Regence | 200 SW Market Street, 11th Floor
Portland, OR 97201

Testimony on HB 2536 Step-Therapy for Metastatic Cancer

February 11, 2025

Chair Nosse and Members of the Committee,

My name is Dr. Tracy Muday and I am the Executive Medical Director for Regence BlueCross BlueShield of Oregon. I am here to express concerns with HB 2536, and how it may unintentionally impact whether Oregonians receive the best and most cost effective cancer care according to the medical evidence

To start, I want to say how challenging treatment decisions are for those experiencing and treating metastatic cancer. Metastatic cancer is usually not curable—although some metastatic cancers are—and people with metastatic cancer may have years of life ahead. We are grateful for the research and continually evolving treatment options that have led to improved survival over the past decades. Regence works hard to ensure that our coverage decisions are evidence-based, and our members receive care in accordance with the standard of care.

Different cancers have a variety of treatments, potentially including medications or chemotherapy, surgery, or radiation. Recommendations for treatment take multiple factors into consideration, including the type of cancer, the degree of spread, previous treatments, and so on. For many metastatic cancers, a person may change treatments several times as the disease progresses. Although there are many individual factors that are taken into account in recommending treatment, the evidence of what is most likely to benefit a person should be the guide, and cost-effectiveness an important consideration.

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Our guidelines follow the current evidence in terms of when and how a patient moves through therapies. Generally, if a medication is supported by strong evidence as a first-line therapy, we would not require other step therapy before a patient moves to that medication. Step therapy tends to be put in place for medications that have only been studied after other, established regimens have failed, or for newer medications that have not been shown to improve outcomes, and which can often be associated with increased toxicity. These medications may also come at a higher cost. Patients' treatment will then proceed through these medications in an evidence-based order, starting with those with the strongest evidence. Notably, Oregon law already contains extensive requirements governing insurer use of step therapy and provider and patient rights when it comes to treatments where step therapy is used. *See* ORS 743B.602.

While the intention of this bill feels like we are making things simpler and better for people with cancer, we have concerns about the consequences of this approach.

Many new treatments, especially in cancer care, are approved through the FDA's accelerated-drug-approvals pathway. Unfortunately, drugs that are not yet proven to be safe and effective are also being brought to market at an increasing rate. This raises concerns about the impact on patients, their families and payers' ability to keep care effective and affordable.

For background, the accelerated approval pathway allows drugs to be approved based on surrogate endpoints—such as lab values or scans, which don't always translate to patients living longer or their symptoms being improved. This means that patients are exposed to the cost and side effects or harm of drugs that have not been shown to provide meaningful health benefits.

Accelerated approvals are contingent on outcomes of future studies. For continued approval by the FDA, clinical benefit must be shown in confirmatory trials that continue while people are being treated with the drug in hopes the studies will show benefit. However, most people receiving cancer treatment don't have a clear understanding of the quality of the evidence. And many of us frequently assume that newer treatments must be better.

The risks associated with these unproven therapies are not just theoretical. In fact, a September 2023 publication by the Lancet revealed that 23 accelerated approvals for cancer indications have been withdrawn, with 74% of these withdrawals occurring in the previous three years[1]. Of note, six additional accelerated approvals have been withdrawn to date since the study was published.

Moreover, a recent publication by JAMA[2] of accelerated approvals in oncology between 2013-2017, showed that:

- 22% have ultimately been withdrawn for demonstrating no actual clinical benefit.
- 57% *did not demonstrate benefit in overall survival or quality of life* within 5 years of accelerated approval, including many ultimately granted standard approval.

Examples of costly market withdrawals where step-therapy would have been used in coverage policies:

- Exkivity **($300k annually)** for metastatic EGFR-20 positive Non-Small Cell Lung Cancer in patients who had failed platinum-based chemotherapy (Accelerated approval: 2021). Takeda withdrew the accelerated approval in 2024 as the confirmatory trial did not demonstrate a clear progression-free survival advantage compared to chemotherapy.

- Tecentriq **($160k annually)** for advanced urothelial (bladder) carcinoma in patients who had failed platinum-based chemotherapy. (Accelerated approval: 2017). Roche/Genentech withdrew the accelerated approval in 2022 when confirmatory trials failed to show a survival benefit compared to chemotherapy.
- Trodelvy **($350k annually)** for advanced or metastatic urothelial (bladder) carcinoma in patients who had failed platinum-based chemotherapy and immunotherapy. (Accelerated approval: 2021). Gilead withdrew the accelerated approval in 2024 when confirmatory trials failed to show a survival benefit compared to chemotherapy.
- Blenrep **($337k annually)** for patients with relapsed or refractory (R/R) multiple myeloma (MM) who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (Accelerated approval: 2020). FDA withdrew the accelerated approval in 2023 when confirmatory trials failed to show a survival benefit compared to other therapies and due to potential for ocular toxicity.

All of these were on the market between 3-5 years where insurers and payers were being charged over $300k annually to result in no benefit. Oversight agencies, including the Office of Inspector General (OIG), have reported that the FDA does not adequately enforce the required follow-up by manufacturers. As a result, many of these drugs remain on the market for years, exposing patients to the cost and toxicity of therapies that have not been shown to provide any health benefits, such as helping people live longer or improving their quality of life. Currently, there are about 67 active accelerated

approvals for cancer, and almost all are for either advanced or metastatic cancer, which is the focus of this bill. Passage of this bill would only exacerbate that problem, reducing the incentive to submit follow-up support for expensive new treatments not supported by strong evidence.

It is crucial for policymakers to reevaluate this legislation, particularly given its scope and potential unintended consequences. The bill impacts fully insured and individual plans in Oregon, which means that the effects of increased costs and risks of unproven treatment will be felt most acutely by individuals and small businesses. Considering that the median cost for a new cancer therapy is about $250,000-$300,000 per year, a significant burden of costs will fall on patients who will be forced to endure the health and financial impacts of these unproven therapies under their plan cost share without a guarantee of positive outcomes. Meanwhile, the cost of the expensive and ultimately ineffective therapies will be paid by all enrollees in increased premiums, and likely by people who can least afford the premium increases.

While we do not think that providers make treatment decisions based solely on financials, the way doctors and facilities are paid for provider- administered drugs results in them getting the highest payment for the most expensive drug. This can incentivize them to select the more expensive treatment when two treatments are equally as effective.

We are concerned that this bill will create scenarios in which Oregonians are responsible for extremely high-cost therapies that have not yet been proven to increase the length or quality of life. We are also concerned to see these drugs getting used in practice differently from how they were studied in clinical trials. In addition,

we are concerned that well-established, cost-effective treatments including biosimilars and generics would be bypassed due to this legislation, with people receiving higher cost and less proven medications first.

Although we understand there is significant interest in newer cancer therapies, our plan covers these based on two requirements: 1) they must be shown to improve clinically meaningful outcomes and 2) they must be used the way they were studied in clinical trials (for metastatic cancer, many drugs are designed to be used after prior therapies). Health plans must maintain the ability to ensure therapies proven to improve the length or quality of life are given priority of coverage before the *promising* but unproven drugs we see entering the market today. We owe it to our members, to our Oregon employers, and to our communities to ensure that their dollars are spent on the most-effective treatments.

While the bill allows for consideration of evidence, it does not rallow for us to prefer treatments based on the quality of that evidence. Peer-reviewed literature varies in quality and often relies on surrogate markers, which do not translate to real-world benefits. The proposal seems to mandate that drugs with unproven survival benefits be treated the same as those with long-term safety and efficacy data, some of those which have proven survival benefits. This poses significant issues for both people receiving care and those who pay for care via their premiums. We strongly urge the legislature to permit insurers to evaluate the quality of evidence when developing step-therapy policies, and to advocate for providers to use the lower-cost drug when the evidence is comparable.

We encourage policymakers to closely evaluate this legislation. Health care systems, insurers, and government programs are paying

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billions with very little leverage to demand effective and cost-efficient treatments. The burden of these costs also falls on patients who endure the health and financial toxicities, without a guarantee of positive outcomes. Step therapy is an important check to ensure that our members are truly receiving evidence-based and cost-effective care.

Dr. Tracy Muday

Executive Medical Director, Regence BlueCross BlueShield of Oregon