

Testimony in Support of LD 178

An Act Regarding Coverage for Step Therapy for Advanced Metastatic Cancer February 5, 2025

Senator Bailey, Representative Mathieson, and Members of the Joint Standing Committee on Health Coverage, Insurance, and Financial Services:

My name is Susan Folk, and I am here today to submit this testimony in support of LD 178: An Act Regarding Coverage for Step Therapy for Advanced Metastatic Cancer. I submit this testimony in my capacity as a Maine-based Certified Family Nurse Practitioner, Advanced Certified Hospice and Palliative Nurse, and as a member of the Maine Nurse Practitioner's Association.

In review of the United States Food and Drug Administration (FDA)website (fda.gov) for medications approved for metastatic cancer, there are 1,077 entries of medications that the FDA has approved for treatment of various, very specific types of metastatic cancers that include: hormone sensitive metastatic prostate cancer, HRR gene-mutated metastatic castration-resistant prostate cancer, ER+, HER2-, ESR1 mutated metastatic breast cancer, MSI-h/dMMR metastatic colorectal cancer, metastatic RET fusion positive Non-small cell Lung cancer, to name a few. The list of specific types of cancer and approved medications goes on and on and on. For example, there are 91 drugs approved for the treatment of Non-small Cell Lung cancer, 88 for breast cancer, and 38 for colorectal cancer, which covers the three most common types of adult cancers in the United States.

Cancer therapies come with various side effects and toxicities including damage to other organs, myelosuppression (bone marrow), heart, kidney, liver, lung, and neurologic systems, and other toxic side effects such as nausea, vomiting, hair loss. Additionally, in the case of immunotherapies, there is the potential for autoimmune reactions to the body's own systems such as colitis and pneumonitis that can also be as life threatening as the metastatic cancer, if not more so. There are also time toxicities: time in an infusion chair, appointments, lab draws, potential for days in an acute care setting because of the side effects and toxicities.

Failure of a drug/therapy is determined by growth of cancer on the drug, or toxicities that are not tolerated by the patient. Many factors can influence the effectiveness of the drug on the cancer, including but not limited to bioavailability (ability of drug to be absorbed and used by the body), volume of distribution (which is affected by gender), weight, plasma proteins, metabolism, excretion (how well the kidneys and liver are working), drug interactions, pH in the tumor, pH in the local tumor environment, or levels of oxygen in the blood or area of tumor.

There are many specific and individual patient parameters and many, many cancer treatment options approved by the FDA for specific tumor types. The toxicities of each treatment option are influenced by the individual patient and their values and goals. What side effects may be tolerable to one patient may not be to another, or one patient's blood protein levels may support the use of one drug but not another. One patient may have a medical history that does not support any tolerance of cardiac side effects, while another patient's medical history does. There are too many variables in individual patients



and in available medications and too many values, goal-based variables for patients and their health care clinicians to weigh to face another extraneous variable: insurance coverage and metrics. If a patient determines that a medication has a time toxicity, such as too many days spent getting labs drawn and days in an infusion chair, and would like to switch to an oral option before a scan that determines if the medicine is working or not--should they be forced to continue with a treatment or go without? These determinations are best made by a health care clinician in close partnership with their patient.

It is also important to consider the various costs of these medications-costs in terms of time, money, side effects, and toxicities. There are numerous options available. The *best option* should be determined by the patient and their healthcare provider after careful consideration of all of the above variables specific to that individual in terms of their own biology, tumor type and locations, acceptable side effects, and unacceptable side effects. Because these vary so widely, one list of medications in hierarchy cannot be applied to a whole group of insured patients with the innumerable permutations of above variables. Healthcare decisions, especially those in such a grave situation as metastatic cancer treatment, should be one of thoughtful consideration of all the above-stated variables between the individual patient and their health care clinician, and not on an arbitrary extraneously imposed timeline or solitary list of drugs in succession.

It is for these reasons that I urge you to vote ought to pass on this important piece of legislation – so that breast cancer patients can receive the individualized treatment they need and deserve.

Thank you, Susan Folk, FNP-C, ACHPN