CSRO
Coalition of State Rheumatology Organizations

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414-918-9825
Email: info@csro.info
Website: www.csro.info

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Gerald Isreal, Jr.
Chief Pharmacy Officer & Assistant Vice President
Blue Cross Blue Shield of South Carolina
P.O. Box 100300
Columbia, SC 29202-3300

Mr. Isreal,

Thank you for your response to our concerns regarding BCBS of SC's latest policy mandating that subcutaneous (sub Q) formulations of medications be utilized first - before the IV formulation - AND **mandating that patients who are stable on the IV formulation be non-medically changed to the sub Q formulation.**

In reading your letter, one of your justifications for this policy is that both formulations "are effective in treating the conditions for which they were approved." As you know, there are many drugs that can treat the same condition, but it doesn't mean that patients can be changed from one drug to another without negative consequences, as data shows that response to medication varies from patient to patient. Additionally, you state that they have "*clinical parity." As there is data refuting clinical parity between the IV and sub Q formulations, specifically in abatacept (Orencia) which we cited in previous communications, and as it is our responsibility to practice data-driven decision making, we would appreciate evidence of peer reviewed studies showing clinical parity, or interchangeability, which requires specific studies to prove.*

NON MEDICAL SWITCHING

This is a case of non-medical switching, when a stable patient is automatically switched from one formulation to another. You are aware that IV formulations are weight based and the sub Q formulations are not. For example, if a patient weighing 225 pounds (102kg) receiving Orencia IV is given 1000mg every 4 weeks IV, and they are switched to the sub Q formulation, they will receive 125mg a week for a total of 500 mg a month. Essentially, switching this stable patient will reduce their dose by 50%, obviously not in the best interest of the patient. I have a patient stable on Simponi Aria who weighs 225 pounds, receiving 204 mg every 8 weeks. His dose will immediately drop to 100mg every 8 weeks if switched to the sub Q form, reducing his dose by 50% as well.

Additionally, if you look at market share of TNF blockers, Simponi's usage lags the other sub Q products. It would seem that the option requiring the least amount of injections (once monthly) would be more popular. Unfortunately, its usage has been markedly limited because breakthrough symptoms prior to the next injection are common. This problem has not been seen in the IV formulation. There is clearly no dosing *parity* in these examples.

We also believe that this forced change in dosing violates the spirit of the South Carolina Drug Product Selection Act as the substitute is not “therapeutically equivalent."

COST EFFECTIVENESS

It was also stated that the sub Q formulation is more cost effective. Reviewing the most available data looking at wholesale and ASP analysis, IV preparations are, on average, half the cost of their sub Q alternatives. We do understand that profitability to the PBM may increase if rebates and fees from the manufacturer are calculated into the cost of the specialty pharmacy sub Q product. But as there is no current transparency to ensure that these savings are making it back to the payers, should this profit be more important than the stability of the patient?

SITE OF CARE

Perhaps you are averaging in site of care cost where hospital charges on drugs have increased dramatically along with excess facility fees. This, however, is not the case for in-office infusions at private rheumatology practices. We would propose that your policy address site of care and direct patients to the most cost effective location of service.

OUTCOME DOCUMENTATION

We would also propose that documentation of clinical response be expected for treatment to be continued, as no treatment is cost effective if it doesn’t work. Outcomes should be documented by the provider regardless of treatment. Disease activity documentation is important whether the patient is on a biologic (IV or Sub Q), jak inhibitor, or any disease modifying agent, and a required proof of response to treatment by outcomes measures would lead to greater medical savings than the requirement of one formulation or mode of delivery over another.

STABLE PATIENTS

Again, we ask that stable patients be able to continue on their IV preparations (grandfathered in) and not forced to sub Q, as there is documented evidence that loss of disease control will occur.

ERISA PROTECTIONS

Those patients that are employees of a business with either a fully insured or a self-funded (most often with stop-loss insurance) health plan are under the protection of ERISA. Forcing stable patients (employees) onto a different formulation often dropping dose by 50% or more may result in a significant potential of increase in disease activity, resulting in increased pain, decreased function/productivity/ quality of life, and even ultimately permanent loss of joint function, constituting ERISA violations. Whether Blue Cross Blue Shield and or the employers are the fiduciaries, you are making or coopting others in relying upon imprecise advice to make fiduciary decisions regarding the use of assets that have been entrusted to an ERISA employee welfare benefit plan, which should be applied in a nondiscriminatory manner, but instead would under your direction be allocating those funds in a manner that is likely to prove highly detrimental to a particular class of employee plan members - patients whose disease has become stable on their infusion medication. Further, without the support of adequate peer reviewed medical and scientific literature, we believe that your decision artificially and purposefully decreases the cost of covered benefit claims, to the benefit of your company and any pharmacy benefit or other affiliates, at the expense of the continued health of many of your insureds. We are asking that you not subject stable patients to this real possibility.

Once again, we are copying the South Carolina Department of Insurance, as well as adding the Department of Labor Employee Benefits Security Administration charged with oversight and enforcement of ERISA.

We hope this additional information is helpful and that you will reconsider the policy revision in light of these most serious outcomes for the patients we both serve.

Sincerely,

Madelaine Feldman, MD FACR
President, Board of Directors
Coalition of State Rheumatology Organizations

Sent via email

CC: South Carolina Department of Insurance (consumers@doi.sc.gov)
US Department of Labor Employee Benefits Security Administration (mihailovic.tamara@dol.gov)
(mulhall.tamara@dol.gov)

Sent via mail

CC: U.S. Department of Labor
Health Plan Standards and Compliance Assistance
N-5655
200 Constitution Ave NW
Washington, DC 20210