollees to participate in such a drug management care coordination program by offering rewards in exchange for enrollee participation. Rewarding drug management care coordination helps encourage participation in a program that works to ensure that enrollees get safe and clinically appropriate medication to treat their condition, and will enable plans to pass on the cost savings generated from more active management of the drug benefit. Consistent with 42 CFR §422.134, plan rewards cannot be offered in the form of cash or monetary rebate, but may be offered as gift cards or other items of value to all eligible enrollees. MA plans should make sure any rewards or incentives comply with all rules at 42 CFR § 422.134 and Chapter 4 of the Medicare Managed Care Manual. Under these rules, the value of the rewards or incentives must be reasonable and appropriate. In this particular context, CMS will presume that the reward or incentive is reasonable and appropriate if it is equivalent to more than half the amount saved on average per participant by a more efficient use of health care resources, promotion of improved health, or prevention of injuries and illness. Also, pursuant to the requirement that information must be made available to CMS about the form and manner of rewards or incentives programs, MA plans offering this particular reward or incentive must include the value of the offered reward or incentive on a per member basis in comparison to the average planned per participant savings in the annual Part C Reporting Requirements submission.

For those plans that did not previously consider initial costs associated with rewards and incentives, these costs need not be separately included in the bid as a non-benefit expense. This is only for rewards and incentives offered in connection with step therapy driven drug management care coordination activities for 2019.

While step therapy requirements may reduce costs to both the enrollee and the MA plan, due to variances in cost-sharing for Part B and Part D drugs, there may be occasions when enrollees could experience higher out-of-pocket costs for the "stepped" Part D drug. CMS reminds MA plans that benefits must be provided consistent with the 2019 benefit packages submitted and

approved by CMS and it is our expectation that step therapy for Part B drugs, and other utilization management practices, should not result in increased costs to enrollees.

Additionally, it is critical that MA plans continue to comply with the statutory requirement that they provide access to all Part A and Part B benefits that would be available in Original Medicare. Step therapy or other utilization management policies may not be used as an unreasonable means to deny coverage of medically necessary services or to eliminate access to a Part B covered benefit, which is why CMS believes it is important to pair step therapy with a beneficiary engagement program. Furthermore, enrollees must be able to request an exception from the plan's step therapy requirement in order to access a Part B covered drug. The ability to request such an exception is consistent with current Part D rules involving exceptions related to the application of utilization management tools, such as step therapy requirements.[3] CMS recommends that MA plans follow the rules governing Part D exceptions in 42 CFR § 423.578(b) and grant an exception whenever it determines that the drug is medically necessary and is a covered Part B drug.

CMS considers plan decisions involving requests for exceptions to be pre-service organization determinations because they involve an MA plan's refusal to provide or pay for services that the enrollee believes should be furnished or arranged by the MA plan.[4] As a result, exception requests are subject to applicable adjudication timeframes and notice requirements in 42 CFR §§ 422.568 and 422.572. Organization determination timeframes require that MA plans make determinations as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days (72 hours for expedited requests) after the date the organization receives the request. CMS strongly encourages that MA plans expedite requests for exceptions in Part B, to align with the 72-hour adjudication timeframe for requests in Part D.

Finally, MA plans should ensure that new step therapy requirements do not disrupt ongoing Part B drug therapies for enrollees. Step therapy may only be applied to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication. Also, Part D transition requirements will continue to apply to Part D drugs that are subject to step therapy where the first "step" is a Part B drug. With these additional tools and enrollee protections in place, MA plans will be able to provide more coordinated and cost-effective care.

Questions related to the information in this memorandum, may be submitted at: https://dpap.lmi.org/dpapmailbox/.

[3] 42 CFR § 423.578(b)
[4] *See* 42 CFR § 422.566(b)(3)