

2025 SENATE HUMAN SERVICES

SB 2248

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee Fort Lincoln Room, State Capitol

SB 2248
1/29/2025
10:15 a.m.

Relating to step therapy protocols; to provide for a report to the legislative assembly; to provide for application; and to provide an expiration date.

10:15 a.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Associated conditions
- Caretaker's responsibilities
- Cost of living
- Commonality of metastatic breast cancer

10:16 a.m. Senator Barta introduced the bill.

10:20 a.m. Bobbie Will, State Policy and Advocacy Manager for Susan G. Komen, testified in favor and submitted testimony #32355, #32356, #32357, #32358, and #32359.

10:29 a.m. Arik Spencer, President of the Greater North Dakota Chamber, testified in opposition and submitted testimony #32573.

10:43 a.m. Rebecca Fricke, Executive Director of the North Dakota Public Retirement system, testified in neutral and submitted testimony #32208.

Additional written testimony:

Courtney Koebele, Executive Director of North Dakota Medical Association, submitted testimony in favor #32344.

Dr. Tara Harding, Doctorate Nurse Practitioner of Simply You Wellness, submitted testimony in favor #32396.

Marcus Caruso, Government Affairs Prime Therapeutics, submitted testimony in opposition #32252.

Michelle Mack, Pharmaceutical Care Management Association, submitted testimony in opposition #32470.

10:49 a.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

TESTIMONY OF REBECCA FRICKE

Senate Bill 2248 – Step Therapy Protocol Limitations for Metastatic Cancer

Good Morning, Madame Chair, and members of the committee. My name is Rebecca Fricke and I am the Executive Director of the North Dakota Public Employees Retirement System, or NDPERS. I appreciate the committee taking the time to analyze Senate Bill 2248, which places limitations on step therapy protocols for metastatic cancer. I am here today on behalf of the NDPERS Board to provide information in a neutral capacity so the policy makers are able to make an informed decision regarding the bill.

Senate Bill 2248 does the following:

- Adds definition of “associated condition” for step therapy protocols, along with limitations
- States that health plans may not require a step therapy protocol for coverage of a recommended prescription drug if approved by the US FDA if prescribed to treat the individual’s diagnosis of metastatic cancer or an associated condition
 - Expands previous language which prohibited step therapy solely to the treatment of metastatic cancer
- Complies with NDCC section 54-03-28(3) that health insurance plan mandates first apply to NDPERS.

Our consultant estimates that the bill would not have a financial impact on the NDPERS health insurance plan and therefore, a fiscal note is not provided. Currently, the plan does not have any step therapy protocols in place that require members to use a certain formulary before moving to a provider’s recommendation.

A possible amendment that I ask be considered is to exclude the NDPERS Medicare Part D Plan. This amendment is attached to my testimony. Medicare Part D Plans are regulated by the Centers for Medicare and Medicaid Services and have specific step therapy protocols that must be adhered to.

Senate Bill 2248 was a bill introduced during the interim, with the analysis provided to the Employee Benefits Programs Committee, which gave the bill a favorable recommendation. The consultant analysis provided to the committee is included as an attachment to the end of my testimony (please note this was bill draft 124, and then rewritten as bill draft 547, during the interim session).

Madam Chair, I appreciate the committee taking the time to learn more about the impact this bill will have to our state. This concludes my testimony, and I'd be happy to answer any questions the committee may have.

PROPOSED AMENDMENTS TO

SENATE BILL NO. 2248

Introduced by

Senators Barta, Dever, Lee

Representatives D. Ruby, Weisz, Louser

1 A BILL for an Act to amend and reenact section 19-02.1-16.3 of the North Dakota Century
2 Code, relating to step therapy protocols; to provide for a report to the legislative assembly; to
3 provide for application; and to provide an expiration date.

4 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

5 **SECTION 1. AMENDMENT.** Section 19-02.1-16.3 of the North Dakota Century Code is
6 amended and reenacted as follows:

7 **19-02.1-16.3. Pharmacy benefits managers - Step therapy protocols - Limitations.**

8 1. As used in this section:

9 a. "Associated condition" means a symptom or side effect associated with
10 metastatic cancer or its treatment and which, in the judgment of the health care
11 practitioner, further jeopardizes the health of an individual if left untreated.

12 b. "Metastatic cancer" means cancer that has spread from the primary or original
13 site to lymph nodes, nearby tissues, or other parts of the body.

14 ~~b.c.~~ "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.

15 ~~c.d.~~ "Step therapy protocol" means a protocol requiring an individual use a drug, or
16 sequence of drugs, other than the prescription drug, or sequence of prescription
17 drugs, the individual's health care provider recommends for the individual's
18 treatment, before the pharmacy benefits manager or health plan allows coverage
19 for the recommended prescription drug, or sequence of prescription drugs.

20 2. A pharmacy benefits manager or a health plan may not require a step therapy protocol
21 for coverage of a recommended prescription drug, or sequence of prescription drugs,
22 approved by the United States food and drug administration if:

- 1 a. The recommended prescription drug, or sequence of prescription drugs, is
- 2 prescribed to treat the individual's diagnosis of metastatic cancer or an
- 3 associated condition; and
- 4 b. The use of the recommended prescription drug, or sequence of prescription
- 5 drugs, is consistent with the United States food and drug administration-approved
- 6 indications or is supported by peer-reviewed medical literature.
- 7 3. This section does not require coverage of a nonformulary prescription drug.
- 8 4. [This section does not apply to the Medicare Part D prescription drug coverage plan.](#)

9 **SECTION 2. PUBLIC EMPLOYEES RETIREMENT SYSTEM - STEP THERAPY**

10 **PROTOCOLS FOR ASSOCIATED CONDITIONS OF METASTATIC CANCER - REPORT TO**

11 **LEGISLATIVE ASSEMBLY.** Pursuant to section 54-03-28, the public employees retirement
12 system shall prepare and submit for introduction a bill to the seventieth legislative assembly to
13 repeal the expiration date for this Act and to extend step therapy protocols for associated
14 conditions of metastatic cancer to all group and individual health insurance policies. The public
15 employees retirement system shall append a report to the bill regarding the effect of the step
16 therapy protocols for associated conditions of metastatic cancer on the system's health
17 insurance programs, information on the utilization and costs relating to the coverage, and a
18 recommendation regarding whether the coverage should be continued.

19 **SECTION 3. APPLICATION.** This Act applies to health insurance benefits coverage
20 provided by the uniform group insurance program under chapter 54-52.1 which begins after
20 June 30, 2025, and which does not extend past June 30, 2027.

21 **SECTION 4. EXPIRATION DATE.** This Act is effective through June 30, 2027, and after that
22 date is ineffective.

Memo

Date: June 12, 2024

To: Rebecca Fricke - Executive Director, North Dakota Public Employees Retirement System
Representative Austen Schauer - Chair, Legislative Employee Benefits Programs
Committee, North Dakota State Government

From: Tim Egan, Dan Plante, Ford Edgerton, and Karno Sarkar - Deloitte Consulting LLP

Subject: **FINANCIAL REVIEW OF PROPOSED BILL 25.0124.01000**

Deloitte Consulting LLP (Deloitte 'I') was engaged to review the proposed legislation and the potential financial impact to the Uniform Group Insurance Program (Program) administered by the North Dakota Public Employees Retirement System (NDPERS), as well as other considerations that may contribute to the evaluation of the legislation.

The information included in the review relies on data provided by NDPERS, as well as publicly available data and industry studies. From the data provided by NDPERS, some of these data sources were developed by NDPERS, while others were prepared or created by third parties and delivered to NDPERS.

As part of the review, all data was reviewed for reasonableness, but an audit was not performed on the data. To the extent the data contains errors or anomalies that were unknown at the time the data was provided, the analysis may be affected by those issues.

OVERVIEW OF PROPOSED BILL

The Bill amends and reenacts sections 19-02.1-16.3 and 26.1-36.6-03 of the North Dakota Century Code relating to step therapy protocols and self-insurance health plans. The amended legislation does the following:

- Amends section 19-02.1-16.3 to include the definition of an “associated condition”
- Restates the definitions of “metastatic cancer”, “pharmacy benefits manager”, and “step therapy protocol”
- Amends current regulation on step therapy that prohibits the use of step therapy protocols for any member seeking prescription drugs to treat metastatic cancer or an associated condition
 - Previous language limited to prohibition of step therapy solely to the treatment of metastatic cancer

ESTIMATED FINANCIAL IMPACT

Based on the current offerings and the stipulations within the current legislation, it is anticipated the proposed legislation will have no impact on the Uniform Group Insurance Program. The Uniform Group Insurance Program currently does not have any step therapy protocols in place that require members to use a certain formulary before moving to a provider's recommendation.

OTHER CONSIDERATIONS

The Uniform Group Insurance Program's healthcare vendor, Sanford Health, currently does not have any step therapy protocols in place. However, Sanford does partner with a specialty vendor, Eviti, to assist cancer patients in navigating their care. Eviti utilizes up-to-date clinical and medical oncology guidance or evidence to assist oncology patients in their care journey. This includes collecting prescription drug data and providing recommendations on effective medications to support cancer diagnoses. However, Eviti is not a step therapy vendor; the objective of Eviti is to assist in the care plan, not navigate to less costly treatments.

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January 29, 2025

The Honorable Judy Lee
Human Services Committee

Via Online Testimony Submission: <https://ndlegis.gov/legend/committee/testimony/public-testimony/4082/?hearing=10569>

RE SB 2248: A BILL for an Act to amend and reenact section 19-02.1-16.3 of the North Dakota Century Code, relating to step therapy protocols; to provide for a report to the legislative assembly; to provide for application; and to provide an expiration date: Oppose

Dear Chair Lee and Members of the Senate Human Services Committee:

Thank you for the opportunity to comment on SB 2248. I represent Prime Therapeutics (Prime), a pharmacy benefit manager (PBM) owned by 19 not-for-profit Blue Cross and Blue Shield Insurers, subsidiaries, or affiliates of those Insurers, including Blue Cross & Blue Shield of North Dakota. SB 2248 seeks to restrict step therapy protocols for “associated conditions” for metastatic cancer, which is defined as a symptom or side effect associated with metastatic cancer or its treatment. It is for this reason that Prime Therapeutics opposes this bill.

Prime helps people get the medicine they need to feel better and live well by managing pharmacy benefits for health plans, employers, and government programs including Medicare and Medicaid. Our company manages pharmacy claims for more than 30 million people nationally and offers clinical services for people with complex medical conditions. Our business model relies on transparency and advocating for simpler, lowest-net-cost pricing for drugs. Importantly, Prime is not focused on driving profit margins. To control costs, Prime’s clients rely on our clinical expertise and drug management tools, such as step therapy.

Prime fully recognizes the need to put all patients first when it comes to care, and Step Therapy is way to do this. Providing an exception to Step Therapy for “associated conditions” as defined in this bill will make it difficult to control costs and care for the entire insured population in North Dakota. We believe in the clinical value of Step Therapy, which is why we are in opposition.

Step therapy programs promote use of safe and cost-effective drugs.

Step therapy programs are clinically based, cost-effective programs used by insurers to encourage use of existing, highly effective, and safe medications before “stepping up” to high-cost drugs.

Step therapy programs:

- Encourage more appropriate use of medicines which may be prone to abuse, misuse.
- Encourage use of cost-effective first line therapy that is therapeutically equivalent and clinically appropriate
- Hold down out of pocket drug costs for North Dakota citizens, plan sponsors (i.e. employers), and insurance plans.
- Step therapy may be used to reduce the risk of overmedication, prescription drug abuse, and addiction.

Costs

As mentioned above, Step Therapy is a tool used to control costs for the entire insured population. Making exceptions to Step Therapy can put the cost on the back of the rest of the insured population through premium increases due to the responsibility of the insurance company to limit risk to their entire population. It’s important to note that an increase in costs can lead to issues with medication adherence and/or health care in general. When a person can no longer afford their premiums, that person cannot seek the treatment/medication

they need.

Respectfully,



Marcus Caruso

Government Affairs, Prime Therapeutics

Cell: 612.845.9870 | Email marcus.caruso@primetherapeutics.com



Senate Human Services Committee
SB 2248
January 29, 2025

Good morning, Chair Lee and Committee Members. I am Courtney Koebele and I serve as executive director of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students.

NDMA supports SB 2248. This bill adds the words “associated conditions” to the current ban on step therapy for metastatic cancer.

Step Therapy necessitates the “fail first” drug therapy requirements, in which patients are forced by insurers to try, and fail, with one or more medications before the cost of the medication originally prescribed will be covered. This process ultimately wastes critical time in treatment, which some patients simply cannot afford to lose.

SB 2248 removes unnecessary barriers and allows patients to gain access to the medication they need at a faster pace. These important provisions would expedite the treatment process for patients who cannot afford to lose valuable time to adhere to insurance policies’ procedures and would allow physicians, who are most in-tune with the patients’ specific needs, to make the ultimate and best decision on the best possible course of medical treatment.

NDMA urges a do pass on SB 2248. Thank you for your time today. I would be happy to answer any questions you may have.

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.

- 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.

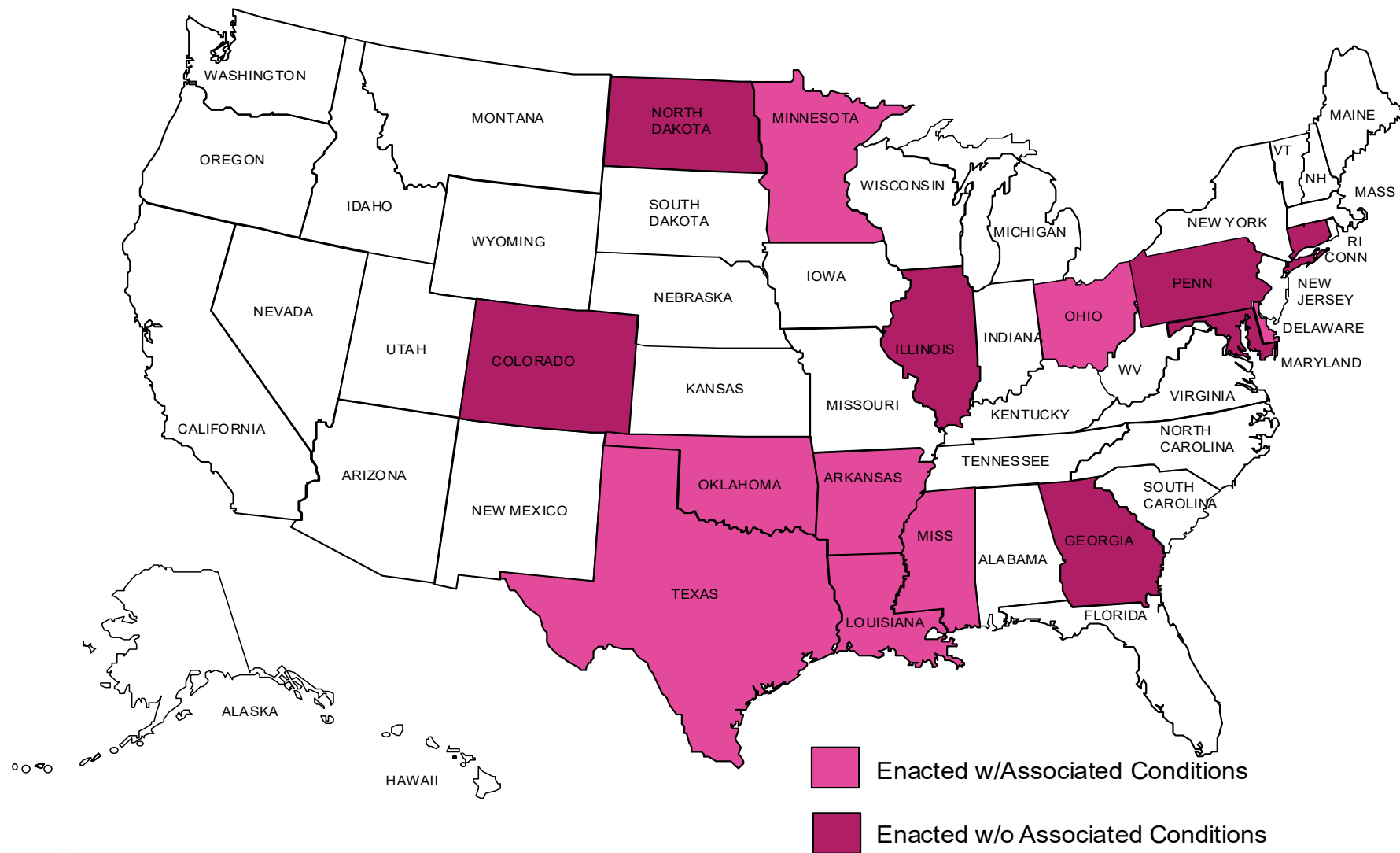
CRITICAL ACCESS

- 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.



Susan G. Komen
Bobbie Will
bwill@komen.org

Metastatic Step Therapy Enacted Legislation





Testimony of Susan G. Komen – Bobbie Will
SB 2248-Metastatic Step Therapy-add Associated Conditions
Senate Human Services

Thank you Chair Lee and Members of the Committee. My name is Bobbie Will the State Policy and Advocacy Manager for Susan G. Komen. I am here to testify in support of SB 2248. Advocating for those living with Stage 4, metastatic breast cancer, and also for those who will be diagnosed with metastatic cancer in the future.

Metastatic breast cancer, also called Stage 4 or advanced breast cancer, is breast cancer that has spread beyond the breast and nearby lymph nodes to other organs in the body, most often the bones, lungs, liver or brain. Treatment for metastatic breast cancer focuses on extending life and maintaining quality of life.

Step therapy, also referred to as “fail first,” requires a patient to first try a health plan preferred drug, have that drug fail them- meaning the treatment didn’t work for the patient-before they can use the treatment their provider prescribed. This health plan technique is used in an attempt to control costs; despite evidence showing step therapy requirements often adversely impact a patient’s treatment and health outcomes. Treatments are highly personalized and must be based on the decisions between the patient and their health care providers in a timely manner.

North Dakotans who have been diagnosed with metastatic cancer do not have the time to wait and try drug after drug while waiting to finally get the drug that their provider originally wanted them to take.

In 2019, North Dakota did pass metastatic step therapy protocol legislation and SB 2248 would ensure that associated conditions are added in the protocols.

Associated conditions means symptoms or side effects associated with advanced, metastatic cancer and/or its treatment. Side effects include, but are not limited to, nausea, low white blood cell count, diarrhea, depression and pain. All metastatic cancer treatments have possible side effects and most people have side effects from treatments. For many people living with metastatic cancer, side effects can be managed and even prevented with the right medications.

Most step therapy protocols rely on generalized information regarding patients and their treatments and don’t consider unique experiences, previous responses to treatments and any comorbidities. Additionally, step therapy policies are particularly burdensome in oncology, given the individualized nature of modern cancer treatments. We believe that



treatment decisions are most effectively made through a collaborative process involving patients and their providers, prioritizing individual needs and not based on insurer policies.

We ask you to vote in favor of SB 2248 because physicians should have the opportunity to choose the best course of treatment and not have to rely on insurer cost containment policies.

Bobbie Will

State Policy & Advocacy Manager – MT, ND, SD & WY

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NovaRest
ACTUARIAL CONSULTING

January 8, 2025

Analysis of 25.0547.02000 Step Therapy Protocol Limitations on Associated Conditions of Metastatic Cancer

Prepared for the North Dakota Legislative Council
Pursuant to North Dakota Century Code 54-03-28

Amanda Rocha
Richard Cadwell, ASA, MAAA
Donna Novak, FCA, ASA MAAA



Table of Contents

I.	Evaluation of Proposed Mandated Health Insurance Services	3
II.	Process	4
III.	Mandated Prohibition of Step Therapy Protocols on Drugs Used to Treat Symptoms or Side Effects of Metastatic Cancer Benefits	5
	Background	5
	Condition.....	5
	Treatment	6
	Prevalence of Coverage	6
	State Employee Retiree Group Health Insurance	6
	Essential Health Benefits Benchmark Plan and Commercial Coverage.....	7
	Analyses Concerning Mandated No Step Therapy for Drugs Used to Treat Symptoms or Associated Conditions of Metastatic Cancer.....	8
IV.	Other State Step Therapy Laws Regarding Metastatic Cancer Drugs	11
V.	Limitations	13
VI.	Reliance and Qualifications	13
	Appendix A: Definitions	14
	Appendix B: NovaRest Assumptions and Methodology	15
	Appendix C: List of prescription drug(s) identified to treat symptoms or side effects of metastatic cancer	16
	References	18



I. Evaluation of Proposed Mandated Health Insurance Services

The North Dakota Legislative Council (NDLC) was asked to perform a cost benefit analysis of 25.0547.02000¹ (Draft Bill or the Bill) for the standing Legislative Assembly pursuant to the North Dakota Century Code (NDCC) 54-03-28. The Draft Bill amend and reenact section 19-02.1-16.3 of the NDCC, provides for a report; provides for an application; and provides an expiration date.

The Draft Bill 25.0547.02000, as proposed, states that “the recommended prescription drug, or sequence of prescription drugs, is prescribed to treat the individual's diagnosis of metastatic cancer or an associated condition.” An associated condition is specified to mean a symptom or side effect associated with metastatic cancer or its treatment, and which further jeopardizes the health of an individual if left untreated per the judgement of a health care practitioner.

NovaRest, Inc. has been contracted as the NDLC’s consulting actuary, and has prepared the following evaluation of the elimination of step therapy protocols for drugs used to treat symptoms or associated conditions of metastatic cancer.

This report includes information from several sources to provide more than one perspective on the proposed mandate to provide an unbiased report. As a result, there may be some conflicting information within the contents. Although we only used sources that we considered credible, we do not offer any opinions regarding whether one source is more credible than another.

NovaRest was asked to provide estimates for the North Dakota Public Employee Retirement System (NDPERS), as well as the impact if the Draft Bill was expanded to the commercial market. We were provided information on four plans administered by NDPERS, 1. Grandfathered PPO/Basic Plan, 2. Non-Grandfathered PPO/Basic Plan, 3. High Deductible Health Plan (HDHP), and 4. Dakota Retiree Plan. For the commercial market we used information from the National Association of Insurance Commissioners Supplemental Health Care Exhibit (SHCE) for individual, small group, and large group markets. Generally, when considering benefits for the individual and small group we considered the Affordable Care Act (ACA) single-risk pool plans, and for large group we considered a sample of plans from the largest three insurers in the North Dakota market.



The NDPERS non-Medicare plans use the same Sanford Health Plan formulary, and we did not identify step therapy on any of the identified prescription drug(s) used to treat symptoms or side effects of metastatic cancer. See Appendix C for the list of prescription drugs identified to treat symptoms or side effects of metastatic cancer.

The NDPERS Humana Insurance Company Medicare prescription drug plan uses a different formulary and only applies step therapy to brand versions of Imiquimod, also known as Zyclara. The generic version of Imiquimod, and all other identified prescription drug(s) used to treat symptoms or side effects of metastatic cancer are not subject to step therapy but they are subject to cost-sharing and Zyclara is a higher tier drug that requires significantly more member out-of-pocket costs. Therefore, we expect little increase in the utilization of Zyclara as the generic version is significantly less expensive, and we estimate there will be no impact on NDPERS Medicare from this proposed mandate.

In the commercial market, all insurers, with the exception of Medica, do not require step therapy for prescription drug(s) used to treat symptoms or side effects of metastatic cancer. Therefore, NovaRest estimates that additional percentage impact of eliminating step therapy protocols for drugs used to treat symptoms or associated with metastatic cancer to health care costs and premiums is 0.00% on a percent of premium basis and \$0.00 - \$0.03 on a per member per month (PMPM) basis for NDPERS and the individual, small group, and large group markets based on the insurer formularies. Please see Appendix B for NovaRest's assumptions and methodology.

Although there is no estimated impact, passing this mandate would ensure that future insurers or products in the market do not implement step therapy on current or future prescription drug(s) used to treat symptoms or side effects of metastatic cancer

II. Process

NovaRest was charged with addressing the following analyses regarding this proposed mandate:

- The extent to which the coverage will increase or decrease the cost of the service;
- The extent to which the coverage will increase the appropriate use of the service;
- The extent to which the coverage will increase or decrease the administrative expenses of insurers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders; and
- The impact of this coverage on the total cost of health care.

NovaRest reviewed literature (including reports completed for other states that were either considering or have passed similar legislation) and developed an independent estimate of the proposed mandate's impact on premiums.



III. Mandated Prohibition of Step Therapy Protocols on Drugs Used to Treat Symptoms or Side Effects of Metastatic Cancer Benefits

The Draft Bill would mandate no step therapy protocols for prescription drug(s) used to treat symptoms or side effects of metastatic cancer. It does not require coverage of a nonformulary prescription drug, which is important considering each formulary we reviewed do not include the identified drugs on their formulary. Additionally, many of the drugs identified also include other utilization management such as prior authorization or prescription quantity limits even where step therapy is not included. These other utilization management methods are not impacted by the Draft Bill.

Background

Condition

Metastasis is when cancer spreads to areas of the body other than where it started. Metastatic cancer is also called metastatic tumor, metastasis (one cancerous tumor), metastases (more than one cancerous tumor), advanced cancer, secondary, cancer, or stage IV cancer.² Almost all cancers have the potential to metastasize but whether it does or not depends on the type, size, and location of the cancer among other factors.³

Metastatic cancer happens when cancer cells break off from the original tumor where they originated. There are three ways in which metastases can occur. One way is that cancer cells can grow directly into the tissue surrounding the primary tumor, they can travel through the bloodstream to other locations like other organs or bones, and they can move through the lymphatic system to other lymph nodes.⁴

There are currently 623,405 people living with the most common metastatic cancers in the United States.⁵ With a total population of 340,110,988⁶ in the United States, this translates to approximately 0.2% of the population living with metastatic cancer.

There are not always symptoms experienced with metastatic cancer. Some general signs and symptoms of advanced and metastatic cancer can include loss of energy and feeling tired and/or weak, unexpected weight loss, pain, shortness of breath or trouble breathing, and finding a new lump or swollen lymph node.⁷ If there are more serious symptoms, it would depend on where the cancer has spread. Some common symptoms are pain and fractures when cancer has spread to the bone, headache, seizures, or dizziness when cancer has spread to the brain, shortness of breath when cancer has spread to the lung, and jaundice or swelling in the belly when cancer has spread to the liver.⁸ Some of the most common sites of metastases are adrenal glands, bones, brain, liver, lungs, liver, and peritoneum.⁹



Treatment

There are many treatments for metastatic cancer that are determined by the type of cancer, where it has spread, and any of the patient's other health issues. Systemic therapy is commonly used for metastatic cancers. This may be intravenous or oral and is beneficial since it can address visible and microscopic cancer throughout the body.¹⁰ Other treatments can include radiotherapy, chemotherapy, hormonal therapies, targeted therapies, surgery, and palliative care.¹¹

The drugs used to treat symptoms of metastatic cancer also depend on the type of cancer and where it has spread. For example, bone metastases where cancer has spread to the bone, are commonly treated with bisphosphonates. Bisphosphonates are drugs that help slow the breakdown of bone and are used to help manage and prevent problems like hypercalcemia, bone pain, and broken bones.¹² The National Cancer Institute (NIH) has compiled a list of drugs approved by the FDA for some conditions caused by the cancer or its treatment.¹³ Please see the list of drugs in Appendix C.

Prevalence of Coverage

State Employee Retiree Group Health Insurance

The formulary for the NDPERS non-Medicare plans do not require step therapy for drugs used to treat symptoms of metastatic cancer. The most recent Sanford NDPERS Dakota Plan Members Formulary¹⁴ was checked for the drugs listed in the table in Appendix C.

The formulary for the NDPERS Medicare prescription drug plan included step therapy on brand versions of Imiquimod. Our understanding is that the generic version of Imiquimod would currently be required to be used first, prior to “stepping” to the brand version (Zyclara) which would not be permitted by the Draft Bill. The most recent Humana NDPERS prescription drug plan formulary was checked for the drugs listed in the table in Appendix C.¹⁵



Essential Health Benefits Benchmark Plan and Commercial Coverage

There are three insurers who offer the majority of the individual, small group, and large group insurance in North Dakota, per the 2023 SHCE, – Sanford Health Plan, BlueCross BlueShield North Dakota, and Medica Insurance Company. The drugs listed in the table above were searched for in each insurer’s formularies. Below are the formularies where we did not identify any step therapy for the drugs listed in Appendix C:

- Sanford ACA Compliant Individual/Small Group 4-Tier Formulary¹⁶
- Sanford ACA Compliant Individual/Small Group 6-Tier Formulary¹⁷
- Sanford Commercial 3-Tier (Large Group/Self-Funded) Formulary¹⁸
- Sanford Commercial 5-Tier (Large Group/Self-Funded) Formulary¹⁹
- Sanford Commercial 6-Tier (Large Group/Self-Funded) Formulary²⁰
- BCBSND Health Ins. Market Individual Small Group 4-Tier Formulary²¹
- BCBSND Health Ins. Market Individual Small Group 6-Tier Formulary²²
- BCBSND Large Group Drug Formulary²³

Please note that the bill does not require coverage of nonformulary prescription drugs. So, not all the drugs listed in the table above are covered by each insurer, but if they are, they do not require step therapy.

The only insurer in the commercial who required step therapy for some of these drugs on their formulary was Medica. Medica’s 2025 Commercial Drug List with ACA Preventive Drugs²⁴ requires step therapy for the following drugs used to treat symptoms associated with metastatic cancer:

- Dexamethasone oral tablets, dose pack
 - We note that Dexamethasone is available as a generic for many forms tablets, intensol, elixir, and oral solution without step therapy. Only the dose pack is subject to step therapy.
- Relistor subcutaneous solution
- Relistor subcutaneous syringe



Analyses Concerning Mandated No Step Therapy for Drugs Used to Treat Symptoms or Associated Conditions of Metastatic Cancer

The extent to which the coverage will increase or decrease the cost of the service.

There is expected to be no impact on the cost of the service for NDPERS non-Medicare plans. There are no step therapy protocols currently implemented for drugs used to treat symptoms or associated conditions of metastatic cancer. The proposed bill would not change that.

The NDPERS Medicare plan would likely remove the step therapy on brand versions of Imiquimod for the Humana prescription drug plan, which may increase the usage of brand versions of Imiquimod (particularly Zyclara) and may impact the cost. We expect a \$0 impact in the cost of Zyclara, due to the small amount of membership in the NDPERS Medicare plan, and the availability of the generic.

If the bill is expanded to include the commercial market, we would expect little to no impact as most insurers, with the exception of Medica, do not require step therapy for these drugs.

For Medica step therapy is applied to the Dexamethasone oral tablet dose pack, while a generic for many forms including tablets, intensol, elixir, and oral solution are available without step therapy. We expect a \$0 impact to the cost of the Dexamethasone oral tablet dose pack, based on potential utilization compared to the market size.

Medica also has step therapy on Relistor, which is included in Appendix C for constipation. Relistor is an expensive brand drug which we expect would only be used in select circumstances. We expect a \$0 impact on the cost due to additional usage likely being very small.



The extent to which the coverage will increase the appropriate use of the service.

For NDPERS non-Medicare we do not expect an increase in the use of any drugs, as all formulary drugs identified are already not subject to step-therapy.

For NDPERS Medicare there may be an increase in usage of Zyclara, however, as the generic version is less expensive and currently available without step therapy and we expect the increase in usage to be de minimis.

If the bill is expanded to include the commercial market, there may be a slight increase in the use of Dexamethasone oral tablet dose pack and Relistor which are subject to step therapy on Medica's formulary, however, Medica's market share is small and therefore we believe the increase in usage to be de minimis.

The extent to which the coverage will increase or decrease the administrative expenses of insurers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders.

The formulary for the NDPERS non-Medicare plans do not require step therapy for drugs used to treat symptoms of metastatic cancer, and therefore we expect a \$0.00 PMPM or 0.0% impact to administrative expenses or premiums as a result of the Draft Bill.

The formulary for the NDPERS Medicare prescription drug plan included step therapy on brand versions of Imiquimod. The removal of step-therapy on drugs may result in a slight decrease in administrative costs on the NDPERS Medicare prescription drug plan only if the Draft Bill is passed, but we believe the decrease is de minimis.

Regarding the premium impact, our understanding is that the generic version of Imiquimod would currently be required to be used first, prior to "stepping" to the brand versions which would not be permitted by the Draft Bill. However, we assume most prescriptions would be for the generic version, and while there is a significant difference in cost, we believe the impact would be very small. All other drugs identified, including other drugs in the same category of Imiquimod, are not subject to step therapy. Therefore, the impact on premiums is the number of prescriptions for the brand version of one formulary drug, where the generic was not prescribed. We believe this impact is de minimis, and therefore expect a \$0.00 PMPM or 0.0% impact to premiums.

If expanded to the commercial market, only Medica would be impacted. As with NDPERS Medicare, removal of step-therapy may decrease administrative costs. We estimate a de minimis impact, however.

Regarding the premium impact to the commercial market, we did not identify any drugs used to treat metastatic cancer associated conditions subject to step therapy on the Sanford Health Plan or Blue Cross Blue Shield North Dakota plan formularies. Therefore we estimate a \$0.00 PMPM or 0.0% of premium impact.



Medica is the only insurer who requires step therapy for drugs used to treat symptoms of cancer (Dexamethasone oral tablet dose pack and Relistor). Medica has membership in the small group and large group markets per the 2023 SHCE. Dexamethasone is available generic in many forms without step therapy, so the difference in cost of the dose pack would be the only impact. For Relistor, we estimated the increase in usage. We estimate a \$0.00 to \$0.03 PMPM increase to premiums or 0.00% (with rounding to the hundredth decimal place) increase to premiums to Medica only if language is expanded to the commercial market.

The impact of this coverage on the total cost of health care.

Changes to the cost of the service or utilization of the service would impact the total cost of health care in North Dakota. We do not anticipate any significant increase in the cost per drug, but the utilization of the services would likely increase slightly since these drugs would be offered to members without having to try other drugs as required by step therapy protocols. We estimate a \$0 increase in the total cost of health care with the passage of the Draft Bill to the NDPERS plans.

If the Draft Bill language is expanded to the North Dakota commercial market, we estimate less than a \$2,600 increase to the total cost of health care in North Dakota due to Medica removing step therapy on the Dexamethasone oral tablet dose pack and Relistor.



IV. Other State Step Therapy Laws Regarding Metastatic Cancer Drugs²⁵

There are many states who have passed laws regarding step therapy protocols. There are even fewer who prohibit step therapy for cancer drugs and none who prohibit step therapy for associated conditions of metastatic cancer. Below are the states who have passed laws limiting step therapy for cancer drugs:

Arkansas – Arkansas Code § 23-99-1114: Step therapy protocols must be created by either a multidisciplinary panel of experts following research and medical practice or in accordance with peer reviewed publications; insurer must follow and publish a clear and convenient process to request exemptions; exemption must be granted if protocol required drug is contraindicated or will likely cause serious adverse reaction, the drug is expected to be ineffective based on the known characteristics of the patient and drug, the patient has previously tried the drug or a similar drug, the drug is not in the best interest of the patient, or the patient is experiencing a positive therapeutic outcome on their current prescribed drug; determination required within seventy-two hours for nonurgent exemption requests and twenty-four hours for urgent exemption requests; insurers may not require step therapy for patients with metastatic cancer unless use of the preferred drug is consistent with FDA approved indications, the National Comprehensive Cancer Network indications, or peer-reviewed recognized medical literature.

Colorado – Colorado Revised Statutes: § 10-16-145: Prohibits step therapy requirements for patients with stage four advanced metastatic cancer unless the preferred drug is consistent with FDA approved indications, the National Comprehensive Cancer Network indications, or peer-reviewed recognized medical literature; insurers may not require step therapy when the patient has tried the step-therapy-required drugs under current or previous health insurance plan and drugs were discontinued for lack of efficacy or adverse effects.

Connecticut – Connecticut General Statutes § 38a-510 and § 38a-544: Prohibits insurers from requiring step therapy for longer than sixty days or for any stage IV metastatic cancer prescription drug; requires insurers to have override process for step therapy regimens if the patient's health care provider deems the step therapy drug regimen clinically ineffective after sixty days of use.

Hawaii Proposed HB 2194²⁶: Prohibits a health insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy prior to covering the insured for certain drugs prescribed by the insured's health care provider, under certain conditions.

Louisiana – Louisiana Revised Statute § 22:1053: Insurer must make step therapy override process easily accessible on their website; insurer must grant step therapy override request if the patient's provider can demonstrate that: the required drug has been ineffective in treating the patient, the required drug is reasonably expected to be ineffective based on the



known characteristics of the patient and drug, the preferred drug is contraindicated or will likely cause harm to the patient, the patient is currently receiving a positive therapeutic outcome for the condition under consideration, or the required drug is not in the best interest of the patient based on medical necessity; prohibits step therapy protocols for the treatment of stage-four advanced metastatic cancer or associated condition if the patient's current drug has an FDA or National Comprehensive Cancer Network indication, or is supported by medical literature; requires determination within seventy-two hours for nonurgent requests and twenty-four hours for urgent requests.

Maryland – Maryland Code, Insurance § 15-142: Prohibits insurers from imposing step therapy requirements if: the required drug has not been approved by FDA for the medical condition, or the patient's provider shows that the current prescription drug was ordered with the past 180 days and was effective in treating the patient's condition; prohibits insurers from imposing step therapy requirements for FDA approved drugs for treatment of patient's stage four advanced metastatic cancer when use of prescription drug is consistent with FDA approved indication or the National Comprehensive Cancer Network indication.

Minnesota – Minnesota Statutes Chapter 62Q § 62q.184: Requires insurers to make step therapy override process easily accessible on website; insurers must grant step therapy exception request if: the required drug is contraindicated or likely to harm the patient or likely to decrease the functional daily ability of the patient, the patient has tried the required drug and it was discontinued by the patient's provider for ineffectiveness or an adverse event, the patient is currently receiving a drug with a positive therapeutic outcome and the patient's provider indicated that a change is likely to be ineffective or cause harm; prohibits step therapy requirements for patients with stage four advanced metastatic cancer or associated conditions if use of the drug is consistent with FDA or National Comprehensive Care Network indications; requires determination within five days for nonurgent requests and seventy-two hours for urgent requests.

Nevada – 2021 Senate Bill 290 § 1: Requires insurers to permit patients with stage three or stage four cancer to apply for exemptions from step therapy protocols by having their provider present the clinical rationale for the exemption; requires insurers to grant step therapy protocol exemptions for patients with stage three or stage four cancer if the required drug has not been effective in treating the cancer, the delay of effective treatment would have severe or irreversible consequences for the patient, the required treatment is contraindicated or is likely to cause the patient harm or is likely to prevent the patient from engaging in daily living activities, or the condition of the patient is stable on their current drug.

North Dakota – North Dakota Century Code § 19-02.1-16.3: Insurers or pharmacy benefits managers may not require step therapy protocols for coverage of FDA approved prescription drugs for the treatment of cancer and usage of the drug is consistent with FDA approved indications or is supported by peer-reviewed medical literature.



V. Limitations

NovaRest has prepared this report in conformity with its intended use by persons technically competent to evaluate our estimate regarding Draft Bill No. 25.0547.02000. Any judgments as to the data contained in the report or conclusions about the ramifications of that data should be made only after reviewing the report in its entirety, as the conclusions reached by review of a section or sections on an isolated basis may be incorrect. Appropriate staff is available to explain and/or clarify any matter presented herein. It is assumed that any user of this report will seek such explanations as to any matter in question.

NovaRest did not have access to actual insurer claims data by service type or reimbursement rates. NovaRest also did not perform an insurer data request for the commercial market, or have access to the most recent rate filings in North Dakota. NovaRest has developed projections in conformity with what we believe to be the current and proposed operating environments and are based on best estimates of future experience within such environments. It should be recognized that actual future results may vary from those projected in this report. Factors that may cause the actual results to vary from the projected include new insurance regulations, differences in implementation of the required coverage by NDPERS, changes in medical treatments and practices, accounting practices, changes in federal and/or local taxation, external economic factors such as inflation rates, investment yields and ratings, and inherent potential for normal random fluctuations in experience.

VI. Reliance and Qualifications

We are providing this report to you solely to communicate our findings and analysis of Draft Bill 25.0547.02000. The reliance of parties other than the North Dakota Legislative Council (NDLC) on any aspect of our work is not authorized by us and is done at their own risk.

To arrive at our estimate, we made use of information provided by Sanford Health Plan for NDPERS, carrier rate filings and other public sources including census data and National Association of Insurance Commissioners financial data. We did not perform an independent investigation or verification. If this information was in any way inaccurate, incomplete, or out of date, the findings and conclusions in this report may require revision.

This memorandum has been prepared in conformity with the applicable Actuarial Standards of Practice.

We have no conflicts of interest in performing this review and providing this report.

We are members of the American Academy of Actuaries and meet that body's Qualification Standards to render this opinion. We meet the Qualification Standards promulgated by these professional organizations to perform the analyses and opine upon the results presented in this Actuarial Report.



Appendix A: Definitions

- a) “Associated condition” 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.
- b) “Metastatic cancer” means cancer that has spread from the primary or original site to lymph nodes, nearby tissues, or other parts of the body.
- c) “Pharmacy benefits manager” has the same meaning as in section 19-03.6-01.
- d) “Step therapy protocol” means a protocol requiring an individual use a drug, or sequence of drugs, other than the prescription drug, or sequence of prescription drugs, the individual’s health care provider recommend for the individual’s treatment, before the pharmacy benefits manager or health plan allows coverage for the recommended prescription drug, or sequence of prescription drugs.



Appendix B: NovaRest Assumptions and Methodology

Data

- NDPERS provided the premiums, claims, membership, and age distribution in NDPERS for 2023.
- The age and gender proportions of North Dakota's population are based on the 2023 Vintage population estimates.²⁷
- Health premiums and member months for the individual, small group, and large group markets are based on the 2023 Supplemental Health Care Exhibit (SHCE).

Assumptions

- We relied on the National Cancer Institute's list of the drugs approved to treat associated conditions of cancer.²⁸
- The formularies for Sanford, Medica, and BlueCross BlueShield of North Dakota's formularies were used to determine if the approved drugs are covered and if there are any limitations on those drugs.
- Zyclara was identified as requiring step therapy in the NDPERS Medicare prescription drug plan, while the generic version Imiquimod is available without step therapy. Member cost sharing for Imiquimod is significantly lower than for Zyclara and we believe due to the cost a very small percentage of people would opt for Zyclara, therefore we assumed a de minimis impact.
- The drugs that require step therapy in the commercial market are dexamethasone oral tablets, dose pack and Relistor. Dexamethasone is used to treat anemia, drug toxicity, and high blood calcium. The percentage of cancer patients who experience these symptoms is 22.7% - 90% for anemia²⁹, 19% - 53% for drug toxicity³⁰, and 10% - 20% for high blood calcium³¹. Relistor is prescribed to patients who experience constipation which accounts for about 43% - 58% of cancer patients.³²

Methodology

- We only expect an additional cost for the commercial market, where we applied the percentage of people with metastatic cancer to Medica's small group and large group populations since they are the only insurer to require step therapy for drugs used to treat symptoms of metastatic cancer.
- Calculated the number of these cancer patients who experience anemia, drug toxicity, high blood calcium, and constipation. These are the symptoms that are treated with dexamethasone and Relistor.
- Found costs for dexamethasone and Relistor and compared them to alternative drugs for them. We assumed no cost for the dexamethasone oral tablets since other options for dexamethasone are covered in the formulary with no restrictions. They are dexamethasone intensol, dexamethasone oral elixir, dexamethasone oral solution, and dexamethasone oral tablet. As an alternative to Relistor we compared the cost with Movantik.
- Calculated the difference between the drugs that require step therapy and alternative drugs who do not, which resulted in a 0.00% impact to premium (rounded to the nearest hundredth).



Appendix C: List of prescription drug(s) identified to treat symptoms or side effects of metastatic cancer³³

Condition	Medication
Actinic Keratosis	Aminolevulinic Acid (Ameluz, Levulan Kerastick) Fluorouracil (5-FU) Topical (Carac, Efudex, Fluoroplex, Tolak) Imiquimod (Aldara, Zyclara)
Aggressive Systemic Mastocytosis	Imatinib Mesylate (Gleevec) Midostaurin (Rydapt)
Anemia (Low Red Blood Cells)	Darbepoetin Alfa (Aranesp) Dexamethasone Epoetin Alfa (Epogen, Procrit, Retacrit) Lenalidomide (Revlimid) Luspatercept-aamt (Reblozyl) Prednisone
Carcinoid Syndrome	Lanreotide Acetate (Somatuline Depot)
Cardiac Toxicity (Heart Side Effects)	Dexrazoxane Hydrochloride (Zinecard) Uridine Triacetate (Vistogard)
Condyloma Acuminata (Genital Warts)	Imiquimod (Aldara, Zyclara) Recombinant Human Papillomavirus (HPV) Nonavalent Vaccine (Gardasil 9) Recombinant Human Papillomavirus (HPV) Quadrivalent Vaccine (Gardasil) Recombinant Interferon Alfa-2b (Intron A)
Constipation	Methylnaltrexone Bromide (Relistor)
Cytokine Release Syndrome	Tocilizumab (Actemra)
Drug Extravasation (Drug Leakage in Tissues)	Dexrazoxane Hydrochloride (Totect)
Drug Toxicity (Severe Side Effects)	Amifostine (Ethyol)—for Cisplatin Toxicity Dexamethasone Dexrazoxane Hydrochloride (Zinecard)—for Doxorubicin Toxicity Glucarpidase (Voraxaze)—for Methotrexate Toxicity Prednisone Uridine Triacetate (Vistogard)—for Capecitabine or Fluorouracil Toxicity
Hemophagocytic Lymphohistiocytosis	Emapalumab-lzsg (Gamifant)
Hemorrhagic Cystitis (Bleeding in the Bladder)	Mesna (Mesnex)



Hepatic Veno – occlusive Disease (Blocked Liver Veins)	Defibrotide Sodium (Defitelio)
Hypercalcemia Malignancy (High Blood Calcium)	Denosumab (Xgeva) Dexamethasone Pamidronate Disodium (Aredia) Prednisone Zoledronic Acid (Zometa)
Malignant Effusion	Bleomycin Talc (Sterile Talc Powder, Sclerosol Intrapleural Aerosol, Steritalc) Thiotepa (Tepadina)
Mucositis (Inflamed Mucous Membranes)	Palifermin (Kepivance)
Nausea and Vomiting	Aprepitant (Cinvanti, Emend) Granisetron (Sancuso, Sustol) Granisetron Hydrochloride Netupitant and Palonosetron Hydrochloride (Akynzeo) Ondansetron Hydrochloride (Zofran) Palonosetron Hydrochloride (Aloxi) Rolapitant Hydrochloride (Varubi)
Neurotoxicity (Nervous System Side Effects)	Uridine Triacetate (Vistogard)
Neutropenia (Low Blood Neutrophils)	Filgrastim (Granix, Neupogen, Nivestym, Zarxio) Pegfilgrastim (Fulphila, Neulasta, Nyvepria, Udencyca, Ziextenzo)
Osteoporosis (Loss of Bone Density)	Denosumab (Prolia) Raloxifene Hydrochloride (Evista)
Paroxysmal Nocturnal Hemoglobinuria	Ravulizumab-cwvz (Ultomiris)
Renal Toxicity (Kidney Side Effects)	Amifostine (Ethyol)
Skin Changes Due to Cutaneous Metastases	Bexarotene (Targretin)
Thrombocytopenia (Low Blood Platelets)	Caplacizumab-yhdp (Cablivi) Dexamethasone Eltrombopag Olamine (Promacta) Fostamatinib Disodium (Tavalisse) Prednisone Romiplostim (Nplate)
Tumor Lysis Syndrome (Cell Breakdown and Organ Damage)	Rasburicase (Elitek)
Xerostomia (Dry Mouth)	Amifostine (Ethyol)



References

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SB 2248

Susan G. Komen/Bobbie Will-Testimony supplemental document Incorrect information to point out on the NovaRest Report on Metastatic Step Therapy

The report on page 11 states that there are **no** states that have prohibited step therapy **for associated conditions** of metastatic cancer in state law. This is inaccurate information. Pages 11-12 list specific state statutes, but some of the laws listed are from prior authorization laws, some step therapy laws, and not relevant to metastatic cancer step therapy prohibition laws. The only state law in the report that is metastatic step therapy is Louisiana, which shows associated conditions, at the top of page 12, although the report said no state has laws for associated conditions.

Below eight states are referencing the law for metastatic cancer with associated conditions.

1. **Arkansas**- *Arkansas Code 23-99-1114- [Act 699](#)*-

SECTION 5. Arkansas Code § 23-99-1114, concerning limitations on step therapy under the Prior Authorization Transparency Act, is amended to add an additional subsection to read as follows:

(d)(1) An insurance policy that provides coverage for the treatment of metastatic cancer shall not limit or exclude coverage under the health benefit plan for a drug approved by the United States Food and Drug Administration that is on the prescription drug formulary of the insurance policy by mandating that a covered person with metastatic cancer undergo step therapy unless the preferred drug is consistent with best practices that:

(A) Use for the treatment of metastatic cancer **or associated conditions** under:

(i) The United States Food and Drug Administration¹⁶ approved indication; or
(ii) The National Comprehensive Cancer Network Drugs and Biologics Compendium indication; or

(B) Evidence-based, peer-reviewed, recognized medical literature.

(2) As used in subdivision (d)(1) of this section, "metastatic cancer" means cancer that has spread from a primary or original site of the cancer to surrounding or nearby tissues, lymph nodes, or other parts of the body.

2. **Texas**

SECTION 1. Chapter 1369, Insurance Code, is amended by adding Subchapter E-1 to read as follows:

SUBCHAPTER E-1. COVERAGE OF PRESCRIPTION DRUGS FOR STAGE-FOUR ADVANCED, METASTATIC CANCER

Sec. 1369.211. DEFINITIONS. In this subchapter:

(1) "Associated conditions" means the symptoms or side effects associated with stage-four advanced, metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardize the health of a patient if left untreated.

(2) "Stage-four advanced, metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body

Sec.1369.213. PROHIBITED CONDUCT. (a) A health benefit plan that provides coverage for stage-four advanced, metastatic cancer **and associated conditions** may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee:

fail to successfully respond to a different drug; or

prove a history of failure of a different drug.

(b) This section applies only to a drug the use of which is:

consistent with best practices for the treatment of stage-four advanced, metastatic cancer or an associated condition;

supported by peer-reviewed, evidence-based literature; and

approved by the United States Food and Drug Administration

3. Oklahoma

Effective: November 1, 2023

[63 Okl.St.Ann. § 7320](#)

§ 7320. Prohibiting step therapy requirements for certain drug to treat advanced metastatic cancer and associated conditions

For the purpose of prohibiting step therapy requirements for certain prescription drugs to treat advanced metastatic cancer and associated conditions.

As used in this section:

1. "Associated conditions" means the symptoms **or side effects associated** with advanced metastatic cancer or its treatment and which, in the judgment of the health care practitioner, will further jeopardize the health of a patient if left untreated; and

2. "Advanced metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.

Laws 2023, c. 81, § 1, eff. Nov. 1, 2023.

63 Okl. St. Ann. § 7320, OK ST T. 63 § 7320

Current with legislation of the Second Regular Session of the 59th Legislature (2024)

4. Louisiana

To amend and reenact [R.S. 22:1053\(A\) and \(D\)](#) and to enact [R.S. 22:1053\(E\)](#), relative to prescription drug benefits for persons with stage-four advanced, metastatic cancer; to prohibit denial of a prescription based upon step therapy or fail first protocols; to define key terms; to provide for an effective date; and to provide for related matters.

D. No health coverage plan shall use step therapy or fail first protocols as the basis to restrict any prescription benefit for the treatment of stage-four advanced, metastatic cancer or associated conditions if the prescribed drug is both of the following:

(1) Consistent with best practices for the treatment of stage-four advanced, metastatic cancer **or associated conditions**.

(2) Supported by peer-reviewed, evidenced-based medical literature

5. Mississippi

TO AMEND SECTION 83-9-36

SECTION 1. (1) As used in this section, the following terms shall be defined as provided in this subsection:

(a) "Associated conditions" means the symptoms or side effects associated with advanced, metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardizes the health of a patient if left untreated.

(b) "Advanced, metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.

(c) "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered by or issued by an insurer to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

(2) A health benefit plan that provides coverage for advanced, metastatic cancer **and associated conditions** may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee:

(a) Fail to successfully respond to a different drug; or

(b) Prove a history of failure of a different drug.

(3) This section applies only to a drug the use of which is:

(a) Consistent with best practices for the treatment of advanced, metastatic cancer or an associated condition;

(b) Supported by peer-reviewed, evidence-based literature; and

(c) Approved by the United States Food and Drug Administration.

6. Minnesota

Statutes Insurance (Ch. 59A-79a) § 62Q.1841. Prohibition on use of step therapy for metastatic cancer

Current as of January 01, 2023 | Updated by [FindLaw Staff](#)

Subdivision 1. Definitions. (a) For purposes of this section, the following definitions apply.

(b) "Health plan" has the meaning given in [section 62Q.01, subdivision 3](#). Health plan includes health coverage provided by a county-based purchasing plan participating in a public program under chapter 256B or 256L or an integrated health partnership under [section 256B.0755](#).

(c) "Stage four advanced metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other parts of the body.

(d) "Step therapy protocol" has the meaning given in [section 62Q.184, subdivision 1](#).

Subd. 2. Prohibition on use of step therapy protocols. A health plan that provides coverage for the treatment of stage four advanced metastatic cancer or associated conditions must not limit or exclude coverage for a drug approved by the United States

Food and Drug Administration that is on the health plan's prescription drug formulary by mandating that an enrollee with stage four advanced **metastatic cancer or associated conditions** follow a step therapy protocol if the use of the approved drug is consistent with:

- (1) a United States Food and Drug Administration-approved indication; and
- (2) a clinical practice guideline published by the National Comprehensive Care Network.

7. Delaware

§ 3338B. Coverage of drugs approved for treatment of certain cancers [For application of this section, see 81 Del. Laws, c. 180, §§ 3 and 4; 84 Del. Laws, c. 338, 3]. (a) No individual policy or contract of health insurance, or certificate issued thereunder, which is delivered, issued for delivery, renewed, modified, altered, or amended in this State by any health insurer, health service corporation or health maintenance organization that directly or indirectly covers the treatment of cancer shall limit or exclude coverage for a drug approved by the United States Food and Drug Administration by mandating that the insured shall first be required to fail to successfully respond to a different drug or drugs or prove a history of failure of a different drug or drugs; provided, however that the use of such drug or drugs is consistent with best practices for the treatment of stage 4 advanced, metastatic cancer or, in the case of other cancers, the use of the drug is supported by national clinical guidelines, national standards of care, or peer reviewed medical literature for the treatment of the cancer, or in the case of targeted therapy, the target at issue. (b) No individual policy or contract of health insurance, or certificate issued thereunder, which is delivered, issued for delivery, renewed, modified, altered, or amended in this State by any health insurer, health service corporation, or health maintenance organization that directly or indirectly cover the associated conditions of metastatic cancer shall limit or exclude coverage for drugs approved by the United States Food and Drug Administration by mandating that the insured shall first be required to fail to successfully respond to a different drug or drugs or prove a history of failure of a different drug or drugs; provided, however that the use of such drug is consistent with best practices for the treatment of the **associated conditions of metastatic cancer** and is supported by national clinical guidelines, national standards of care, or peer reviewed medical literature. (c) For purposes of this section, “associated conditions” mean the symptoms or side effects associated with metastatic cancer or its treatment and which, in the judgment of the health-care practitioner, further jeopardizes the health of a patient if left untreated. (81 Del. Laws, c. 180, § 1; 84 Del. Laws, c. 338, § 1.)

8. Ohio

Section 3902.60 | Advanced cancer fail first drug coverage definitions.

(A) Notwithstanding section [3901.71](#) and sections [3901.831](#) to [3901.833](#) of the Revised Code, a health benefit plan issued, delivered, or renewed in this state on or after the effective date of this section that directly or indirectly covers the treatment of stage four advanced metastatic cancer shall not make coverage of a drug that is prescribed to treat such **cancer or associated conditions** dependent upon a covered person demonstrating either of the following:

- (1) Failure to successfully respond to a different drug;
- (2) A history of failing to respond to a different drug or drugs.

(B) Division (A) of this section applies only to uses of such drug or drugs that are consistent with either of the following:

(1) An indication approved by, or described in, as applicable, either of the following for the treatment of stage four advanced metastatic cancer:

(a) The United States food and drug administration;

(b) The national comprehensive cancer network drugs and biologics compendium.

(2) The best practices for the treatment of stage four advanced metastatic cancer, as supported by peer-reviewed medical literature.

(C) A violation of this section is an unfair and deceptive practice in the business of insurance under sections [3901.19](#) to [3901.26](#) of the Revised Code.

Chairwomen Lee, members of the Senate Human Services,

My name is Dr. Tara Harding, and I am the owner and doctorate nurse practitioner of Simply You Wellness. We are a private practicing clinic serving North Dakota, South Dakota, Minnesota, Montana, and Colorado. I provide care to women facing various health challenges, including metastatic cancer. I am writing to express my strong support for Senate Bill 2248, which seeks to amend section 19-02.1-16.3 of the North Dakota Century Code, relating to step therapy protocols.

In my practice, I have observed that step therapy protocols can delay access to the most effective treatments for patients with metastatic cancer. This change would allow healthcare providers to prescribe the most appropriate treatments without unnecessary delays, improving patient outcomes. By passing Senate Bill 2248, you will empower healthcare providers to make timely, evidence-based treatment decisions, ultimately enhancing the quality of care for women battling metastatic cancer in our state.

Thank you for your consideration.

Sincerely,

Dr. Tara Harding



January 29, 2025

The Honorable Judy Lee, Chair Senate Human Services Committee
The Honorable Kent Weston, Vice Chair Senate Human Services Committee
North Dakota Senate Human Services Committee
North Dakota State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: **SB 2248 – Relating to Step Therapy Protocols – “Associated Condition” to
Metastatic Cancer
PCMA Testimony in Opposition to SB 2248**

Dear Chair Lee, Vice Chair Weston, and Members of the Committee:

My name is Michelle Mack, and I represent the Pharmaceutical Care Management Association, commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 275 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though employers, health plans, and public programs are not required to use PBMs, they do so because PBMs help lower the costs of prescription drug coverage.

PCMA appreciates the opportunity to provide testimony on SB 2248, a bill that would prohibit a step therapy protocol if a drug or sequence of drugs, is prescribed to treat an individual's diagnosis of an “associated condition” to metastatic cancer. PCMA respectfully opposes SB 2248.

Step therapy is a process that ensures that the patient gets the safest, most cost-effective drug by requiring the patient to try proven, more affordable therapies before drugs that cost more. Generic drugs are typically much less expensive than their brand name counterparts. The FDA indicates that prices fall when there are multiple generic competitors. When there are six or more



generic competitors, prices fall by more than 95%.¹ Step therapy is designed to capture those savings while achieving the medically desired outcome.

According to the National Academies of Sciences, Engineering, and Medicine (NASEM): "Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower tiered drug or offers another medical reason for switching."² This process safeguards against the use of step therapy from being too restrictive.

Plans and PBMs rely on independent Pharmacy and Therapeutics (P&T) Committees, comprised of physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs, ensuring these controls do not impair the quality of care and safety is of utmost importance.

Metastatic cancers are often complicated to treat; oncology medications have dangerous side effects and have guidelines that are constantly changing. PBMs follow criteria consistent with guidelines from the National Comprehensive Cancer Network (NCCN) and other generally accepted industry sources of clinical information and research to ensure that patients receive optimal treatment based on the medications prescribed. By adding the definition of "associated conditions" as written in SB 2248, the patient may be put at more risk for side effects and decreased quality of life. Many cancer patients require a team of doctors to treat them, and it is important to run the necessary checks against all medications prescribed to ensure the patient is receiving optimal treatment.

It is for these problematic provisions noted above that we must respectfully oppose SB 2248.

Thank you for your time and consideration. Please contact me should you have any questions or concerns.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Mack".

Michelle Mack
Senior Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

¹ Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020. Ryan Conrad, PhD; Kristin Davis, JD; Lukas Glos, MA; William Liu, PhD. U.S. FDA. Aug. 2022. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. Ryan Conrad, PhD, and Randall Lutter, PhD. U.S. FDA. Dec. 2019.

² "Making Medicines Affordable: A National Imperative." National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.



GREATER NORTH DAKOTA CHAMBER
SB 2248
Senate Human Services Committee
Chair Judy Lee
January 29, 2025

Mr. Chairman and members of the Committee, my name is Arik Spencer, and I am the President and CEO of the Greater North Dakota Chamber. GNDC is North Dakota's largest statewide business advocacy organization, with membership represented by small and large businesses, local chambers, and trade and industry associations across the state. We stand in **opposition to Section 2 of SB 2248.**

In our 2024 ND Economics and Employer Survey of our membership, when asked to name one thing the state government could do to help your business, the top answer was to make healthcare more affordable, not more expensive, which SB 2248 may do.

Last fall, the Insurance Commissioner approved small group insurance premium increases between 6.3 and 15.3 percent for the 2025 plan year. Healthcare and prescription drug coverage mandates, like SB 2248, increase business burdens and costs. These increases leave employers with hard decisions. Do they continue offering employer-sponsored health insurance, or do they provide cost-of-living raises to help employees pay for rent and groceries?

The bill's lack of a fiscal note is concerning as increases in benefits should be weighed by the costs employers will bear. If this bill were only applicable to state employees, we would not have an issue. We will be the first to say that employers should have autonomy in developing compensation packages. However, this bill specifically includes a requirement that PERS draft a bill for the next legislative session, applying this to the private sector.

As drafted, rather than making healthcare more affordable, this will increase business costs by shifting them to the employer, especially when you consider that there are eight other bills this session that include healthcare and drug mandates that would or could be applied in the future. These costs add up, and they don't go away.

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee Fort Lincoln Room, State Capitol

SB 2248
1/29/2025

Relating to step therapy protocols; to provide for a report to the legislative assembly; to provide for application; and to provide an expiration date.

3:05 p.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Associated conditions
- Employer provided plan

3:10 p.m. Senator Hogan moved Do Not Pass.

3:10 p.m. Senator Weston seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kent Weston	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Kristin Roers	Y
Senator Desiree Van Oosting	Y

Motion passed 6-0-0.

Senator Weston will carry the bill.

3:10 p.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

REPORT OF STANDING COMMITTEE
SB 2248 ([25.0547.02000](#))

Human Services Committee (Sen. Lee, Chairman) recommends **DO NOT PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2248 was placed on the Eleventh order on the calendar. This bill does not affect workforce development.