Canadian Breast Cancer Network
Réseau canadien du cancer du sein

A BREAST CANCER PATIENT'S GUIDE TO PRECISION ONCOLOGY IN CANADA

A toolkit to help you understand, access, and advocate for equitable germline and somatic testing in Canada.

This 2025 update of the Canadian Breast Cancer Network's "*A Breast Cancer Patient's Guide to Precision Oncology in Canada*" toolkit was developed by Bukun Adegbembo, Rebecca Armstrong, and JK Miller.

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In the historical approach to treating cancer, treatment plans were mostly determined by location, type, and stage of the cancer. More and more, precision medicine is being used to guide cancer treatment plans.

Precision medicine, also called personalized medicine, is an approach where treatment is tailored to the individual person. When this personalized approach is used specifically for cancer care or cancer research, it is called precision oncology. This approach is now a common strategy in understanding and treating cancer. It looks at both individual patient characteristics and their unique tumour biology to make treatment decisions.

Precision oncology is a vast topic. *A Breast Cancer Patient's Guide to Precision Oncology in Canada* is specifically for people diagnosed with breast cancer in Canada. This toolkit

- Provides a brief introduction to precision oncology and its general uses in breast cancer care and treatment.
- Focuses on germline (hereditary) and somatic (tumour) testing, including how these tests might impact a person's treatment plan, and how to access these tests in Canada.
- Discusses system gaps and inequities related to accessing germline and somatic testing in Canada.
- Provides advocacy steps to take to ensure equitable access to germline and somatic testing in Canada.

The information this toolkit provides is not exhaustive and is not meant to substitute medical advice. For more on precision oncology, visit the Resources and References section of this toolkit.

To learn how precision oncology might personally benefit you, speak to your healthcare provider.

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PRECISION ONCOLOGY

Precision medicine, also called personalized medicine, is an approach where treatment is tailored to the individual person. When this personalized approach is used specifically for cancer care or cancer research, it is called precision oncology.

What Is Precision Oncology?

As researchers and doctors learn more about cancer, they realize that there is not one standard approach to treating it. Instead, there are many factors to consider as they develop treatment plans for each person.

In the historical approach to treating cancer, treatment plans were mostly determined by location, type, and stage of the cancer. More and more, precision medicine is being used to guide cancer treatment plans. Precision medicine, also called personalized medicine, is an approach where treatment is tailored to the individual person. When this personalized approach is used specifically for cancer care or cancer research, it is called precision oncology.

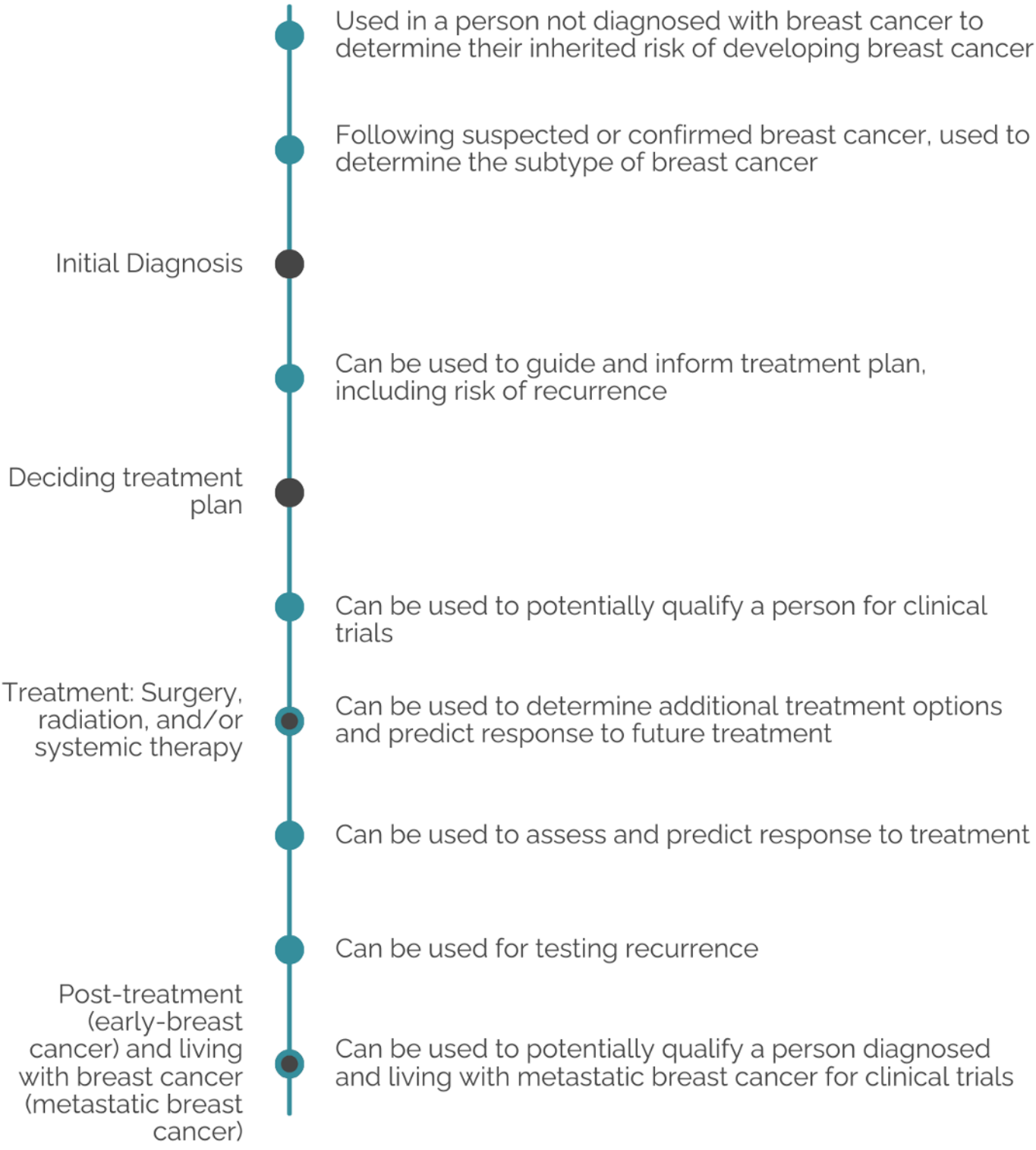
This approach is now a common strategy in understanding and treating cancer. It looks at both individual patient characteristics and their unique tumour biology to make treatment decisions.

In precision oncology, treatment plans are personalized for each person based on their genes and how their cancer behaves. Genes are instructions inside cells that help the body function normally. These instructions are coded in your DNA. Precision oncology uses information about the cancer to guide treatment, including:[1]

- Genetic information, which looks at changes in a single gene that may be causing the cancer to grow
- Genomic information, which looks at how a whole set of genes work together within the cancer cells
- Molecular (or biomarker) information, which includes other features inside cells (like proteins or small molecules) that can affect how the cancer behaves or responds to treatment

How Precision Oncology Can Help People Diagnosed With Breast Cancer

Precision oncology is a fast-growing field, and its use and value continue to expand. Let us discuss the main ways precision oncology can help people who have been diagnosed with breast cancer.



The above image provides a general timeline of how precision oncology might be integrated into breast cancer care and treatment.

Identify What is Causing the Cancer to Grow

Depending on the subtype of breast cancer that you are diagnosed with, precision oncology can be used to understand what is causing the cancerous tumour to grow. There are a variety of tests available that can be used to identify receptors, genetic mutations, biomarkers, and more.

Receptors are proteins located in or on a cell, and they work by making signals that tell cells what to do, such as growing and dividing.

Genetic mutations are changes or alterations in your DNA. Genetic mutations can be harmful, helpful, or neutral in terms of their impact on how cells work. Genetic mutations can be inherited from your parents (germline mutations) or in the tumour itself (somatic mutations).

A biomarker is a measurable substance found in blood, tissue, or other fluids in the body. It can be a sign that the body is working properly or it can show the presence of a condition or disease.

Identifying receptors, genetic mutations, biomarkers, and more that are present in the cancerous tumor can explain what caused your cancer or show what is making it grow. This information could be used to create a personalized treatment or care plan. For example, it can help determine the type of drug therapy, the amount of radiation, and the breast cancer surgery options that would be right for you.

Help to Avoid Unnecessary Treatments

Precision oncology can help identify which treatments are likely to work and which ones may not. This is done by understanding your cancer's genetic makeup, as well as any biomarkers that may be in the cancerous tumour. For example, there are tests that can predict how well you might respond to a certain therapy.

If it is determined that a drug treatment or surgery option is unlikely to work in reducing the risk of the cancer coming back or in delaying progression of metastatic disease, then it can be avoided.

There are many ways that precision oncology can be used for breast cancer. This includes:

- Identifying what is causing the cancer to grow;
- helping to avoid treatments that may not be needed;
- reducing the harmful side effects of systemic treatment;
- predicting the chance of the cancer coming back;
- and more!

Reduce Harmful Side Effects From Treatment

Another benefit of precision oncology is the potential to find therapies that target specific features in your tumour, like certain receptors, genes, mutations, or biomarkers. These are called targeted therapies. Unlike (non-targeted) systemic therapies that affect the whole body, including the cancerous tumour and healthy cells, targeted therapies focus mostly on the harmful cells and try to leave healthy cells alone. Doing this means that harmful side effects may be reduced, although side effects, called off-target effects, still do occur.

Targeted therapies tend to be more effective and may also have fewer or more manageable side effects than systemic therapies. For example, chemotherapy, a systemic therapy, comes with many harmful side effects such as fatigue, medically-induced menopause, impacts to fertility, nausea, neuropathy (nerve pain), and hair loss. Targeted therapies still come with side effects due to off-target effects, but they are usually less severe.

Predict the Chance of Recurrence

There are certain tests that can help predict the chance of an early-stage breast cancer coming back after treatment ends (known as recurrence). These tests results can help determine a treatment plan that either avoids unnecessary treatment or adds additional treatment that reduces the risk of recurrence.

Other Benefits of Precision Oncology

Precision oncology also offers other benefits, like identifying people who do not have cancer but have a high risk of developing it. For example, a genetic test can be done to determine whether you have inherited mutations that increase your risk of developing cancer. Results from this test can be used to make decisions about your health, such as getting a prophylactic (preventive) mastectomy or increasing how often you get a mammogram.

Through precision oncology, Quinn Obrigewitch found out that she was at high risk of developing breast cancer. Click on the articles below to read about the healthcare decision she made as a result of this finding.

We Are All the Divine Feminine

Navigating the Stop Signs: A Story of Genetic Testing

Another benefit of precision oncology is helping people who have been diagnosed with breast cancer access clinical trials. If you are diagnosed with early-stage or metastatic breast cancer, there might be reasons that you want to participate in a clinical trial. For some trials, your eligibility might depend on whether certain genetic mutations, biomarkers, or receptors are present. Through precision oncology, results from a given test can help you become eligible to participate in a clinical trial.

Clinical trials provide doctors with a way to closely monitor and test treatments, medical procedures, or therapies for various diseases. Clinical trials are essential to driving progress in breast cancer care.

Learn more about clinical trials by clicking on the articles below.

A Surgical Oncologist Answers Your Questions About Breast Cancer Clinical Trials

Canadian Precision Oncology Trial Finder

Clinical Trials Connected e-Newsletter

Clinical Trials Series Part 1: What Are Clinical Trials and Are They Right for Me?

Clinical Trials Part 2: Debunking Common Myths About Clinical Trials

Deconstructing Clinical Trials Workshop

Why Clinical Trials Are Crucial for People with Breast Cancer

GERMLINE TESTING

A germline (hereditary) test is a specific type of genetic test that looks for hereditary (inherited) changes in a person's genes, gene expression, or chromosomes. If a person has a certain disease, germline testing can be done to understand if the disease is hereditary.

What Is Germline Testing?

A germline (hereditary) test is a specific type of genetic test that looks for hereditary (inherited) changes in a person's genes, gene expression, or chromosomes. Usually, a germline test is simply called a genetic test. Germline tests are often used in healthcare to learn more about a person's risk for developing certain diseases, along with other uses. If a person has a certain disease, germline testing can be done to understand if the disease is hereditary. Germline tests that look specifically for cancer risk inherited from your parents are called hereditary cancer genetic tests.

Germline testing can help determine if your breast cancer is linked to a hereditary, or inherited, genetic change called a germline mutation. Germline mutations are genetic changes in your genes that you are born with. These mutations can be passed down from parents to children (inherited) and may increase the risk of certain inherited cancers, or explain its cause. When breast cancer is caused by a germline mutation, it is called hereditary breast cancer. About 5 to 10% of breast cancer cases are believed to be hereditary.[2]

Germline mutations can also be called:

- Gene variants
- Genetic mutations
- Inherited mutations
- Pathogenic variants

Germline testing is usually done using a sample of blood or saliva. A sample of hair, skin, and other tissue can also be used to perform a germline test but these are less common to use. Once a sample is collected, it is sent to a lab where specialists look at your DNA, chromosomes, genes, and proteins. The test results are then sent to the doctor, genetic counsellor, or directly to you, depending on who requested the test.

Potential Test Results and Impact on Treatment Plans

There are three potential results that can be reported from a germline test following a breast cancer diagnosis: no mutation was found (negative), a mutation of unknown significance was found (uncertain), or a mutation was found (positive).

Germline test results that report that no mutation was found mean that you have not inherited a mutation that explains the cause of your breast cancer diagnosis. A germline test that reports that a mutation of unknown significance was found means that a mutation was found, but it is not clear how this mutation explains your breast cancer diagnosis. Mutations with unknown significance are not used to determine your treatment plan since their impact on your diagnosis is unclear.

If the results of your germline test report that a germline mutation was found, it means that the cause of your breast cancer diagnosis is due to the inherited mutation that was found. As of 2025, germline mutations to the following genes have been found to be associated with breast cancer:

- *ATM*
- *BARD1*
- *BRCA1* and *BRCA2*
- *CDH1*
- *CHEK2*
- *NF1*
- *PALB2*
- *PTEN*
- *RAD51C and RAD51D*
- *STK11*
- *TP53*

This list does not outline all the germline mutations linked to breast cancer but the more common or emerging mutations.[3] [4]

Appendix A of this toolkit categorizes the possible genetic mutations that can be found through germline testing by their predictive and prognostic factors. It also outlines which are germline and which are somatic.

Three potential results from a germline test are:

Negative - No mutation was found

Uncertain - A mutation of unknown significance was found

Positive - A mutation was found

While there are many germline mutations that have been linked to breast cancer, the level of risk they carry can vary. For example, people with *BRCA1* or *BRCA2* mutations have up to an 85% [2] chance of developing breast cancer in their lifetime. Meanwhile, people with a *RAD51C* mutation have a lower risk: 20%.[5] For comparison, the average lifetime risk of developing breast cancer among females who do not have any germline mutations is 12.5%.[5]

A mutation is considered 'actionable' when identifying it helps your doctors make a particular decision about your treatment. Finding an actionable, germline mutation after a breast cancer diagnosis can impact your treatment and care plan in a number of ways. This can involve prescribing a specific therapy or may include recommending a particular type of surgery.

There are also actionable mutations that have targeted therapies designed specifically to treat them. For example, PARP inhibitors are a type of targeted therapy designed to treat people diagnosed with early-stage and metastatic breast cancer who have mutated *BRCA1/2* genes. The specific impact of an actionable germline mutation on your treatment plan will be determined by your healthcare provider as it depends on a number of factors. These factors can include the specific mutation that is found, personal treatment goals, the type and subtype of your diagnosis, and more.

Germline testing for breast cancer may not always provide immediate answers to help you make decisions about your health or treatment options. However, just because a mutation is not actionable at the time it is found does not mean that it might not be actionable in the future. Targeted treatments continue being researched and developed. As the field of precision oncology grows, we can expect to see more actionable germline mutations.

It is also important to know that germline testing technology changes over time, and that germline mutations linked to cancer may not yet be discovered. This means that a germline test done today may report that no mutation was found or that a mutation of unknown significance was found,

In 2021, Stacy Zelazny was diagnosed with breast cancer at just 35 years old. Following her diagnosis, she got a genetic (germline) test done. Click the article below to read how the results of this test impacted her treatment plan.

My Genetic Test Results Changed my Treatment Plans

even if your breast cancer is hereditary. The connection between your breast cancer and a germline mutation could be uncovered in the future.

When results from a germline test do provide useful information, it can be used to create a more personalized approach to your breast cancer treatment plan. Following a germline test, it is important to speak with a genetic counsellor and with your cancer care team before making any treatment decisions. They will work with you to find a personalized treatment plan based on your full health and history.

Accessing Germline (Hereditary) Testing in Canada

Your ability to access germline testing for breast cancer depends on many things, including which province or territory you live in. Your access to testing can also depend on meeting certain eligibility criteria. Your eligibility is generally based on a combination of the following risk personal and family history factors of hereditary breast cancer:[3]

Personal history

- You were diagnosed with breast cancer when you were younger than 50 years old
- You have been diagnosed with a primary breast cancer twice (meaning two separate breast cancers that started independently of each other)
- You were diagnosed with triple negative breast cancer (TNBC; meaning the cancerous tumours do not have the estrogen, progesterone, or HER2 receptors)
- You have been diagnosed with ovarian, pancreatic, or high-risk prostate cancer
- You were diagnosed with male breast cancer
- You have Ashkenazi Jewish (Eastern European) heritage

In Canada, your ability to access germline testing for breast cancer depends on many things, including which province or territory you live in.

Family history

- You have more than one blood relative (family member related to you by birth, not by marriage or adoption) that has been diagnosed with breast cancer
- You have a family member that was diagnosed with breast cancer when they were younger than 50 years old
- You have a family member that has been diagnosed with a primary breast cancer twice
- You have a family member that has been diagnosed with TNBC
- You have a family member that has been diagnosed with ovarian, pancreatic, or high-risk prostate cancer
- You have a male family member that has been diagnosed with breast cancer
- There is a known genetic mutation linked to breast cancer in your family

The above is a list of potential eligibility criteria. It does not reflect any specific eligibility criteria in Canada. Provinces and territories set their own rules on the specific criteria you must meet to be eligible to access germline testing. They may require all the factors above, only some, or have other criteria not outlined above. For example, a province might require a specific number of blood relatives to have had cancer for you to be eligible for testing. As another example, you might not be able to access germline testing in a specific province even if you have Ashkenazi Jewish heritage.

In addition to this, meeting the eligibility criteria where you live might not mean you can access testing automatically. For example, some regions might offer you germline testing once you fit their eligibility criteria. In other places, you or your healthcare provider might need to request it. Public funding for germline testing also varies by province and territory. It is important to speak to your healthcare provider to understand if germline testing might be helpful to you, how you might be able to access it, and who will pay for it.

Provinces and territories set their own rules on the specific criteria you must meet to be eligible to access germline testing. However, meeting the eligibility criteria where you live does not always mean that you can access testing automatically.

If you have determined that germline testing would be helpful for you, but you do not fit the provincial or territorial criteria to get it, or because it is not publicly covered where you live, you may choose to pay for this test by yourself.

If you pay for germline testing by yourself, you can access it through:

- A private clinic
- Direct-to-consumer (DTC) tests. DTC tests are tests that you can order and complete yourself without needing a referral from a doctor. Two well-known companies that provide DTC genetic tests are Invitae and Blueprint Genetics.
- Out-of-province testing
- Out-of-country testing

If you have private insurance, check with your provider to see what your plan offers in relation to germline testing.

You can also try to access germline testing through a clinical trial or through programs like the Women's College Hospital's Screen Project.

Regardless of which option you go with, it is important to discuss your test results with a genetic counsellor. A genetic counsellor will help you understand the results of your test and walk you through potential next steps.

If you cannot access germline testing where you live and choose to pay for it by yourself, you can access it through:

- A private clinic;
- DTC tests;
- another province;
- or another country

Questions to Ask Your Healthcare Provider About Germline Testing

After learning about germline testing, you may be wondering how you can get this test done in order to personalize and tailor your treatment plan. It is important to understand that not everyone who has been diagnosed with breast cancer will get the same benefit from germline testing. Speak to your healthcare provider to understand how you may benefit from testing and how to access it. They might also be able to tell you about additional benefits from germline testing beyond those covered in the toolkit.

Below, we provide a list of questions that you can use to guide this conversation.

	Have you considered a hereditary cause for my cancer?
	Would it be helpful to know about my other family members who have had cancer?
	Do my risk factors make me eligible for germline testing?
	When is the best or most appropriate time for me to get germline testing done?
	What are my options for accessing germline testing and what are the associated costs?
	Are there clinical trials that I can enroll in to access germline testing?
	What is the wait time to be referred for germline testing?
	Where will the germline test be done? Do I have to travel for it?
	How long does it take to get the results back from a germline test?
	How might the results of a genetic test affect my treatment plan/outcome?
	Can the results of a germline test make me eligible for a clinical trial?
	Can I get germline testing done after I have already started treatment or while I am in treatment?
	With new research and information being discovered all the time, how often do you suggest I get a germline test done?

SOMATIC TESTING

Somatic (tumour) testing is a lab test that looks for genetic changes in a tumour's DNA. It help doctors understand how the cancer behaves, how fast it might grow or spread, and which treatments are likely to work best.

What Is Somatic Testing?

Somatic (tumour) testing is a lab test that looks for genetic changes in a tumour's DNA. It can be done using a sample of blood, body fluids, or tissue in tumor cells from a biopsy or surgery. This helps doctors understand how the cancer behaves, how fast it might grow or spread, and which treatments are likely to work best.

Unlike germline testing which looks at hereditary changes in a person's DNA, somatic testing looks at changes in a tumour's DNA, focusing on acquired changes, rather than inherited ones.[6] Acquired changes refer to changes that happen over the course of a person's lifetime. This means that while germline testing can be performed on anyone, somatic testing can only be performed on someone with cancer. Most breast cancers are caused by somatic mutations, rather than germline mutations.[2] Some gene mutations, such as mutations to the *BRCA1* and *BRCA2* genes, can be either somatic or germline.[7] Appendix A of this toolkit outlines which mutations are somatic, germline, or both.

Somatic testing looks at genes, receptors, biomarkers, and more in a cancerous tumour to provide information about the tumour, such as how fast it grows, how aggressive it is, and whether it might spread to other parts of your body. In some cases, this information can be used to guide treatment.

Somatic testing for breast cancer can include the following types of tests and techniques:

- Biomarker testing
- Comprehensive genomic profiling (CGP), which looks at very large panel of hundreds of genes, as well as other biomarkers
- Multi-panel testing, which analyzes a set number of genes
- Immunohistochemistry (IHC)
- In-situ hybridization (ISH), dual in-situ hybridization (DISH), and fluorescence in-situ hybridization (FISH)
- Gene expression profiling

Somatic testing is performed on a sample of cancer cells. This sample is usually taken during surgery or biopsy. Sometimes other bodily fluids, such as blood, urine, or other fluids, such as the fluid around the lungs, are used. When the sample is taken from the tissue of the cancerous tumour, it is called a tissue biopsy. When the sample is taken from bodily fluids, it is called a liquid biopsy. Tissue biopsies tend to be more reliable than liquid biopsies since the sample for a tissue biopsy is taken directly from the cancer and usually contains more numbers of cancerous cells. On the other hand, liquid biopsies look for samples of the cancer in the fluid being tested.[8]

Once a sample of the cancer cells is collected, it is sent to a lab for testing. A report is created by specialized healthcare professionals based on the findings and sent to the specialist who requested it.

Potential Test Results and Impact on Treatment Plans

The results of a somatic test depend on the specific test that is used, whether a tissue or liquid biopsy is performed, and if multi-panel testing or comprehensive genetic profiling is used. There are different reasons you may have one type of test, biopsy, or panel over another, and the decision about which to use is usually specific to your tumour type.

There are a number of genes changes, receptors, biomarkers, and more, that somatic tests can find in breast cancer cells.[7 9 10] The most common of these, as of 2025, are listed below:

Routinely Tested

- Hormone receptor status for both estrogen (ER) and progesterone (ER)
- Human epidermal growth factor 2 (HER2) status

Commonly Tested

- Ki-67
- PD-L1

Tested on Advanced Tumours

- *AKT1*
- *BRCA1* and *BRCA2*
- c-MET
- *EGFR*
- *ERBB2 mutations*
- *ESR1*
- FGFR1, FGFR2, FGFR3, and FGFR4

The results of somatic testing depend on the specific test that is used, whether a tissue or liquid biopsy is performed, and if multi-panel testing or comprehensive genetic profiling is used.

- Homologous repair deficiency (HRD)
- Microsatellite instability high status (MSI-H)
- *MYC*
- *NTRK1, NTRK2, and NTRK3*
- *PIK3CA*
- *PTEN*
- *RB1*
- *TP53*

Other

- circulating tumour DNA (ctDNA)
- Mismatch repair deficiency (dMMR)
- Tumour mutation burden (TMB-H)

Results from somatic tests can impact your treatment plan in a number of ways, depending on whether they are predictive or prognostic. Predictive biomarkers found in your tumour help doctors understand how well a specific treatment is likely to work for your cancer.[11] If a predictive biomarker is found, it can help guide whether you should use one treatment over another.

Prognostic biomarkers found in your tumour can help doctors understand how likely your cancer is to grow, come back or affect your overall survival.[11] Unlike predictive biomarkers, this information is not linked to a specific treatment. Instead, the information that prognostic biomarkers provide can be helpful to understand how the cancer behaves on its own. This can be used to determine whether a more aggressive treatment plan is recommended or if it is safe to reduce the amount of treatment you might receive.

Appendix A of this toolkit categorizes the possible results from a somatic test by their predictive and prognostic factors. It also highlights which gene mutations are germline, somatic, or both.

Predictive biomarkers found in your tumour help doctors understand how well a specific treatment is likely to work for your cancer.

Prognostic biomarkers found in your tumour can help doctors understand how likely your cancer is to grow, come back or affect your overall survival.

Somatic Tests that Analyze Hormone Receptor and HER2 Status

The estrogen (ER), progesterone (PR), and HER2 receptors sit on the outside of both normal and cancer cells and respond to signals that tell the cell to grow and divide. Testing for these receptors status is typically done when breast cancer is diagnosed and is used to determine the subtype of your cancer.

Knowing which of these receptors is present in your tumour can help determine the type of treatment you will get. For example, there are drug therapies designed to target the HER2 receptors. These drugs block the growth of cells that have a HER2 receptor on the outside of the cell. The number of receptors that are found also helps determine the type of treatment that is needed.

Somatic Tests that Analyze Risk of Recurrence

There are somatic tests that can be done to analyze the risk of a cancer coming back. These tests are only relevant if you are diagnosed with an early-stage breast cancer, but not if you are diagnosed with late-stage, metastatic breast cancer. Results from these tests can help determine your treatment path, such as whether chemotherapy is needed or can be skipped.

The following tests are for early-stage, hormone receptor-positive, HER2-negative (HR+, HER2-) breast cancers:

- Oncotype DX Breast Cancer Recurrence Test
- Oncotype DX Breast Cancer DCIS Test
- MammaPrint
- Prosigna Breast Cancer Prognostic Gene Signature Assay
- EndoPredict

Somatic Tests that Can Provide Access to Targeted Therapy

A companion diagnostic[12] is a type of biomarker test that is done to guide your treatment plan and the use of a specific targeted therapy. Some treatments require positive results for certain mutations or biomarkers before they can be used. For example, if you have metastatic breast cancer, there are companion diagnostic tests that can make you are eligible for treatments that are targeted for *PIK3CA* or *ESR1* mutations or PD-L1 expression.

As a medical doctor and scientist with over 20 years of experience in genomics, Dr. Catalina Lopez Correa was eager to delve deeper into her tumor's makeup following her breast cancer diagnosis. Click the article below to read about her experience analyzing her tumor through various somatic tests.

My Genomics Journey as a Breast Cancer Patient

As with germline testing, the results from somatic testing might not immediately impact your treatment plan. Not all genes, receptors, or biomarkers that are found at one point in time are actionable or linked to a specific targeted therapy. Since somatic tests give a snapshot of your cancer's makeup at one point in time, retesting might be necessary to get results that can be used to guide your treatment plan. Cancers can sometimes change their genes over time, or more information is gathered from research that affects treatment options. Results from somatic testing that are not actionable now might change in the future as more precision oncology research is conducted.

Treatment decisions based on results from somatic testing should be made with your healthcare provider to ensure that the full picture of your health and treatment goals are considered.

Accessing Somatic (Tumour) Testing in Canada

Somatic Tests that Analyze Hormone Receptor and HER2 Status: In Canada, the presence of ER, PR, and HER2 receptors are tested in every person diagnosed with breast cancer. Payment for these tests are also covered publicly.

Somatic Tests that Analyze Risk of Recurrence: As of 2025 in Canada, somatic tests to determine risk of recurrence are routinely done in some provinces and territories, but not others. Coverage for these tests also varies by province and territory as some provinces or territories cover certain types of recurrence tests while others do not.

Somatic Tests that Can Provide Access to Targeted Therapy: As with broader somatic tests, access to and funding of companion diagnostics depends on where you live in Canada. You access to companion diagnostics can also depend on the specific targeted therapy.

Certain receptors, genes, or biomarkers are only tested in certain cases in Canada and may not always be covered by public health plans. The first step to accessing somatic testing is to ensure that it is right for you. Not everyone with breast cancer will benefit from getting this type of testing done.

Whether you will benefit from somatic testing or not is based on a number of factors. It is important to speak to your healthcare provider who can guide you through if testing is right for you, the potential benefits of testing, how you might be able to access it, and who will pay for it.

If you have determined that a specific somatic test would be helpful in guiding your treatment plan, but you cannot access it where you live, you may choose to pay for these tests by yourself. If you are willing to pay out-of-pocket for a test, it is important to speak to your healthcare provider about this, rather than pursuing it on your own. Your healthcare provider can make arrangements through the hospital to help you access the test that you need. This will help to ensure that the test and test results are useful in guiding treatment decisions. It can also help you avoid paying for and getting unnecessary tests.

Additionally, accessing a somatic test on your own can delay your treatment process if your sample is not analyzed in a timely manner, making it ineligible and requiring that another biopsy is done. Accessing germline testing on your own, through DTC tests, is acceptable because the samples are taken at home and do not need to be conserved or used for other tests. This is not the case with somatic tests as they are done on the tumour or on tissue. To maximize utility, it is important that accessing somatic tests is done through your oncologist.

If you have private insurance, check with your provider to see what your plan offers for somatic testing and to understand what they may cover.

If you are willing to pay out-of-pocket for somatic testing, it is important to speak to your healthcare provider about this, rather than pursuing it on your own. Unlike germline testing, accessing DTC somatic tests is not recommended.

Questions to Ask Your Healthcare Provider About Somatic Testing

After learning about somatic testing, you may be wondering how you can get this test done in order to personalize and tailor your treatment plan. It is important to understand that not everyone who has been diagnosed with breast cancer will get the same benefit from somatic testing. You might also benefit from one type or technique of somatic testing, but not another. Speak to your healthcare provider to understand how what tests you may benefit from and how to access them. They might also be able to tell you about additional benefits from somatic testing beyond those covered in the toolkit.

Below, we provide a list of questions that you can use to guide this conversation.

	Is my type or subtype of breast cancer eligible for somatic testing?
	What type and technique of somatic testing would be most appropriate for me?
	When is the best or most appropriate time for me to get somatic testing done?
	What are my options for accessing somatic tests and what are the associated costs?
	Are there clinical trials that I can enroll in to access somatic testing?
	What is the wait time to get a somatic test?
	Where are the various types of techniques of somatic testing done? Do I have to travel for them?
	Are there companion diagnostics that might make me eligible for a targeted therapy?
	How long does it take to get the results back from the various types and techniques of somatic tests?
	How may the results of somatic testing affect my treatment plan/outcome?
	Can the results of a somatic test make me eligible for a clinical trial?
	Can I develop new mutations over time? Can the biomarkers in my tumor change over time?
	Can I get somatic testing done after I have already started treatment or while I am in treatment?
	With new research and information being discovered all the time, how often do you suggest I get a somatic test done?

SYSTEM GAPS AND INEQUITIES

Access to precision oncology depends in large part on where you live in Canada. Such uneven and unequal access can create inequity or make existing inequities larger

As mentioned earlier in this toolkit, your access to germline tests and the various types and techniques of somatic tests, as well as broader access to precision oncology and precision medicine, depends in large part on where you live in Canada. Such uneven and unequal access can create inequity or make existing inequities larger.

While there are a number of system and access gaps related to the use of precision oncology in Canada, this section of the toolkit focuses on three: access and eligibility inequity; funding and coverage inequity; and gaps in education, awareness, and patient-facing materials. You can read about the full range of system gaps and inequity related to precision oncology in Canada here and here.

Access and Eligibility

Access to germline and somatic testing across Canada is currently inequitable since access often depend on where you live. A number of systemic factors contribute to this inequality. One key issue is the differences in eligibility criteria between provinces and territories. These eligibility criteria often depend on a combination of the type, stage, and subtype of breast cancer you have, and these criteria are different across Canada. This leads to access being based on where you live. This is true of both germline and somatic testing.

As a result, what is considered standard of care also varies greatly in Canada, from differences between provinces and territories, to differences between hospitals in the same city. Since eligibility and standards of care vary across the country, it is possible that even if two people have the same cancer type, stage, and subtype, where they live and are being treated can be the deciding factor of how much they can benefit from precision oncology. For example, in one province a person might automatically receive germline or a particular somatic testing once they are diagnosed with breast cancer. However, in another province, a person with the exact type, stage, and subtype of breast cancer may need to complete multiple lines of therapy before receiving the same testing. This creates an unfair situation where one person may have the opportunity to gain insights that could help shape their treatment plan, while another does not.

Similarly, test availability and clinical use vary widely across provinces. Test availability refers to which germline or somatic tests are available. Clinical use speaks to how these tests are part of your cancer care and treatment. Currently, there is variation in which tests are available to healthcare providers as part of their standard of care.[13] For example, automatic *BRCA1/2* testing is not the standard of care across the country.

Inconsistent availability of germline and somatic tests means that some patients may receive more comprehensive and informative results than others. These inconsistencies can limit the value and benefit of a personalized treatment plan to some people while others are potentially missing out on therapeutic options that may be better than the standard of care. These variances in eligibility criteria, test availability, and clinical use have caused what many refer to as a "postal code lottery" when it comes to accessing timely and meaningful germline and somatic testing.[13]

To address these inequities, provincial, territorial, and federal governments must work together with the goal of ensuring that everyone, regardless of where they live, has access to the best possible care through timely and appropriate germline and somatic testing.[13] It is only through coordinated efforts that the postal code lottery can be eliminated and true equitable access to precision oncology in Canada can be achieved.

Funding and Coverage

Closely tied to the issue of access to germline and somatic testing, is how these tests are funded across Canada. In some cases, grants or drug manufacturers provide temporary funding.[13] There are also significant differences in how provinces evaluate which tests to fund. Each province and territory has its own process for assessing which tests to reimburse, along with varying quality and performance standards.[14] This lack of standardization means that two patients with similar clinical needs in different parts of the country may not receive the same level of care.

When public coverage of germline and somatic tests is not available for a particular test, sometimes people with breast cancer may be required to pay out-of-pocket for testing.[14] Although some people can afford to pay out-of-pocket for testing when they cannot access publicly covered tests, not

It is only through coordinated efforts that the postal code lottery can be eliminated and true equitable access to precision oncology in Canada can be achieved.

everyone has the means for this option. This creates inequity where access is based on ability to pay, rather than health needs. Not everyone can afford the high costs associated with these tests, and unequal access to out-of-pocket options only makes existing equity gaps wider.[15]

Another issue when people do not have access to publicly funded germline and somatic testing is the concern about the reliability and clinical usefulness of tests that they get through private companies. When public testing is not available, people may choose to use DTC or privately accessed testing. DTC and private tests can be very useful in filling the gaps we currently see in our public system. However, when someone chooses this option, they also take on the responsibility of determining which tests are reliable and clinically useful.

When someone with breast cancer takes on the responsibility of determining reliability and clinical usefulness, there is a risk of paying for tests that give results that are not useful in informing their care and treatment. In a publicly funded model, health authorities can ensure that tests they use are high quality, have the potential to inform cancer care, and produce useful results. Additionally, this model helps prevent situations where someone pays for a test that is designed mostly to make money, rather than help the individual.

Each province or territory may also have different policies on how they use test results from private tests to inform a patient's treatment plan. This is significant because although private testing may be an option for some who would not otherwise have access to testing, they may still encounter barriers in using the test results to inform their treatment plan.

Without coordinated action by provincial, territorial, and federal governments, access to precision oncology will continue to vary based on healthcare budgets and priorities.[13] This must change so that everyone in Canada has access to the right tests at the right time, without financial barriers. Ultimately, a pan-Canadian approach is needed to determine how germline and somatic tests are funded across the country.

Coordinated action by provincial, territorial, and federal governments, is needed so that everyone in Canada has access to the right tests at the right time, without financial barriers.

Education, Awareness, and Patient-Facing Materials

In May 2025, the Canadian Breast Cancer Network (CBCN) conducted a jurisdictional scan of patient-facing materials related to germline and somatic testing. While we were able to locate most of the information we were looking for on germline testing, there was still information, such as eligibility criteria and funding availability, that was missing for some provinces and territories. For somatic testing, specifically biomarker testing, patient-facing information on access, eligibility, and funding for specific biomarkers was almost entirely absent.

These findings are significant because they mean that basic information about germline testing varies across the country, while information about the various types and techniques of somatic testing is largely unavailable. Without clear, accessible information, people with breast cancer may not have what they need to make a choice that's right for them.

There should be information that includes which tests are available, what mutations and biomarkers the tests cover, who is eligible for testing, how tests will be paid for, and how to access relevant tests. When people are not provided with adequate educational information, it limits their involvement in making decisions about their treatment. This is particularly concerning given the increasing role of precision oncology in cancer care. Without clear and accessible resources, patients may not be aware of testing options that could meaningfully shape their treatment plans.

Care providers also need the right information to support the people they care for. When healthcare providers do not have up-to-date information on germline or somatic tests, patients may miss opportunities for testing that could benefit them. This is also true when they are unaware of the criteria and funding structures where they live. This means some patients may receive better care than others simply because of the information their healthcare provider has access to.

A State of Readiness Progress Report shows the need for healthcare providers to have the right information. The report found that a person's access to testing can be influenced by how informed their clinician is about germline and somatic testing. This is significant because patients rely on their healthcare providers to guide them through treatment. Unfortunately, when healthcare providers do not have the right information, people are left uninformed or they may seek education elsewhere. This can result in misinformation, using out-of-date information, only finding resources relevant to other countries, and mistrust. All of which can lead to confusion, disappointment, and frustration.

To address these gaps in education and awareness, people with breast cancer, caregivers, and healthcare providers must be adequately informed about germline and somatic testing. This includes patient-friendly materials and tools such as publicly available information on eligibility criteria, test availability, and funding source. Unfortunately, these navigation tools are currently lacking across Canada.

Test formularies, which are a directory of all tests available in a province or territory, would be a good first step to improve the availability of public-facing information. These formularies should include a standardized list of common germline and somatic tests, including the gene mutations and biomarkers they look at, and indicate whether they are available or not. This way, people are not left guessing about the availability of unlisted tests.

Another way to improve education and awareness of germline and somatic testing is healthcare system navigators and educators. Navigators can help people with breast cancer, caregivers, and healthcare providers understand and access appropriate testing. For example, navigation tools such as test directories, referral guidelines, eligibility checklists, and care clinic directories are essential to improving access.[13] When these tools are available, navigators can interpret the information to see how they fit into someone's care plan. This could also include having champions for germline and somatic testing in a region, whether these are patients, families, or healthcare providers.

Creating consistent, accessible, and reliable education materials for people with breast cancer, caregivers, healthcare professionals and the public is essential to making precision oncology equitable and effective across Canada.

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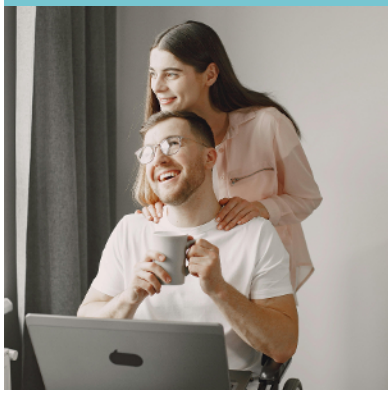

Addressing System Gaps and Inequities

Earlier in this toolkit, we provided options to access germline testing and somatic testing if you do not fit the eligibility criteria set by your province or territory, or if the cost of these tests are not publicly covered. Individual access to these tests is important, especially when timely access is required. It is equally as important to advocate for systemic changes that make access to these tests, and use of precision oncology in Canada, equitable for all individuals facing a breast cancer diagnosis.

The following section covers ways you can advocate for system equity to ensure that individuals, no matter where they live in Canada, have the same access to these tests, as well as education and awareness of precision oncology.

Educate Yourself and Others

The first step to advocating for germline and somatic testing, and the use of precision oncology in Canada is to first educate yourself on what they are and how they can benefit you and others like you. Resources like this toolkit and those provided in the Resources and References section are great starting points. As you learn more about precision oncology for breast cancer patients in Canada, share what you have learned with your family and friends. Speak to your healthcare provider to understand how precision oncology approaches, such as germline testing and somatic testing, might guide your treatment plan, qualify you for a clinical trial, or be beneficial to your health and care in the future.

Learning about precision oncology will also help you understand where there might be education and awareness gaps where you live. By visiting your regional health or cancer care website, you can identify what additional information would be helpful to you and you can address these gaps using the other advocacy steps described in this toolkit.

There are a number of ways that you can advocate for system equity to ensure that individuals, no matter where they live in Canada have the same access to these tests, as well as education and awareness of precision oncology.

Share Your Story

If you have experience with germline, somatic, biomarker, or other related testing that uses precision oncology, sharing your personal story is a great way to raise awareness of precision oncology in Canada. A personal account of precision oncology helps to bring a human touch to a complex topic. It helps people see precision oncology in action and allows them to hear directly from those it benefits the most.

The Canadian Breast Cancer Network (CBCN) and Know Your Genome are two platforms that invite you to share how precision oncology has impacted your health and treatment plan. Access CBCN's platform to share your story here. Access Know Your Genome's platform here.

Connect With a Patient Advocacy Group

There are a number of patient advocacy groups doing work to bring equitable access to precision oncology in Canada for a number of cancers. Consider becoming a part of one or two of these groups and joining their advocacy efforts. The collective and strategic efforts of patient advocacy groups can help to address many of the system inequities and gaps previously mentioned. Here are some options of patient advocacy groups you might consider connecting with:

- Canadian Breast Cancer Network – Become a Supporter
- Colorectal Cancer Resource & Action Network (advocates for precision oncology for multiple cancers, including breast cancer) – Get Involved
- Know Your Genome – Shape the Conversation
- ReThink Breast Cancer – Take Action

Contact Government Officials

The system inequities and gaps discussed above involve various levels of government. Government officials are important stakeholders in addressing issues related to access, funding, and education gaps. While they are not the only stakeholders that will bring about change to the precision oncology landscape in Canada, they are some of the most influential in the conversation.

There are various strategies you can use if you choose to engage government relations. You may decide to employ a single strategy or a combination of strategies to address precision oncology in Canada. These strategies include, but are not limited to petitions, demonstrations, lobbying, and letter writing.

Contacting government officials to advocate for equitable access to and use of precision oncology in Canada involves first identifying the appropriate level of government to approach. If you have experience with using precision oncology or can share how access to precision oncology would benefit you, be sure to add this when you contact government relations.

You can get started on contacting the government through the following avenues:

- Know Your Genome – Sample Advocacy Letter
- Access to Genomic Testing – Call on your Provincial Government to Take Action (for Alberta, British Columbia, Nova Scotia, Ontario, and Québec)

Contact the Media

Contacting the media as a form of advocacy allows you to raise awareness of precision oncology on a large scale. Media is a large umbrella that covers everything from radio stations to online magazines, to national publications. Contacting the media can be helpful in addressing the education and awareness gaps of precision oncology, as well as sharing information about the access and funding inequities that exist in Canada. As with contacting government officials, using a personal story or angle in your outreach can extend the reach and impact of your advocacy efforts.

Using the media to advocate for precision oncology in Canada can involve letters to an editor or interviews. While you can reach out to individuals in the media for an interview on your own, getting involved with a patient advocacy group can also be another way to get in contact with media relations. Patient advocacy groups are often approached by those in the media, and they can refer you to interviewers to give a patient perspective on precision oncology.

Write An Article for a Blog

Blogs are a great space to be creative and advocate for the use of precision oncology in Canada exactly the way you want. As with the above avenues of advocacy, blogs can be used to address a number of the gaps and inequity issues regarding precision oncology in Canada. You can share your personal experience with getting a genetic test done, you can raise awareness of precision oncology by sharing how it benefits patients, you can put together several articles that share educational information on precision oncology.

Blogs can also be used to discuss the inequitable use and access of germline and somatic testing in Canada. In blog format, you decide how much or how little you choose to share. You may choose to create an entire blog dedicated to precision oncology or only publish a number of articles on it. There are some platforms, such as the CBCN's Our Voices, that invite you to submit an article and advocate for precision oncology through their blog, without you having to create and manage one by yourself.

Use Social Media

Social media is another great avenue for raising awareness of precision oncology in Canada and can also be used to address a number of its gaps and inequity issues. Like blogging, you can choose to dedicate an entire social media account to advocating for or sharing your experience with precision oncology. You also have the option of making one-off posts on your current social media accounts.

There are many social media platforms, each designed for unique types of content. Some are designed for long-form written content, others prioritize short videos, while other platforms are best used for audio-only. With so many different social media platforms, you have options of what works best for you.

Social media can also be a great tool to share and extend the reach of your other advocacy efforts. If you get interviewed for your perspective on precision oncology, share it on your social media. You can extend the work that patient advocacy groups are doing in advocating for access and use of precision oncology in Canada by sharing about it on your social media. Planning to advocate directly to the government? Share your petition on your social media to get more support and signatures.

CBCN's Digital Advocacy and Storytelling Toolkit can guide you through advocating for equitable access, coverage, and education for precision oncology in Canada. Visit the links below for support with various advocacy methods.

Sharing Your Story

- Communicating Your Story as an Advocacy Tool
- Determining Your Strategy

Contacting Government Officials

- Contacting Government Relations for Advocacy
- Contacting Government Relations for Advocacy: Sample Letters

Contacting the Media

- Contacting Media Relations for Advocacy
- Contacting Media Relations for Advocacy: Sample Letters

Writing Articles for a Blog

- Blog Writing for Advocacy

Using Social Media

- Social Media for Advocacy

CONCLUSION

Cancer treatment is changing quickly with the rise of precision oncology. While the potential is exciting, not all Canadians currently have equal access to this technology. Thankfully, there are ways to address these concerns. As cancer research continues, the opportunities for highly personalized treatments will only grow.

Cancer treatment is changing quickly with the rise of precision oncology, an approach that uses advanced tests to better understand the unique makeup of each person's cancer. Germline and somatic tests, just a small part of precision oncology, are transforming cancer care by helping doctors match the right treatment to the right patient. This shift means treatments can be more effective, side effects may be reduced, and unnecessary treatments can be avoided. For patients, this can lead to better quality of life and longer survival. For the healthcare system, it can mean faster, more efficient care and lower overall costs.

While the potential is exciting, not all Canadians currently have equal access to this technology. Differences in eligibility and access; funding and coverage; and education and awareness across Canada means that some patients may face delays or may not be offered these tests at all. These are just some of the systemic issues related to germline and somatic testing. Thankfully, there are pathways and actions that can be taken to address these concerns.

As research continues to identify more genetic mutations and biomarkers, the opportunities for highly personalized treatments will only grow. This new way of treating cancer has the power to change outcomes for patients and shape a more efficient, equitable healthcare system for all Canadians.

RESOURCES AND REFERENCES

Resources

Canadian Breast Cancer Network's Resources on Precision Oncology

Blog articles – Genetics

Factsheet - Hereditary Breast Cancer Syndrome

Podcast episode – Breast Cancer and Personalized Care: What You Need to Know

Podcast episode – Understanding Testing in Breast Cancer: Genetic, Genomic, and Biomarkers Explained

Report – Precision Oncology and Breast Cancer: Considering Canada's Approach in an Evolving Landscape

Webinar – A Genetic Counsellor Answers your Questions about Genetic Testing

Webinar – How Precision Oncology Can Help People with Breast Cancer

Webinar – Understanding the Role of Genetic Testing

Other Resources on Precision Oncology

Access to Genomic Testing – A State of Readiness Progress Report

Canadian Cancer Clinical Trials Network – Canadian Precision Oncology Trial Finder

Canadian Journal of Health Technologies – An Overview of Comprehensive Genomic Profiling Technologies to Inform Cancer Care

Colorectal Cancer Resource & Action Network – Generating a Cost-Benefit Analysis to Help Support Access to Comprehensive Genomic Profiling (CGP) for Five Metastatic Cancers in Canada: Helping to Ensure CGP Becomes a Standard of Care in Canada!

Colorectal Cancer Resource & Action Network - Precision in Practice: Costs and Benefits of Comprehensive Genomic Profiling for Five Stage 4 Cancers

Know Your Genome – Precision Oncology Awareness

Papalexis, P., Georgakopoulou, V.E., Drossos, P.V., et al. (2024). Precision medicine in breast cancer (Review). Molecular and Clinical Oncology, 21(78). https://doi.org/10.3892/mco.2024.2776

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APPENDIX A

The potential results from germline and somatic tests can have predictive and/or prognostic factors. Additionally, specific gene mutations can be germline (inherited and in the individual), somatic (acquired and in the tumor), or both. The tables on this and the following page categorize the potential findings from germline and somatic testing according to these attributes. Table 1 on the right outlines which gene mutations are germline, somatic or both. Table 2 on the following page outlines the predictive and prognostic factors of some of the potential results from germline and somatic testing.

This table is provided for educational purposes and was generated based on independent review of the literature in November 2025. The information should not be considered exhaustive or accurate. With the rapid development of scientific knowledge, new evidence may come out between the time the table was developed and when the toolkit is published or read. Since the information is not continually updated, it may not reflect the most recent evidence.

The information is not intended to guide treatment decision making. It is not a substitute for medical advice. Speak to your healthcare provider before making any healthcare-related decisions.

Germline and Somatic Gene Mutations Associated with Breast Cancer

	Germline	Somatic
AKT1		■
ATM	■	
BARD1	■	
BRCA1 and *BRCA2*	■	■
CDH1	■	
CHEK2	■	
EGFR		■
ERBB2 mutations		■
ESR1		■
MYC		■
NF1	■	
NTRK1, *NTRK2*, and *NTRK3*		■
PALB2	■	
PIK3CA		■
PTEN	■	■
RAD51C and *RAD51D*	■	
RB1		■
STK11	■	
TP53	■	■

Table 1

Predictive and Prognostic Status of Findings from Germline and Somatic Testing for Breast Cancer		
	Predictive	**Prognostic**
AKT1	■	
BRCA1 and *BRCA2*	■	
dMMR	■	■
ER and PR status	■	■
ESR1	■	■
FGFR1, FGFR2, FGFR3, and FGFR4	■	
HER2 status	■	■
HRD	■	
Ki-67	■	■
MSI-H	■	■
NTRK1, *NTRK2*, and *NTRK3*	■	
PD-L1	■	
PIK3CA	■	
PTEN	■	■
TMB-H	■	
TP53		■

Table 2