

January 12, 2015

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Patient Protection and Affordable Care Act; Draft Letter to Issuers in the Federally-Facilitated Marketplace

The Arthritis Foundation, on behalf of the more than 50 million adults and children in the U.S. living with arthritis, welcomes the opportunity to comment on the Draft Letter to Issuers in the Federally-facilitated Marketplace. The Arthritis Foundation commented on many policies addressed in this letter during the open comment period for the Notice of Benefit and Payment Parameters for 2016. We respect CMS's request to comment on policies in this letter that are not being proposed in other rulemaking processes, and therefore we will direct our comments to the relevant sections specific to this guidance.

Chapter 2, section 9 ii, QHP Discriminatory Benefit Design

We applaud CMS for proposing a review of each QHP to identify outliers based on out-of-pocket costs associated with standard treatment protocols for specific medical conditions, including rheumatoid arthritis (RA). People with RA often rely on specialty medications to manage their disease and prevent further joint damage. Not having access to these medications can lead to severe disability and in many cases the need for costly surgeries, hospitalizations, and procedures like joint replacements.

Increasingly, insurers are subjecting their members to 40-50% cost-sharing requirements for specialty medications, which makes these medications unaffordable and out of reach for many people with arthritis. RA medicines are subject to co-insurance in approximately 60% of health plans, with an average co-insurance of 35% for medications. This translates to up to \$3,000 in monthly out-of-pocket costs for a single fill of an RA medication. A recent Health Affairs study noted that RA is one of the top two specialty drug categories, and that higher out-of-pocket costs for RA drugs lead to higher rates of non-adherence. The study found a trend towards greater non-adherence when cost sharing exceeded \$250 a month, and significantly greater non-adherence when cost sharing exceeded \$500 a month.

Chapter 2, section 10 ii, Review of Prescription Drugs Based Upon Clinical Appropriateness

We appreciate the CMS proposal to review each QHP's prescription drug coverage for clinical appropriateness and analyze the availability of covered drugs recommended by clinical guidelines used in the treatment of certain conditions, including RA. The treatment of arthritis can be extremely nuanced and one drug in a class might work well while a seemingly similar drug in the same class might not. It is important that patients have access to the drugs that work best for them. Utilization management tools like step therapy and prior authorization are often used for the more

expensive and complex drugs, used to treat people with inflammatory forms of arthritis like RA. For this reason, it is important that stable patients are able to remain on their medications and not be required to go through a step therapy protocol more than once. A recent Health Affairs study showed that three quarters of utilization management programs for RA require failure on a non-biologic treatment before covering specialty drugs, and over half the programs require patients to fail on the insurer's preferred biopharmaceutical before approving a non-discounted drug.

These practices may lower costs in the short term but often have detrimental effects on the long-term health of people living with arthritis. For certain types of arthritis, early, aggressive treatment – often biologic drugs – are the best way to achieve stabilization and disease remission. We believe that the experiences our patient population is having in the marketplace support the need for the type of analysis proposed by CMS. We believe this oversight is essential to ensure patients have access to the drugs their physicians deem most appropriate to treat their disease and that they are not subject to inappropriate utilization management techniques based solely on cost.

Again, thank you for the opportunity to comment on the Draft Letter to Issuers in the Federally-facilitated Marketplace. We look forward to future opportunities to work with you as you finalize and implement this guidance. If you have any questions or if we can be of assistance in any way, please contact Sandie Preiss, Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org.

Sincerely,

A handwritten signature in black ink that reads "Sandie G. Preiss". The signature is written in a cursive, flowing style.

Sandie Preiss
Vice President, Advocacy and Access
Arthritis Foundation