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555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414.918.9825
Email: info@csro.info
Website: www.csro.info

May 28, 2025

Aetna
Attention: Policy Review Committee
151 Farmington Avenue
Hartford, CT 06156

Subject: Urgent Request to Reconsider Aetna's July 1 Policy Reclassifying Remicade and Evenity

To Whom It May Concern,

Dear Aetna Policy Review Committee,

The Coalition of State Rheumatology Organizations (CSRO), representing over 40 state and regional rheumatology societies, advocates for policies that promote access to timely, safe, and effective treatment for patients with autoimmune and musculoskeletal disease. We are deeply concerned about Aetna's recent policy update—July 1, 2025, Summary of Change – Medical Drugs—which reclassifies infliximab (Remicade) and romosozumab (Evenity) as pharmacy benefit-only drugs. This shift imposes serious clinical risks, introduces avoidable logistical delays, and destabilizes patient care.

Supply Chain Disruption and Patient Harm

While this policy change may appear procedural, its consequences for patient safety and care quality are substantial. Under the traditional buy-and-bill model, providers maintain full control over the procurement, storage, preparation, and administration of infused medications. This continuity ensures that safety protocols are followed at every step, reducing the likelihood of preventable errors.

By contrast, the white bagging model requires the drug to be sourced, handled, and shipped by a third-party pharmacy before arriving at the provider's office. This fragmented supply chain removes the provider's oversight and introduces opportunities for breakdowns in cold chain maintenance, mislabeling, contamination, and missed deliveries. Improper handling anywhere along the way—an all-too-common occurrence—can have serious clinical consequences, including adverse events or diminished efficacy.

For a drug like Remicade, the stakes are especially high due to its immunogenicity and individualized dosing. Even minor delays in administration can result in the formation of anti-drug antibodies, leading to infusion reactions, anaphylaxis, or complete loss of therapeutic effect. Adding to this risk, Remicade is dosed based on patient weight and frequently adjusted at the time of infusion. In clinical practice, providers often modify the dose in real time based on the patient's current weight, laboratory results, or disease activity. Under a white bagging model, the medication is shipped in advance from a specialty pharmacy—often based on outdated dosing information—leaving no room for same-day adjustments. If the dose delivered does not match what is needed at the time of care, the correct amount is simply unavailable, forcing providers to cancel or delay treatment until a new shipment arrives. This not only disrupts therapy but increases the likelihood of reduced response and adverse outcomes.

Evenity, while different in mechanism, also requires highly coordinated care. It is administered monthly for 12 months to prevent fractures in patients with severe osteoporosis. Requiring practices to coordinate monthly delivery of a specialty pharmacy drug—over which they have no control—dramatically increases the risk of missed or delayed doses, eroding the drug's intended benefit and increasing the risk of clinical failure.

Operational Burdens and Drug Waste

In addition to compromising patient safety, white bagging policies introduce unnecessary waste and inefficiency. Because white bagged drugs must be labeled for a specific patient and tied to a specific administration date, any change in schedule—such as an acute illness, insurance issue, or therapy adjustment—can render the drug unusable. Providers are legally barred from redirecting that dose to another patient, even if the drug remains viable.

This scenario results in wasted medication, unnecessary cost to the system, and, in self-funded employer plans, higher downstream expenses. The buy-and-bill model avoids this entirely: drugs are kept in on-site inventory, tracked rigorously, and used at the time of administration based on real-time clinical needs. This system minimizes waste, improves responsiveness, and maintains a safer chain of custody.

Impact on Independent Practices and Access

Many private rheumatology practices are unable or unwilling to accept white bagged drugs due to legal and logistical liabilities. As a result, patients are often pushed toward hospital-based infusion centers that are more expensive, harder to access, and less personalized. This undermines the value of community-based care, where costs are lower and outcomes often better.

Moreover, shifting patients to new treatment sites can sever long-standing relationships with their trusted providers. For patients with complex, chronic diseases like rheumatoid arthritis and osteoporosis, continuity of care is not a luxury—it is essential to long-term disease control.

Legal Inconsistencies Across States

We also wish to highlight that several states—including Arkansas, Delaware, Louisiana, Kentucky, Tennessee, Texas, and Virginia—have enacted laws that prohibit insurers or pharmacy benefit managers from mandating white bagging for provider-administered medications. In these jurisdictions, enforcing Aetna's July 1 policy may not only undermine patient care—it may also be inconsistent with state law and subject to legal challenge. We encourage Aetna to conduct a careful legal review before applying this policy uniformly across state lines.

Fiduciary Risks to Self-Insured Employers

Aetna's policy mandating white bagging—requiring that provider-administered drugs be sourced through insurer-owned specialty pharmacies rather than the traditional buy-and-bill model—can inadvertently place self-insured employers at risk of breaching their fiduciary duty under ERISA by increasing overall costs to the health plan. White bagging often results in higher drug wastage: since drugs are dispensed specifically for individual patients, any unused medication due to last-minute dose changes or therapy switches must be discarded and cannot be repurposed for other patients. In contrast, the buy-and-bill model allows providers to use inventory more flexibly and avoid unnecessary waste. As a result, employer-sponsored health plans may be forced to pay for drugs that are never administered—driving up plan costs without benefit to patients.

Furthermore, real-world data have shown that the cost of white bagged drugs can significantly exceed what employers would pay through physician-sourced inventory. For example, CSRO is aware of data from a large employer (UPS) in which the cost of Remicade was nearly four times higher when white bagged through a specialty pharmacy than when billed by a physician in a non-hospital infusion suite. These increased costs, combined with the administrative burden and potential delays in care, challenge the employer's obligation to prudently manage plan assets and act in the best interest of plan participants—potentially constituting a fiduciary breach when lower-cost, clinically equivalent alternatives are available but not utilized.

Request for Reconsideration

CSRO urges Aetna to reverse or amend this policy and preserve medical benefit access for Remicade and Evenity when administered by in-network physicians. Maintaining provider-based drug procurement ensures continuity of care, protects against unnecessary waste, reduces adverse events, and contains costs through optimized site-of-service use.

We would welcome the opportunity to meet with your medical policy team to further discuss how we can align practices that prioritize safety, value, and access for rheumatology patients nationwide.

Sincerely,

Aaron W. Broadwell, MD
President, Coalition of State Rheumatology Organizations (CSRO)
Phone: (414) 918-9825
Email: info@csro.info

CC:
David M. Cordani, CEO