

AMERICAN COLLEGE OF RHEUMATOLOGY

POSITION STATEMENT

SUBJECT: Drug Pricing

PRESENTED BY: Committee on Rheumatologic Care

FOR DISTRIBUTION TO: Members of the ACR

Centers for Medicare and Medicaid Services

Pharmacy Benefit Management/Administrator Companies

Managed Care Entities

Members of Congress

POSITIONS

1. All patients should have safe, convenient and affordable access to rheumatology treatments that control disease activity and prevent permanent joint and organ damage, thereby limiting disability and early death.
2. The ACR supports rational policies that mitigate rapid escalations in pricing of rheumatologic drugs.
3. Transparency with medication cost adjustments from drug manufacturers through pharmacy benefit intermediaries should be made available on a public domain.
4. The ACR believes that a safe and efficient biosimilar approval pathway and marketplace will improve access to treatment by lowering costs.
5. Any comprehensive proposal to deal with rising drug prices must simultaneously address these primary concerns: cost to the healthcare system, continuity of care, and out of pocket affordability to patients.
6. The ACR supports preserving patient access to physician-administered drugs by recognizing the role of rheumatologists and rheumatology professionals in providing specialized, continuous care.

BACKGROUND

The past 40 years has brought about dramatic improvement in the ability to treat rheumatic disease. Due to rigorous scientific study, the optimal medication, dosing, and timing of treatment are better understood than at any time in history. Advances in bioengineering have resulted in new classes of medications, such as the biologic medications first approved for rheumatology

diseases in 1998. Biologic medications now represent some of the most powerful therapies available for those afflicted by rheumatology diseases. Many diseases that once led to high levels of morbidity are now better controlled with significant reductions in disability and pain and improvements in overall health (1).

Price Discrepancies

Unfortunately, these improvements have been associated with higher costs, with subsequent limitations in access for some. Historically, as medication patents expire and drugs become generic, costs are significantly reduced with resulting increase in access for patients of all income levels. Yet sometimes perturbations in this process have arisen. Hydroxychloroquine and methotrexate, two generic drugs that have become the backbone of rheumatoid arthritis treatment by virtue of their effectiveness and affordability, have seen shortages and dramatic price swings from month to month (2). Colchicine, long a staple in the treatment of acute gout, costs \$8.70 for a one month supply in a direct drug manufacturer to patient online pharmacy, compared with an average retail price of \$156 if purchase under a private insurance pharmacy plan (3). The rapid increases in the price of many established treatments have led many Americans to struggle with paying for necessary medications (4). Generic drug price escalations such as those for methotrexate, hydroxychloroquine and colchicine are not unique to rheumatologic care, and the FDA and federal government have become increasingly involved (5, 6).

In addition to increases in the cost of medicine, the price of insurance coverage has continued to rise yearly with both higher premiums and deductibles, and these increases are predicted to accelerate in the coming years (7). The increased financial burden on patients can lead to decreased health care use that has included prescription abandonment, lack of initiation of recommended medications, and lack of persistence with medications (8).

Need for Transparency in Drug Pricing

While newer biologic medications have brought about improved control of disease, especially in those with severe disease, the cost of these interventions is notably higher and rising yearly. The current mechanism for those with private insurance to obtain biological and newer small molecule medications involves a complex interaction that involves the drug manufacturer, the Pharmacy Benefit Manager (PBM) or pharmacy benefit administrator (PBA), and the Insurer.

The PBM and PBA act as the intermediary or “middlemen” in this transaction, generally deriving concessions from manufacturers (such as rebates on the drug price), in return for placing certain drugs on payer formularies. The disposition of these concessions is rarely clear, although it is clear that PBMs derive significant profit. The top three pharmacy benefit managers (PBMs) have a combined market share of nearly 80%. (9)

The overall process of pricing and contracting is hidden from public view, such that the exact nature and profit margin taken by those involved is not disclosed to the largest stakeholder in the process, the patient. The ACR believes that rheumatologists should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient’s unique circumstances. The ACR opposes the imposition by insurance companies, PBMs, and PBAs of restrictive

formularies that exclude medications considered necessary in the provision of high quality medical care. The ACR policy toward rational and transparent drug pricing is aligned with similar policies of the American Medical Association and other specialties to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase (10).

Biosimilar Availability and Cost Reductions

Biological medications for rheumatologic diseases have been available since 1998 with the FDA approval of etanercept (Enbrel[®]). Many products that began the wave of available biological medications are now off of patent or nearing the end of their patent. Several biosimilar medications, drugs that are nearly identical in chemical structure to the original biologic and produce comparable clinical outcomes, are now available in the US with many more close to FDA approval. These clinically biosimilar drugs have lowered the price of the original biological medications in Europe by close to 80% in some cases due to competitive bidding and a marketplace with more governmental driven healthcare (11, 12). In the US, the introduction of biosimilars had been delayed relative to uptake in much of the world, but access to biosimilars in the US is increasing (13). Even when the biosimilar medication is available and marketed in the United States, there has been a significant lag to obtain market share. The slow uptake has been limited due to a business model that makes the established, more expensive bio-originator more lucrative to the insurer and PBM and thereby distorts price competition. The shift toward mergers of large companies and inflated drug prices has diminished the expected price decline of biologics with the availability of biosimilar medications (13). Despite the slow change in pricing, recent evidence does demonstrate that biosimilar competition can drive the price of biologic medications lower in the United States. Cost savings of 24-35% have been reported, and additional competition has the potential to lead to additional savings (13,14).

Value to Provider Administered Treatment

A number of treatments for rheumatologic conditions are administered by the provider in the office setting. Many of these are administered parenterally by the medical provider in a monitored setting. Rheumatologists must acquire these drugs in a timely fashion for patient treatment, inventory, and store them to ensure drug delivery in a safe setting by expert clinical personnel. As such, rheumatologists occupy a critical “patient focused” segment of the drug distribution channel, and rely upon revenue from drug purchasing to maintain these services. Both commercial and government payers have proposed removing rheumatologists from this process with concern related to the cost of these medications and concern over drug choice being driven by profit.

When evaluated in depth, however, it is of note that recently the cost of the intravenously administered drugs (given in an office setting) have essentially matched inflation while the self-administered drugs have increased much more dramatically (in some cases over 100% in 5 years) (10, 15). Other analysis has demonstrated that the choice in medication for Medicare Part B drugs was not influenced by reimbursement to the provider (16). The unintended consequences of limiting the administration of medications given in the office could not only increase the overall cost, but it could also limit access for many. The resulting loss of patient access to safe

treatment in a monitored setting would have a negative impact on the health and outcomes of this most vulnerable of patient populations.

Care of those afflicted with rheumatic disease takes place in a large spectrum of practice settings from small practices to large hospital-based systems. As policy is developed to help slow health care expenditures, caution must be exercised to minimize the disruption in the patient-provider relationship across these settings. Any changes that are considered should take into account the financial impact on the patient and the ability of the practice to care for the patient. A reduction in reimbursement has the potential to reduce patient access to less expensive medications, such as intravenous biological medications, or even to their local rheumatologist.

In aggregate, the dramatic increases in the cost of essential medication, lack of competition for the most expensive medications and changes in the private insurance landscape across the United States have left many patients struggling to afford the necessary treatment for their disease. Any future changes in policy will need to give consideration to the multitude of factors that affect the cost of care. Thoughtful policy change will help ensure that all patients receive safe, convenient and affordable access to rheumatology treatments.

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