

January 25, 2019

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services Attn: CMS-4180-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-8013

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

On behalf of Prevent Blindness and the millions of people of all ages whom we represent across the country who live with low vision, vision impairment, and vision-related eye diseases, we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Notice of Proposed Rulemaking titled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" [File Code CMS-4180-P, RIN 0938-AT92]. We look forward to working with CMS as it continues its efforts in reducing costs to patients and curb national expenditures for high-value care.

Introduction

Prevent Blindness is the nation's leading nonprofit, voluntary organization committed to preventing blindness and preserving sight. Prevent Blindness is first and foremost a public health organization. We strive to improve our nation's vision and eye health by enhancing state and community capacities through our core competencies of early detection, patient support, care coordination, public policy, research, advocacy, public awareness, and health education. As well, protecting and expanding access to sight-saving care is our priority for patients across the age continuum.

As part of the Administration's goal to reduce expenditures on drugs and lower the out-of-pocket costs of drugs for Medicare beneficiaries, CMS is proposing changes to the regulatory framework governing Medicare Advantage ("MA") (Part C) and the Medicare Prescription Drug Benefit program (Part D). Specifically, CMS proposes new requirements that would allow for use of step therapy for Part B drugs in MA plans. We are submitting comment with respect to the latter portion of the proposed rule, particularly the allowance of step therapy for Part B drugs within MA plans, and to provide further insight regarding the impact of this rule on patients who face progressive vision loss or visual impairment as a result of eye disease, aging, or chronic illness that complicates eyesight.

Summary of Proposals

CMS is proposing requirements under MA plans that would employ step therapy as a utilization management technique for coverage of Part B drugs. CMS cites for its rationale that the use of this and other previously permitted prior authorizations will allow for MA plans' greater negotiating power for Part B drugs, ultimately leading to lower costs to MA plan enrollees and maintaining access to Medicare-covered drugs and services. CMS also rationalizes that lower costs per unit will ultimately result in decreased costs to the Medicare program. As part of these proposals, CMS offers various proposed parameters to ensure these proposals are implemented in a manner that will reduce costs to beneficiaries and the Medicare program.

Prevent Blindness Guidance

We have significant concerns with the potential impact of step therapy and other forms of utilization management, which affects coverage for patients and can impede access to medications that slow progressive vision loss due to blinding eye diseases. Prior to the release of the August 7, 2018 Health Plan Management System (“HPMS”) memo, “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage,” CMS prohibited MA plans from using step therapy for Part B drugs as it would create a barrier to access and coverage of Part B drugs that MA plans are required to provide enrollees. With the codification of this memo under the proposals of this rule, CMS intends to allow for step therapy using the rationale that, “utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate costs of providing Part B drugs.” CMS further indicates that step therapy is “a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost-effective drug therapy and progresses to other drug therapies if medically necessary.” We feel this is an inadequate rationale for justifying the coverage options of Part B drugs in MA plans, which are required to be similar to those offered in traditional Medicare.

While we appreciate that CMS is attempting to find ways to lower out-of-pocket costs of drugs to patients, achieve better negotiation, and improve competition, Prevent Blindness does not support policies that seek to achieve savings if they negatively impact patient safety, quality of care including outcomes of care, and timely access to necessary and appropriate treatment. Under these proposals, step therapy inherently prohibits access to a certain covered Part B drug if a patient has not demonstrated that another drug, perhaps one that is less effective, older, or is cheaper, did not work. CMS implies in the regulatory text that coverage for treatment begins with a therapy that is either “most preferred” or “cost-effective,” but does not define what “most preferred” means. We recognize that, if these proposals are finalized, step therapy for Part B drugs under MA plans would not apply to new administrations of Part B drugs and, for new enrollees or enrollees who change plans, would utilize a 108-day lookback period. However, as worded, we are concerned that “most preferred” does not necessarily mean the patient will receive the “most preferred therapy as based on clinical effectiveness” and instead could mean “most preferred based on cost-effectiveness.” This approach appears to place costs as the driving factor for a patient’s treatment decision, giving the plan authority to determine coverage. For patients seeking timely access to treatments that could slow progressive vision loss due to a disease of the eye or another chronic illness, coverage options for treatments must be based not on the costs of a certain therapy or whether that patient has “failed” to achieve a clinical outcome that, as inferred by regulatory text, appears to be at the MA plan’s discretion, but by the clinical effectiveness and appropriateness of the treatment as determined by the provider and available evidence-based clinical protocols.

Prevent Blindness has vocalized our intention of working with CMS and the Administration to achieve lower out-of-pocket costs to patients, better negotiation processes, and improved competition as well as identifying ways to curb our national expenditures, and we echo our commitment to CMS in response to these proposals. However, we are concerned that CMS’s proposals are designed to achieve savings at the expense of patient safety, quality of care and clinical outcomes, timely access to and necessary and appropriate treatment, and ultimately a patient’s vision and eye sight that cannot be restored once lost. Patients who face progressive vision loss and eye disease that could compromise their vision do not have the luxury of time in accomplishing multiple steps prior to using a drug that, based on the clinical recommendations of his or her eye care provider, will be the most effective in treating the condition. We urge CMS to reconsider step therapy as the best mechanism for controlling costs to patients and the Medicare program and not move forward with these proposals.

Prevent Blindness Recommendations

While we ask CMS to reconsider its proposal to implement step therapy for Part B drugs within MA plans, should the agency move forward with its proposals, we insist on careful consideration of patient protections against the adverse consequences of step therapy to ensure that MA plans provide the full set of benefits under Part B and that plans do not deny coverage for medically necessary services.

Specifically, CMS should:

- Require plans to adhere to evidence-based guidelines and that step therapy protocols follow clinical practice guidelines and best practices that have stood the test of the peer-review process, including beginning the step therapy process *at the clinically recognized standard of care*, even if it results in the use of a drug that is not the most cost-effective;
- Require plans to establish an appropriate evaluation process of enforcing its protocols when “the enrollee’s healthcare provider’s assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for the enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug)”;
- Require that the pharmacy and treatment (P&T Committee) structure include a non-MA plan affiliated specialist to be part of step therapy decisions for the given therapeutic area in order to best serve patient care, including physicians who are knowledgeable about specialty drugs and how patients respond to treatment on different potential treatments;
- Actively monitor plans to ensure they do not impose step therapy requirements on patients receiving a particular treatment regardless of the plan year; and
- Improve the appeals and exceptions process, which has historically been a point of beneficiary frustration, and engage stakeholders to move it to the point of sale or at least within 24 hours.

If CMS insists on taking this direction, we urge the agency to take a direct and active role in ensuring the patient protections outlined here are developed and implemented with the plans. CMS should retain its oversight authority over these processes to ensure that plans are not coming in between the patient and the provider of his or her choice, and to mitigate the consequences of basing sight-saving care solely on the cost of that care.

Conclusion

Once again, Prevent Blindness appreciates the opportunity to submit comments on this NPRM. We stand ready to work with CMS and the Administration to develop policies that truly lessen the cost burden for patients and creates true access for those facing vision loss and eye disease. Please do not hesitate to contact Sara D. Brown, Director of Government Affairs, at (312) 363-6031 or email at sbrown@preventblindness.org if you or your staff would like to discuss these issues in greater detail.

Sincerely,



Jeff Todd
President and Chief Executive Officer
Prevent Blindness