September 8, 2015

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1631-P

Dear Mr. Slavitt:

On behalf of the more than 50 million adults in the United States with doctor-diagnosed arthritis, the Arthritis Foundation welcomes the opportunity to comment on the biosimilars reimbursement provision of the proposed 2016 Medicare Physician Fee Schedule. We are concerned with the current proposal to assign one Healthcare Common Procedure Coding System (HCPCS) code to all biosimilars of a particular reference product. We believe this policy would limit patient access by stifling innovation, and we request that you replace it with a policy that assigns each biosimilar a separate reimbursement code.

Biologics have revolutionized the treatment of rheumatoid arthritis and other inflammatory forms of arthritis, preventing joint damage and preserving function and mobility for patients, enabling them to participate as productive members of society, Arthritis can be complex to treat, and among arthritis patients who take biologics, the response rate can vary widely. One estimate of RA patients who took one of the three first-generation biologics for at least 6 months showed that between 40-50% of them failed to meet the American College of Rheumatology 50% improvement criteria.[1] Of patients who fail on a biologic, rheumatologists switch their patients to another biologic 90% of the time.[2] Since response rates vary so widely, it is important that patients have access to as many innovative biologic therapies as possible.

We believe that treating biosimilars as multiple source products stands counter to other biosimilar policies and the intent of Congress in passing the Biologic Price Competition and Innovation Act. Each biosimilar is a unique drug, and therefore is not an exact replica of its originator product, unlike generics. While Remicade may work to effectively treat RA in one patient, the biosimilar of Remicade may not. The recent FDA proposed rule on

[1] Renda-Baum, Regina; Wallenstein, Gene; Koncz, Tamas; Kosinski, Mark; Yang, Min; Bradley, John; Zwillich, Samuel. "Evaluating the Efficacy of Sequential Biologic Therapies for Rheumatoid Arthritis Patients With an Inadequate Response to Tumor Necrosis Factor-a Inhibitors." *Arthritis Research and Therapy.*13(1); 2011.
[2] Ibid.

naming recognizes this distinction by proposing a unique name in the form of a 4-letter suffix for the 6 biosimilars with applications at the FDA, including infliximab to treat arthritis. Unique names and separate reimbursement codes are an extremely important component to ensuring patient safety and will help ensure stronger adverse event tracking capabilities. Further, this proposal is not consistent with other CMS reimbursement policies, which treat biosimilars as single source drugs within certain Part D programs and Medicaid.

This type of policy may also negatively impact patient access, by serving as a disincentive for manufacturers to invest the amount of time and money needed to get approval for new indications of drugs, and proving interchangeability. Since there is already one biosimilar to treat arthritis awaiting FDA approval and several more in the pipeline, this issue is critically important to people with arthritis, particularly those who have yet to find a biologic that works for them.

We urge CMS to reconsider its proposal to group all biosimilars within the same code, and instead assign each biosimilar its own reimbursement code. Thank you for your consideration of this request and for the opportunity to comment on the 2016 Medicare Physician Fee Schedule. Should you have any questions or for more information, please contact Sandie Preiss, Arthritis Foundation Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org.

Sincerely,

Sandie Preiss
Vice President, Advocacy and Access
Arthritis Foundation