



SB0515: “Health Insurance – Step Therapy or Fail-First Protocol – Revisions.”
Submitted by Kim Czubaruk, Senior Director, Strategy and Policy, CancerCare
February 21, 2023

Senator Lam and members of the Senate Finance Committee, I am Kim Czubaruk, Senior Director of Strategy and Policy for CancerCare, the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. In 2022, our staff answered more than 38,000 calls to our helpline and served clients with 90 different types of cancer, from all 50 states. Our comments are informed by the stories we hear from our clients as they navigate the confusing, expensive, and frustrating process of accessing and paying for vital – and sometimes life-saving – cancer care and treatment. I am writing in support of SB0515: Health Insurance – Step Therapy or Fail-First Protocol - Revisions.

Step therapy, sometimes called “fail-first, is a utilization management (UM) tool implemented by plans which requires patients to first try treatments that the plan prefers (often due to lower plan cost or larger PBM rebate) and have them fail before the plan will cover the treatment prescribed by the clinician.

When cancer patients don’t get the right drug at the right time, the length and severity of illness can increase and major setbacks may occur in managing the disease. Delayed, disrupted, and denied treatment due to step therapy causes serious harm in the time-sensitive fight against cancer and other aggressive diseases. One study found that breast cancer patients who endured a three-month or more delay in treatment had a 12% lower five-year survival rate. The uncertain process of waiting for lesser drugs to fail can take weeks or months and step therapy has been shown to reduce the long-term effectiveness of a treatment. Step therapy policies often require patients to retry treatments that have already failed for them, such as when a patient switches plans or the formulary changes. People respond differently to treatments with regard to both effectiveness and adverse reactions. Despite payers’ insistence on requiring step therapy, oncology drugs often do not have substitutes that are equally effective and less costly.

The revisions in SB0515 establish necessary and clearly defined requirements that protect patients from the potential serious consequences of step therapy. Current procedural ambiguities in the application of step therapy lead to harmful delays and barriers to patients receiving or maintaining effective treatment prescribed by their clinician. By requiring plans to establish an exceptions process to their step therapy protocol and describing the necessary steps for that process, SB0515 will prevent procedural ambiguity from being a catalyst for delay. Furthermore, delineating time parameters for plans to respond to an exception’s request or an appeal of a denial, and including that such requests be granted by default if a plan fails to timely respond, ensures the process is timely and patient-centered.

SB0515 also restores respect for clinicians’ expertise and knowledge and the importance of the patient-clinician shared decision-making process. For too long step therapy has allowed plans’ financial interests to be prioritized over the professional judgment of clinicians on how best to efficaciously and safely



treat their patients' disease. Currently, Maryland law limits clinicians' use of their professional judgement to override step therapy protocol to situations when the effective drug has been prescribed within the past 180 days. This limitation negates the value of clinicians' medical knowledge and expertise and jeopardizes the health and safety of their patients. SB0515 reaffirms the knowledge and expertise of clinicians by requiring a step therapy exception request be granted if, based on the professional judgement of the prescriber, the expanded parameters established for an exception in SB0515 are met. Importantly, as described below, this requirement applies in some circumstances when the drug is covered under the current policy or contract or under a previous source of coverage. The expanded parameters of SB0515 on which prescribers may base their professional judgement to obtain a step therapy exception are:

- The step therapy drug is contraindicated or will likely cause an adverse reaction, physician harm, or mental harm to the patient; or
- The step therapy drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or
- The patient is stable on a prescription drug prescribed for the medical condition under consideration while covered under the entity's policy or contract or under a previous source of coverage; or
- While covered under the entity's policy or contract or a previous source of coverage, the patient has tried a prescription drug that:
 1. Is in the same pharmacological class or has the same mechanism of action as the step therapy drug; and
 2. Was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

Approximately one in four individuals with cancer has clinical depression. SB0515 includes another important step therapy provision that prohibits the imposition of step therapy if the prescription drug is used to treat a patient's mental health (as defined in the source referenced in the bill) that results in a serious functional impairment that substantially interferes with or limits one or more major life activities. SB0515 will ensure that medication prescribed by a clinician to treat their patient's serious mental health condition will not be delayed or denied by a plan's imposition of step therapy.

Thank you for the opportunity to provide this written testimony and for your thoughtful consideration of this important legislation.