



# STEP THERAPY PROTOCOLS

## SB140 | 2022 LEGISLATIVE SESSION

Kentucky was a pioneer in patient protections when it enacted step therapy reforms a decade ago. Now, more than half of the states have stronger laws in place. In 2022, in the wake of evolving clinical practices and insurance policies, Sen. Max Wise introduced Senate Bill 140 to update and clarify existing statutes that address step therapy protocols mandated by insurers and pharmacy benefit managers. The legislation was unanimously approved by both chambers and signed by the governor, taking effect on Jan 1., 2023.

The new law requires step therapy protocols to be based on widely accepted medical and clinical guidelines and will update the clinically justified circumstances for a patient and health care provider to override a step therapy protocol.

## HIGHLIGHTS



Establishes requirements for clinical review criteria and clinical practice guidelines used to establish step therapy protocols.



Requires certain notices and disclosures relating to step therapy protocols; establish requirements for exception requests, internal appeals, and external reviews of step therapy protocols.



Requires Medicaid, the Kentucky Children's Health Insurance Program, self-insured employer group health plans provided by the governing board of a state postsecondary education institution, and the state employee health plan to comply with the step therapy protocol requirements.

## EXCEPTIONS

Pursuant to §304.17 A-163 Kentucky Revised Statutes, the patient qualifies for an exception to the step therapy protocol because any one of the following conditions has been met: (Determinations required within 48 hours.)

- The required drug is contraindicated.
- The required drug is likely to cause an adverse reaction or physical or mental harm.
- The required drug is expected to be ineffective based on the known clinical characteristics of the patient and the drug regimen.
- The required drug is not in the best interest of the patient because it is expected to cause a significant barrier to adherence or compliance with a plan of care, worsen a comorbid condition, or decrease ability to achieve reasonable functional ability performing daily activities.
- The patient tried the required drug, or another drug in the same pharmacologic class or with the same mechanism of action, and it was discontinued due to lack of efficacy, effectiveness, diminished effect, or an adverse event.
- The patient is stable on a prescription drug other than the required drug.

**SB140 is one of many KMA priorities that have been signed into law, thanks to the advocacy of KMA members. For more information on this and other legislative successes, visit [kyma.org/advocacy](https://kyma.org/advocacy).**





# BIOMARKER TESTING COVERAGE

## HB180 | 2023 LEGISLATIVE SESSION

Biomarker testing allows physicians to analyze a patient's tissues or blood to find specific markers indicating normal biological processes, diseases, or responses to medications in order to help determine the best treatment. In 2023, the Kentucky General Assembly passed HB180, which requires health insurance plans to cover biomarker testing when ordered by a qualified healthcare provider, following certain medical and scientific evidence criteria. The new law took effect Jan. 1, 2024.

### HIGHLIGHTS



Coverage is not meant for routine screening but rather for diagnosis, treatment, management, or monitoring of specific diseases.



The law applies to both private health insurance plans and Medicaid beneficiaries, with compliance required from the Department for Medicaid Services and managed care organizations.



While most current applications of biomarker testing are in oncology and autoimmune disease, there is research underway to benefit patients with other conditions including heart disease, neurological conditions like Alzheimer's disease, infectious disease and respiratory illness.

### BIOMARKER TESTING & HEALTH EQUITY

Despite its potential, there are disparities in Kentucky's access to biomarker testing, particularly affecting older individuals, Black communities, and those with limited insurance coverage. This inequality is evident in lower testing rates in community settings compared to academic medical centers. The consequences include hindered health equity, reduced quality of life, and increased disparities in cancer outcomes based on factors like race, ethnicity, income, and geography. The passage of HB180 hopes to improve these outcomes.



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