

Metastatic Step Therapy Prohibition-amending 19-02.1-16.3 to add associated conditions SB 2248

Metastatic step therapy legislation offers relief for some of North Dakota's most critically ill patients, those with metastatic cancer, from step therapy protocols that may delay individualized and time-sensitive drug decisions as determined by their doctors.



METASTATIC CANCER

- Cancer that spreads from where it started to other areas of the body is called metastatic cancer. For many types of cancer, it is also called stage IV cancer. Some of the most common forms of metastatic cancers begin in the breast, kidney, lung, prostate, and thyroid and frequently metastasize to the bones, lungs, liver, or brain.
- Metastatic cancer accounts for up to 90 percent of all cancer deaths in the U.S. each year.
- According to the National Cancer Institute, there are 693,452 people living with metastatic breast, prostate, lung, colorectal, or bladder cancer or metastatic melanoma in the U.S. in 2025.
- While metastatic cancer is treatable, there is no cure. Treatment focuses on slowing tumor growth, easing symptoms, and extending a patient's life. Treatment often continues until the cancer starts growing again or until side effects become unacceptable. If this happens, other drugs might be tried.
- Treatment is highly personalized and must be based on decisions made by the patient and their healthcare providers.

STEP THERAPY

- Step therapy, also referred to as "fail first," requires a patient to first try a health plan-preferred (often generic alternative) drug and have that drug fail them prior to receiving coverage for the originally prescribed drug.
- Most step therapy protocols rely on generalized information regarding patients and their treatments as opposed to considering unique experiences, previous responses to treatments, and any comorbidity (additional disease) factors.

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- Step therapy creates additional barriers for a patient to receive their medically prescribed treatment, which can ultimately exacerbate their medical condition and result in higher medical utilization costs.

CRITICAL ACCESS

- Ensuring patients receive consistent and effective treatments is even greater in situations when treating patients with potentially life-ending diseases such as metastatic cancer, where any delays or deviations could be deadly.
- **North Dakota passed metastatic step therapy protocol legislation in 2019 SB 2248 adds an associated condition**, which means a symptom or side effect associated with metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardizes the health of an individual if left untreated.
- Metastatic patients and physicians should have the opportunity to choose the best course of treatment from the outset, without the burden of harmful cost-containment policies.
- This legislation is needed to ensure that consumers enrolled in state-regulated health plans have access to the most current and appropriate cancer treatments as soon as their physician deems them necessary.
- The prohibition on step therapy in the proposed legislation includes drugs used for cancer treatment and any associated conditions, or side effects from the primary treatment, such as nausea, diarrhea, low white blood cell counts, and bone loss.



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