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October 9, 2024

Senate Commerce Committee Committee Room 1, First Floor State House Annex Trenton, New Jersey

Re: Support S.3533 - Step Therapy Patient Protections

Members of the Senate Commerce Committee:

The Coalition of State Rheumatology Organizations (CSRO) supports S.3533, which would put in place select guard rails to protect patients from unnecessary step therapy and ensure they receive the medications they need to manage their health. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

This legislation creates step therapy protocols that ensure transparent, streamlined, and consistent exceptions pathways available to physicians and their patients. To be clear, this legislation **does not** ban the use of step therapy, but instead creates a limited, common sense exception process in five scenarios if the health plan requires a drug that:

- 1. Would require the patient to stop taking a drug that has stabilized their medical condition
- 2. The patient has already tried, but was proven to be ineffective
- 3. Is contraindicated or is likely to cause an adverse reaction
- 4. Is expected to be ineffective based on the patient's medical history
- 5. Is not in the best interest of the patient based on their medical necessity

We believe all of these exceptions are in the best interest of the patient and should be made without any change in cost-sharing to the patient.

Without commonsense step therapy exceptions, patients are whipsawed back and forth between medications at the whim of their insurance plan and their pharmacy benefit manager. The plan may choose to change its formulary several times within the same calendar year, often without any warning to the patient or their provider, and thus altering the step therapy protocol. These midyear changes and corresponding new steps are harmful to the patient's management of their health condition and can ultimately cost the healthcare system more due to unnecessary complications from delays in care. These five exceptions can better enable patients to maintain their health and ultimately save patient lives.

Rheumatologists treat patients with extremely complex chronic conditions, such as rheumatoid arthritis (RA). Complex chronic conditions such as RA are temperamental and present unpredictably on a case-by-case basis. This necessitates a high degree of individualized care and attentive management. Stabilizing these conditions is a process that can take months or even years of trial and error. The resulting course of treatment must carefully balance each patient's unique medical history, disease environment, and drug interactions.

The stakes for these patients are high. Step therapy protocols are often burdensome barriers that prevent patients from receiving the personalized care they need. Instead of treating each patient according to their individual needs, step therapy protocols are a one-size fits all approach that hampers treatment decisions arrived at through the course of the doctor-patient relationship. Variations between drugs, even those in the same therapeutic class, can cause serious adverse events for patients. The resulting disease progression can be irreversible, life threatening, and result in increased utilization of healthcare resources. Existing appeals pathways have failed to rectify these problems.

We recognize that there can be a role for utilization management protocols, but utilization controls have become so stringent that they interfere with patients receiving therapies in their best interest. Step therapy protocols may provide reasonable guidelines for broad populations, but patients with complex chronic conditions require a different approach. There must be a role for the doctor-patient relationship, and there must be clear and transparent scenarios. The exceptions processes outlined in S.3533 allow for that balance between utilization management and clinically appropriate patient care.

We appreciate your consideration, and we are happy to further detail our comments to the Senate Commerce Committee upon request.

Respectfully,

Gary Feldman, MD, FACR

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