

Maryland General Assembly – Senate Finance Committee

Testimony of Shannon Wood

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Support for SB 515: Health Insurance – Step Therapy or Fail First Protocol – Revisions

Chair Griffith, members of the Senate Finance Committee: thank you for the opportunity to provide testimony in support of SB 515, to provide important and necessary revisions to Maryland's step therapy protocols.

Multiple sclerosis, or MS, is an unpredictable disease of the central nervous system. Currently there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes and vision issues. An estimated 1 million people live with MS in the United States. Early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS.

Step therapy or “fail first” policies are a form of utilization management that health plans may use as a mechanism to control the order in which patients take certain therapies. Step therapy protocols require that patients must try one or more medications selected by their insurer before the plan will grant coverage for the drug originally prescribed by the healthcare provider. Under step therapy protocols, for a given diagnosis, insurers cover specific drugs in a specific order, meaning an individual must be prescribed medications in the step order so that they are covered by the insurer. Insurers often defend the use of step therapy protocols as a method to ensure that safe, appropriate, and affordable drugs or other treatments are provided to patients. Plans rely on this process, among others, to help guide utilization of prescription drugs or other services and control the cost of treatment.

Patients (including people with MS) and healthcare providers have voiced concern regarding the potential adverse effects of step therapy, when it is not paired with protections for patients. Step therapy protocols transition medical decisions from a shared decision-making approach, between the provider and the patient, towards more standardized policies that focus on cost-effective care. These policies may not take into account detailed conversations between healthcare providers and patients, as they discuss the right medication for each person—factoring in things like efficacy, dosage, route of administration and side effects.

In addition, step therapy protocols may involve significant paperwork and documentation from healthcare providers and patients. Staff in provider offices must dedicate time to communicating with insurance companies to find out whether a prescribed drug will be covered—or appealing treatments that are denied. The time providers spend on these often-burdensome processes affects the office workflow and leaves them with less time to treat patients. This process is not only challenging for providers, but also a challenge for patients, who may spend many hours working with their provider's office to access the prescriptions they need.

When patients are required to cycle through and document a “step”—or in some cases, more than one step or medication—the process may result in substantial delays in treatment deemed appropriate by their healthcare provider. This process may affect patients’ ability to immediately start treatment, or in some cases, their ability to continue a treatment that has been effective. Prolonging ineffective treatment (and delaying the medication initially prescribed by the healthcare provider) may result in disease progression for patients. For those with diseases such as multiple sclerosis, which may be severe or debilitating, delaying treatment can be a serious outcome. According to “The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence,” a consensus paper by the Multiple Sclerosis Coalition, evidence supports the initiation of treatment with an FDA-approved disease-modifying therapy (DMT) as soon as possible following a diagnosis of relapsing MS. It can take years following an MS diagnosis to find the most effective course of treatment and when a patient does, they should remain on that drug uninterrupted. Considering the cost of MS medications, patients cannot afford to take drugs out of step order and without coverage. In 2022, the median annual price of the MS DMTs is close to \$94,000, up nearly \$25,000 from 2015. Six of the MS DMTs have increased in price more than 200% since they came on market, with nine now priced at over \$100,000.

Although insurers utilize step therapy as a means to control cost, research has demonstrated that step therapy can in fact lead to higher spending over time. For example, while Georgia’s Medicaid program initially saved \$20 per person per month after introducing step therapy protocols for schizophrenia medications, the state ultimately ended up spending \$32 per person per month on outpatient care, due to the use of ineffective medications by patients (Clinical Therapeutics, 2008, as cited in Health Affairs, 2016). The use of ineffective treatment has been associated with higher costs due to additional office visits, increased drug costs, and even the increased likelihood of needing additional treatment or hospitalization. Additionally, in the case of MS, effectiveness of the drug should not be the only factor considered. The risk profile of the medication as well as side effects and the ability for an individual to adhere to the medication must also be taken into account.

The National MS Society urges this committee – and the larger legislative body – to pass Senate Bill 515 this session. Allowing individuals, especially those with chronic diseases such as MS, access to step therapy protocol exceptions will not only improve their quality of life but may ultimately end up saving the state money. Protect the residents of Maryland and ensure that they receive the best care possible.

Please contact me if I can be of further assistance: shannon.wood@nmss.org.