



November 30, 2010

Roger L. Williams, MD
Chief Executive Officer
U.S. Pharmacopeia Headquarters
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Dr. Williams:

The American College of Rheumatology commends the work of the US Pharmacopeia, as you enter into another cycle of revisions on the ever important Medicare Model Guidelines. The American College of Rheumatology, the premier rheumatology association in the United States, supports the committee's attempt to strike a balance of assuring beneficiary access to safe and effective drugs they need. The ACR appreciates the opportunity to provide comments on the v5.0 update.

Three-year Process

The ACR has some concerns about the current 3-year review process for the USP. Numerous drugs are approved in a 3-year process and this delays proper placement by USP. USP notes this concern in the materials that have been released with the Draft Model Guidelines. Given the current timeline, the next review will not happen until 2013 with the next plan released in 2015. New medications that will benefit patients will not be included in a timely manner which could prevent patients from having access to appropriate treatment. This is particularly difficult for many rheumatic diseases where patients have co-morbidities or patients with few treatment options. The Centers for Medicare and Medicaid have provided information on how to include newly approved drugs during the interim, but we are concerned that patients will not have the appropriate access to new medications, as the drugs could be miscategorized. The ACR requests that the USP develop a process to include new medications or modify the current 3-year timeline.

Anti-gout medications

Under the current Draft Model Guidelines (v.5.0.), anti-gout drugs are listed by their therapeutic indication under "antigout agents." However, this category includes medications that have completely different mechanisms of action and different niches in clinical medicine. Several gout medicines have recently entered the market and/or have obtained FDA approval for the treatment of gout. Each of these agents work in different ways. At this time, it would be prudent to modify the anti-gout category by mechanism of action instead of therapeutic indication.

The ACR's concern is that of patients having access to appropriate drugs and treatment. With new or newly-approved drug treatments available and indicated for patients with certain needs, it is important to separate the anti-gout medications by mechanism of action to ensure that patients are able to have the right drug at the right time in order to relieve their gout manifestations. The most common treatment for gout attacks are nonsteroidal anti-inflammatory drugs (NSAIDs),

which reduce the inflammation caused by deposits of monosodium urate crystals, but have no effect on the lowering the urate stores within the body. Other gout medications function as urate-lowering therapeutics and reduce uric acid levels by inhibiting production (xanthine oxidase inhibitors) or promoting catabolism (uricase). The mechanisms of action of the available gout therapeutics are vastly different. Therefore, the ACR requests that the anti-gout category be divided by mechanism of action to ensure patients have access to appropriate medication.

Fibromyalgia

Currently, fibromyalgia is not a therapeutic category. However, fibromyalgia is a relatively common, painful condition with established diagnostic criteria and evidence based recommendations for management. Currently 3 medications are FDA approved for the management of fibromyalgia. Appropriate management of fibromyalgia patients requires access to these medications that have been demonstrated to improve quality of life.

The ACR respectfully requests that USP include the updated information in the 2012-2014 guidelines in order to provide our patients and your beneficiaries with the most appropriate treatment for their care. Please feel free to contact me if you have any additional questions directly at 805-925-8899.

Sincerely,

Karen S. Kolba, MD

Karen S. Kolba, MD
Chair, Committee on Rheumatologic Care