Rheumatology care: Is lower drug cost worth limited access?

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> The Centers for Medicare & Medicaid Services (CMS) recently finalised a rule that alters how drug prices are negotiated, a move intended to curb healthcare costs. But for patients with complex, chronic conditions like rheumatoid arthritis or lupus, changes to drug access and development could have significant downstream effects. The American College of Rheumatology (ACR) has voiced concerns that the new policy, while aiming for affordability, may inadvertently disrupt the delicate balance of innovation and patient access in rheumatology.

KEY TAKEAWAYS

- The Pivot: CMS's new drug price negotiation rule aims to lower costs but may impact drug development and patient access.
- The Data: No specific numeric data is available, but the rule targets high-cost drugs lacking generic or biosimilar competition.
- The Action: Clinicians should monitor changes in drug availability and formulary coverage for their patients with rheumatic diseases.

Rheumatic diseases, a broad category encompassing conditions such as rheumatoid arthritis, psoriatic arthritis, and systemic lupus erythematosus, are chronic inflammatory disorders that often require lifelong management with complex and expensive therapies. These conditions can lead to progressive joint damage, organ dysfunction, and significant disability if not adequately treated. The current standard of care often involves biologics and targeted synthetic disease-modifying antirheumatic drugs (DMARDs), which have revolutionised outcomes for many patients but come with substantial price tags. The unmet need remains high for patients who fail multiple lines of therapy or experience intolerable side effects, driving continuous research into novel mechanisms of action.

The CMS rule, part of the Inflation Reduction Act, mandates that Medicare negotiate prices for certain high-cost drugs that lack generic or biosimilar competition. The initial phase targets ten drugs, with more to be added in subsequent years. The selection criteria focus on drugs with the highest Medicare spending that have been on the market for a specified period without competition. While the intent is to reduce out-of-pocket costs for beneficiaries and lower overall Medicare expenditures, the ACR and other medical societies argue that the policy's structure could have far-reaching implications beyond simple price reduction.

The Impact on Drug Development

One primary concern is the potential chilling effect on pharmaceutical innovation. Drug development is a lengthy, costly, and high-risk endeavour, particularly for novel therapies in complex disease areas like rheumatology. Companies invest

billions into research and development, often with many failures for every successful drug. The prospect of mandatory price negotiation, especially for drugs that have not yet recouped their development costs, could disincentivise investment in certain therapeutic areas. This could be particularly problematic for conditions affecting smaller patient populations or those with particularly challenging biological pathways, where the return on investment might already be marginal.
The rule's timeline for negotiation initiation, which varies based on whether a drug is a small molecule or a biologic, is a point of contention. Small molecule drugs become eligible for negotiation nine years after approval, while biologics are eligible after 13 years. This differential treatment, according to critics, could skew research efforts towards biologics, potentially neglecting small molecule innovations that might offer advantages in terms of oral administration, manufacturing cost, or specific patient profiles. This could limit the diversity of treatment options available to clinicians and patients in the future, particularly for conditions where oral therapies are preferred or more accessible.

Access and Formulary Changes

Beyond development, the rule could also affect patient access to existing therapies. As drug manufacturers face reduced revenues from negotiated prices, they may alter their market strategies. This could include prioritising certain markets over others, or even withdrawing drugs from the market if they become unprofitable. For European GPs and specialists, this might translate into changes in drug availability or formulary coverage, potentially forcing patients to switch stable, effective treatments for less optimal alternatives. Such disruptions are particularly challenging for patients with chronic autoimmune diseases, where treatment stability is often paramount to disease control and quality of life.
The ACR also highlights the risk of unintended consequences for biosimilar uptake. Biosimilars are essential for driving competition and lowering drug costs, but their market penetration can be slow. If the original biologic's price is significantly reduced through negotiation, it could diminish the incentive for biosimilar manufacturers to enter the market, thereby undermining the very competition the policy aims to foster. This would be a self-defeating outcome, as robust biosimilar competition is a proven mechanism for sustainable price reduction without stifling innovation.

The Patient Perspective

For patients, the immediate benefit of lower out-of-pocket costs is clear. But the long-term implications for access to novel therapies and continuity of care are less certain. Patients with rheumatic diseases often rely on a specific drug regimen that has been carefully titrated to manage their symptoms and prevent disease progression. Any policy that introduces uncertainty into the availability or affordability of these treatments can create significant anxiety and potentially lead to poorer health outcomes. The importance of patient-reported outcomes in assessing the true impact of such policy changes cannot be overstated, as they capture the lived experience of disease management.
The rule also raises questions about the balance between cost containment and fostering a research ecosystem. While controlling healthcare spending is a legitimate policy goal, doing so in a way that inadvertently stifles the development of future treatments for debilitating conditions like lupus or rheumatoid arthritis would be a significant setback. The complexities of real-world evidence often reveal nuances in drug effectiveness and patient needs that are not always captured in initial clinical trials, making broad policy strokes potentially problematic.
The CMS rule represents a significant shift in the pharmaceutical pricing market. While the stated goal is to make essential medicines more affordable, the ACR's concerns about its potential impact on drug innovation and patient access in rheumatology are not trivial. The long-term effects on the pipeline for new treatments and the stability of care for

patients with chronic autoimmune diseases will require careful monitoring. Clinicians should remain vigilant regarding formulary changes and engage in advocacy to ensure patient needs are not overlooked in the pursuit of cost savings. For a comprehensive understanding of rheumatological conditions and their management, the Oxford Handbook of Rheumatology (5th ed) remains an invaluable resource.

CLINICAL IMPLICATIONS

This CMS rule, while well-intentioned, introduces a layer of uncertainty into the drug development pipeline that rheumatologists cannot ignore. The immediate relief of lower out-of-pocket costs for some patients is a positive, but it comes with the potential for reduced innovation in the long run. We may see fewer novel small molecules, pushing research towards biologics, which is not always clinically optimal for every patient or condition.

Clinicians should anticipate potential shifts in formulary coverage and drug availability. Patients stable on a negotiated drug might face pressure to switch, which is rarely a benign event in chronic autoimmune diseases. Managing these transitions will require careful patient education and proactive engagement with pharmacy benefit managers.

The policy's impact on biosimilar uptake is a critical, often overlooked, consequence. If negotiated prices for reference biologics undercut the economic incentive for biosimilar development, we lose a powerful market force for sustainable price reduction. This could paradoxically lead to less overall competition and higher long-term costs for the healthcare system.

The balance between affordability and innovation is delicate. While cost control is necessary, policies that inadvertently stifle research into new treatments for debilitating conditions like rheumatoid arthritis or lupus are a disservice to patients. We must advocate for policies that support both access and a robust pipeline of diverse therapeutic options.

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