

ACR Responds to CMS Medicare Part D and Medicare Advantage Proposed Rule

Rheumatology Leaders Urge CMS to Adopt Safeguards Protecting Medicare Advantage Beneficiaries from Step Therapy; Encourage More Price Transparency in Part D
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By Jocelyn Givens - American College of Rheumatology

ATLANTA, GA – In comments submitted to the Centers for Medicare and Medicaid Services (CMS), the American College of Rheumatology (ACR) expressed its continuing concern with a recent CMS policy allowing Medicare Advantage (MA) plans to utilize step therapy for Part B drugs. In the comment letter, rheumatology leaders urged the agency to establish safeguards to protect beneficiaries from potential harm.

“While we appreciate the agency’s efforts to make prescription medications more affordable, we have serious concerns regarding the decision to allow Medicare Advantage plans to implement step therapy for Part B drugs and cross-manage Part B and D drug utilization,” said Paula Marchetta, MD, MBA, president of the ACR. “We begin the 2019 benefit year with no safeguards in place to protect beneficiaries from changes that could seriously threaten their access to needed medications. At a minimum, CMS should immediately issue updated guidance that will clarify patient protections for the current year and beyond.”

Step therapy, sometimes known as “fail first,” is a utilization management technique employed by most health insurers that forces patients to try medications preferred by the insurance company before approving the medication prescribed by the patient’s doctor – even when there is no evidence the “insurer preferred” option will be effective. This practice often leads to delays in patient access to appropriate, evidence-based treatment and undermines the clinical expertise and judgment of health care providers.

In its comments to the agency, the ACR urged CMS to establish the following safeguards before moving forward with its step therapy policy:

- Make clear that a patient’s provider must determine if a patient “fails” a treatment. This decision should not be made by another entity such as an insurance company.
- Provide exceptions to step therapy if:
 - The treatment is contraindicated for a patient’s specific condition.
 - The provider determines, based on medical evidence, that the treatment is likely to be ineffective, likely to cause a harmful reaction, or impede the patient’s ability to perform daily activities or responsibilities and/or adhere to the treatment plan.
 - The provider believes the new treatment will put the patient’s life in jeopardy or irreparably harm his/her physical or sensory functions.
- Require MA plans to disclose that Part B drugs may be subject to step therapy in the

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plan's Annual Notice of Change and Evidence of Coverage Documents.

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- Implement a 365-day "lookback" period for Part B therapies instead of the current 108-day period used in Medicare Part D plans.

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- Preclude plans from implementing step therapy via a different utilization management process such as prior authorization.
- Increase monitoring of plans' usage of utilization management practices and require that all denials include the clinical rationale for the decision while making clear a beneficiary's appeal rights.

The ACR also commented on CMS' decision to make changes to the Part D program, namely the agency's new requirement that drug pricing information and lower-cost therapeutic alternatives be included in the plan's Explanation of Benefits document. The ACR commended CMS for implementing a ban on "gag clauses" that prevent pharmacies from disclosing if a drug's cash price is lower than the price with insurance. It also urged the agency to consider establishing common definitions for terms used during plan negotiations with Pharmacy Benefit Managers.

"The ACR is dedicated to ensuring that rheumatologists and rheumatology care professionals have the resources they need to provide patients with appropriate, high-quality care and that safe and effective treatments be available to all patients at the lowest possible cost," Dr. Marchetta concluded. "We appreciate the opportunity to respond to this proposed rule and look forward to serving as a resource for the agency as it continues its work."

About the American College of Rheumatology

The American College of Rheumatology (ACR) is the nation's leading advocacy organization for the rheumatology care community, representing more than 7,700 U.S. rheumatologists and rheumatology health professionals who are committed to improving healthcare for Americans living with rheumatic diseases.