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To Whom It May Concern:

As a pediatric neurologist at Children's Mercy Kansas City who cares for children with multiple sclerosis, a severely disabling disease, step therapy protocols for drug prescriptions have made a significant negative impact on my practice. These protocols provide a cookie cutter approach to what medications insurance providers will allow physicians to prescribe regardless of an individual patient's needs. Step therapy protocols are intended to keep physicians from prescribing medications that are more expensive when there are other cheaper and similarly effective medications available, but this good intention has led to physicians' hands being tied when a patient has a more severe presentation of disease that would require stronger therapies not typically allowed in initial step therapy plans.

I would like to share an example of how step therapy has negatively impacted my patients and practice. I diagnosed an 11-year-old boy with multiple sclerosis recently. He presented to our hospital a few weeks earlier with double vision. He was found to have difficulty getting his left eye to move in sync with his right eye. An MRI of the brain was performed and revealed more than 20 different lesions in his brain in a pattern that would fit with multiple sclerosis. Testing from a spinal tap confirmed the diagnosis. He was treated with high dose steroids by IV in the hospital and his symptoms resolved. He remained on steroids by mouth until I saw him in my clinic a week or two later. At that visit, after reviewing his very abnormal MRI findings I was concerned that this young man's disease was much more severe than the average patient diagnosed with multiple sclerosis. I wanted to start him on a more potent drug for multiple sclerosis because when untreated or poorly treated the disease can be very disabling with flares of the disease potentially leading to multiple lifelong symptoms including the inability to walk or lifelong incontinence. When I prescribed this more potent drug through the specialty pharmacy required, I received a denial letter from his insurance 7 days later. Along with the denial I was told that the insurance company would approve initial therapy with one of 7 different options that they listed out. All of the options provided were drugs that had been around for over twenty years with drugs in these two classes providing minimal protection for the disease compared to drugs put on the market in the last decade or so. While 7 drugs were listed as options the drugs all worked in such a similar manner in the body that there were only two different ways that these drugs worked among those 7 options. These drugs that were listed collectively are so weak in controlling how often flares occur in multiple sclerosis that some of them control the disease with less than 50% efficacy over two years, meaning more than half of the patients on those drugs will have another lesion develop on the drug and this child had 20 lesions develop prior to treatment putting him in a risk category that would very likely relapse on these weaker medicines. Because the step therapy protocol was put in place in such a way as to keep stronger medications out of reach my team had to put time and effort into getting the insurance company to approve the stronger medication that this child needed to control his disease. With all of our efforts we were able to circumvent step therapy for this young man after 12 days, but it required an hour of a doctor's time who had already used clinical reasoning and judgment to make the best decision for my patient, 4 hours of a pharmacist's time collecting data from the medical literature to back up our claim, and 4 hours of a nurse's time to collate all of the paperwork required by the insurance company to make this happen. I don't ask that step therapy be abolished, but I do think we need to find a way to circumvent these types of protocols when they do not fit the mold for our patients in a way that is more efficient than a two-week turnaround. It's what any one of us would want if we were in a position where the disease we were diagnosed with was more severe than expected and would get patients with disabling diseases on the right medications sooner.

A handwritten signature in cursive script that reads "Tyler Allison MD".

Tyler Allison, MD  
Pediatric Neurologist