

Lisa Subeck

STATE REPRESENTATIVE

To: Assembly Committee on Health
From: Representative Lisa Subeck
Date: February 16, 2022
Subject: Testimony in support of Assembly Bill 745

Chairman Sanfelippo and members of the Committee on Health:

Thank you for the opportunity to testify on Assembly Bill 745, which would exempt patients with metastatic cancer from the requirements of step therapy protocols.

Last session, 2019 Act 12 was enacted through a bipartisan effort to permit exceptions and create transparency to step-therapy protocols. Assembly Bill 745 builds upon that law to offer relief for some of Wisconsin's most critically ill patients, those with metastatic cancer. This legislation is needed to ensure consumers enrolled in state-regulated health plans have coverage and access to the most current and appropriate cancer treatments as soon as their physician deems them necessary.

Metastatic cancer, sometimes referred to as Stage IV cancer, is cancer that has spread from its primary site and surrounding lymph nodes to other areas of the body. 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, or liver. Usually, metastasized cancers have no cure, and their cells can remain inactive for years before beginning to grow again.

There are treatments available that can slow growth, ease symptoms, and extend a patient's life. These patients need personalized treatments as determined in consultation with their physicians. Unfortunately, access to effective and affordable drugs is often impeded due to utilization management practices such as "fail first" step-therapy protocols. "Fail-first" requires patients to try and "fail" a preferred or older treatment method, as determined by the payer – not the patient's health care provider, before a patient is allowed to access more advanced and potentially more effective treatments, putting the financial interests of the payer ahead of the health of the patient.

A cancer diagnosis frequently results in a life-long financial burden, even for the insured. According to a 2017 study from Duke University, at least a 1/3 of insured individuals undergoing cancer treatment end up paying more for their care than they initially anticipated, with the median out-of-pocket cost of \$703 per month.

Fail First step-therapy protocols can cost metastatic cancer patients additional out-of-pocket costs on failed treatments instead of using state-of-the-art therapies from the start. Beyond the financial cost, fail first step-therapy protocols may cost terminally ill patients precious time. Simply put, metastatic cancer patients do not have the time or the money for continual trial and error or a "one-size-fits-all" approach to their treatment needs.

Similar laws eliminating step therapy protocols for primary treatments for patients with metastatic cancer have passed in eight states and have been introduced in at least seven others. States that have

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passed similar legislation include Colorado, Connecticut, Delaware, Georgia, Illinois, Maryland, North Dakota, and Pennsylvania. We should follow their lead and pass this important legislation.

Thank you again, Chairman Sanfelippo and Health Committee members, for your time and consideration of Assembly Bill 745. I would be happy to answer any questions.



Written Testimony Supporting AB 745
Submitted to the Assembly Health Committee
State Senator Janis Ringhand
February 16, 2022

Chairman Sanfelippo and Assembly Health Committee members' thank you for the opportunity to speak in support of Assembly Bill 745.

Assembly Bill 745 affords people diagnosed with metastatic cancer the right to obtain a course of treatment decided by themselves and their healthcare team. Unfortunately, that is not always the case under current law because of step therapy policies. Commonly, called "fail-first" policies step therapy requires patients to first try lower-priced medications before being granted access to the medication originally prescribed by their doctor.

Why does this occur? According to Christi Shaw, an employee of Lilly Bio-Medicines at Eli Lilly and Company in a February 2019 Washington Post article it happens because of the way pharmaceutical rebates work. Pharmaceutical companies offer billions of dollars in rebates each year to health plans and pharmacy benefit managers. In exchange, these health plans and pharmacy benefit managers give those therapies preferential access, creating "steps" that require patients to try those medicines first before giving them a newer medicine which their doctor and clinical studies may determine is best for them. This system is called "step therapy."

In same article Ms. Shaw stated that "when the system works as intended, some payers use those rebates to cover drugs and to help reduce the premiums that patients pay for health insurance — helping more people afford coverage.

But rebates also put new medicines at a financial disadvantage from the start. New products, of course, launch with fewer prescriptions than older medicines with an established market presence. Because rebate revenue is the product of a medicine's list price, volume, and rebate rate, a new product with less volume inevitably gives health plans less in total rebates than an older product with established volume. Because insurers are able to spread the cost of medications to patients (via deductibles and co-pays) without passing on the rebate savings they negotiate with pharmaceutical companies, launching a new product at a discounted price is often not a viable strategy for gaining access."

She also points out that "more new medicines are launching than ever before—and it's vital that patients in need can get them. Recent research by Columbia University has shown that every

dollar spent on newer medicines saves at least \$2.50 in hospital costs. And for every year that recent medical advances extend people's lives, newer medicines are responsible for nearly nine months of those gains."

Unfortunately, we all probably know someone or have heard of someone who has had to go through step therapy. They feel helpless, discouraged and that they are wasting their time. People with metastatic cancer should not face additional barriers in their treatment. They should get the treatment they need. It's what we would want for ourselves, loved ones and friends.

Chairman Sanfelippo I urge you to move this legislation forward. Patients and their doctors should decide a patient's treatment not an insurers policy.

**Written Testimony from Ann Marie Doedens
Submitted to the Assembly Health Committee
Regarding AB 745**

Mr. Chairman and Members of the Committee, my name is Ann Marie Doedens. Thank you for the opportunity to provide testimony regarding AB 745.

I am a 41 year old female (daughter, sister, employee, wife, and mother) who on December 31, 2020 was diagnosed with Stage 4 breast cancer after my maintenance medication from fighting Stage 2 breast cancer (diagnosed and treated in 2019-2020) failed. Since my medical insurance did not cover post-treatment scans without a reason, and the monthly blood work showed nothing of concern, it wasn't until a new spot was found on my breast (post double mastectomy, chemo and radiation) and additional scans were then ordered to see the cancer had spread into multiple parts of my bones.

I am a personal victim of step therapy protocols for metastatic cancer through two recent examples. The first in early 2021, when first diagnosed stage four. One of the first medications to begin when breast cancer has spread to your bones is a bone strengthener to fight against the cancer spots eating away in the bones. When my Oncologist presented this to me in January 2021, I was told I would start Zometa (an infusion drug) because the other alternate was more of a name brand drug (Xgeva) and insurance would not cover it, unless there was a very specific medical reason/situation. So, in mid-January 2021, I received my first Zometa infusion. I was then sick for about 48 hours – very high fever, aches, chills, and many other side effects. The drug did not agree with me. It was at that time, my medical team stated they now could submit through insurance the prescription of Xgeva, because they had medical reason that was a better alternative. Xgeva is more expensive and is not an infusion, it is a quick easy shot. After now over a year of Xgeva shots, I can confidently say that my reaction to Xgeva has been minimal, the shots are super quick, easy and uneventful and I only wished I could have started on this from the beginning, as my quality of life was greatly impacted by Zometa (which is known to have severe side effects.)

The second recent example was in September 2021 when my bone scan showed my cancer had once again spread to my right shoulder bone. My Radiation Oncologist had to submit (two times) the type of radiation she thought was best for that area – SBRT. It was denied both times – with insurance stating they felt it best to do a more general, proven radiation treatment of the area. After again, seeing the cancer in my January 2022 scan, my Radiation Oncologist then put through an appeal to my health insurance company for this treatment. While in appeal, I worked with my VP of Benefits in HR to help along my appeal and in early February 2022, the appeal was approved, and the former denials were overturned. Although I didn't participate, in this case, with step therapy (as my Radiation Oncologist and I agreed it would be better to hold than pursue the treatment my insurance would approve), this is another example of not receiving the recommended and prescribed treatment in a timely manner. I've had to wait 5 months to start the type of treatment needed.

I am asking for the Committee to support the AB 745 bill. As a relatively new patient on this journey, I hope to have many years ahead of medications and treatments that are the best and timeliest for my situation, to extend my life as long as possible.

Thank you for your consideration.

Ann Marie Doedens
Metastatic Breast Cancer Patient
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Written Testimony Supporting AB 745
Submitted to the Assembly Health Committee
February 16, 2022
By Susan G. Komen

Chairman Sanfelippo and Members of the Committee, thank you for the opportunity to provide testimony in support of AB 745, which prohibits requiring a step therapy protocol for a drug that is prescribed for metastatic cancer or a cancer-associated condition. My name is Dana Carter, and I am the Regional Manager of State Policy and Advocacy for Susan G. Komen®.

Komen is the world's leading nonprofit breast cancer organization representing the millions of people who have been diagnosed with breast cancer. Komen has an unmatched, comprehensive 360-degree approach to fighting this disease across all fronts—we advocate for patients, drive research breakthroughs, improve access to high quality care, offer direct patient support and empower people with trustworthy information. Komen is committed to supporting those affected by breast cancer today, while tirelessly searching for tomorrow's cures. We believe patients and their physicians should be able to make treatment decisions based on the particular needs of each patient.

Metastatic breast cancer is an advanced stage of breast cancer where tumor cells have spread to other parts of the body, such as the bones, liver, lungs, or brain. It is estimated that nearly all of the 43,780 breast cancer deaths expected this year will be a result of metastasis, including more than 700 people in Wisconsin.

The 5-year relative survival rate for people whose breast cancer is contained to the breast is 99 percent. Once breast cancer metastasizes to areas outside of the breast—the 5-year relative survival rate drops to 27 percent.

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. Unfortunately, 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 comorbidities.

According to a study published in the American Journal of Managed Care, step therapy may create barriers for patients receiving their medication, and ultimately result in higher medical utilization costs. These protocols should optimize affordable, effective, and appropriate access to care, not lead to delayed treatments, poorer patient outcomes and increased medical costs.

Ensuring patients are receiving consistent and effective treatments is even greater in situations when treating patients with potentially life ending diseases such as metastatic breast cancer, where any delays or deviations could be deadly. Although metastatic breast cancer cannot be cured, it can often be treated. Treatment is highly personalized and must be based on joint decision making between patients and their healthcare providers, as they are most capable in determining the most appropriate treatment options.

As committed partners in the fight against breast cancer, we know how deeply important it is for metastatic cancer patients to have fair and equal access to the treatments that may save their lives. As such, we strongly support AB 745 and urge you to pass this critical legislation.

Thank you for your consideration.



**Wisconsin
Association of
Health Plans**

From: Tim Lundquist, Senior Director of Government & Public Affairs
Wisconsin Association of Health Plans
To: Assembly Committee on Health
Re: Assembly Bill 745
Date: February 16, 2022

The Wisconsin Association of Health Plans appreciates the opportunity to provide comment on Assembly Bill 745, legislation to prohibit the use of step therapy for drugs prescribed for metastatic cancer or a cancer associated condition. The Association is the voice of 12 community-based health plans that serve employers and individuals across the state in a variety of commercial health insurance markets and public insurance programs. Community-based health plans are committed to ensuring their members have access to the right treatment at the right time, including drugs prescribed for metastatic cancer or cancer associated conditions.

Community-based health plans are concerned Assembly Bill 745 would harm existing efforts to ensure patients with metastatic cancer or cancer associated conditions receive the safest and most effective medications. Health plans work every day with doctors and patients across Wisconsin to ensure ready access to cost-effective, clinically appropriate treatments, such as those recommended by the National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 31 leading cancer centers devoted to patient care, research, and education. Under state law, health plans may follow NCCN or other similar guidelines when developing and applying step therapy protocols. For patients with metastatic cancer or cancer associated conditions, the proposed legislation would effectively prohibit health plans from relying on guidelines established by cancer experts to reduce the use of treatments that are more toxic, less effective, and/or more costly than the standard of care.

What is Step Therapy? Health insurance providers' step therapy protocols are designed in collaboration with clinicians, and based on well-established and widely accepted scientific evidence and clinical information. Step therapy encourages prescribers to use prescription drugs in a measured approach based on research and data. Step therapy protocols are **not** put in place to delay or deny patients from getting evidence-based, appropriate medical care.

Wisconsin Law Requires Exceptions to Step Therapy. The approach to step therapy described above is not just industry practice—it reflects the framework established by 2019 Wisconsin Act 12, which applies to all prescription drugs—including those prescribed in the treatment of metastatic cancer and cancer associated conditions.

2019 Act 12 also regulates the step therapy exception process. Under Wisconsin statute, insurers are required to grant an exception to a step therapy protocol if any of the following are satisfied:

The Voice of Wisconsin's Community Based Health Plans

- The prescription drug required under the step therapy protocol is contraindicated or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to cause a serious adverse reaction in the patient, decrease the ability to achieve or maintain reasonable functional ability in performing daily activities, or cause physical or psychiatric harm to the patient.
- The prescription drug required under the step therapy protocol is expected to be ineffective based on sound clinical evidence or medical and scientific evidence, the known clinical characteristics of the patient, and the known characteristics of the prescription drug regimen as described in peer-reviewed literature or the manufacturer's prescribing information for the prescription drug.
- The patient has tried the prescription drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action, under the policy or plan or a previous policy or plan, the patient was adherent to the prescription drug regimen for a time that allows for a positive treatment outcome, and the patient's use of the prescription drug was discontinued by the patient's provider due to lack of efficacy or effectiveness, diminished effect, or adverse event.
- The patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while covered under the policy or plan or a previous policy or plan.

Finally, 2019 Act 12 provides that an insurer must grant or deny a request for any exception to the step therapy protocol within three business days of receipt of the complete, clinically relevant written documentation required to support a step therapy exception request or the receipt of a request to appeal a previous decision. In exigent circumstances, an insurer must grant or deny a request for an exception to the step therapy protocol by the end of the next business day after receipt of the complete, clinically relevant written documentation supporting a step therapy exception request.

Community-based health plans respectfully request members reject Assembly Bill 745 and allow well-established clinical best practices and the existing step therapy exception process under state law to guide patients with metastatic cancer or cancer associated conditions to safe and effective treatments.



To: Chairperson Joe Sanfelippo
Members, Assembly Committee on Health

From: R.J. Pirlot, Executive Director
Rebecca Hogan

Date: February 16, 2022

Re: Opposition to AB 745, prohibiting step therapy protocols for certain cancer drugs

The Alliance of Health Insurers (AHI) is a nonprofit state trade advocacy organization created to promote essential and effective health insurance industry regulations that serve to foster innovation, eliminate waste, and protect Wisconsin health care consumers. We oppose Assembly Bill 745 and appreciate the opportunity to share our concerns with the Assembly Committee on Health.

Once a drug is on the market, a physician can prescribe it as he or she sees fit, including uses that are not approved by the FDA and/or where the science supporting the drug's use may not yet be fully developed or be as robust. Step therapy protocols and other prior authorization-like protocols rely on evidence-based medicine to dictate whether a drug should be covered in a particular clinical situation. While everyone would like to believe their provider is practicing optimal medicine, that's not always the case. Insurance company utilization management practices are a check and balance to the medical system, with health plans employing healthcare professionals to help ensure treatments are timely, appropriate, and safe.

Specifically, to this bill and certain cancer drugs, AHI plans generally do not have concerns with a prohibition of step therapy protocols for chemotherapy. Our plans are concerned with the language in the bill about cancer-associated conditions. There are many associated conditions with metastatic cancers, a most common one being nausea. For the numerous associated conditions, plans should be allowed to use typical utilization management practices and, particularly, if we are using practicing oncologists in that review.

We are also concerned with the vagueness of the language in section four, lines 17-20. The bill is not acknowledging there are many articles about best practices in medicine and peer-reviewed publications based on evidence-based research. Sometimes these are in conflict. Plans use their utilization management practices to work through potentially self-serving and conflicting information. At minimum, you should acknowledge the fluid nature of medical treatment and require a "gold-standard" or prevailing standard of care.

Thank you for this opportunity to submit testimony today and we respectfully ask you oppose Assembly Bill 745.