

CBCN Advocacy Guide: Accessing Genomic Testing in Canada



What is Genomic Testing?

Rather than treating cancer based on its location in the body, researchers and doctors are moving towards individualizing treatments based on **genomics**, the study of a person's DNA, as well as environmental and lifestyle factors. This may be referred to as **precision medicine** or **personalized medicine**. While **genetics** involves the function of a **single gene**, **genomics** tries to understand how **all genes** influence the whole body.

Genomic testing is an important aspect of precision medicine as it looks for **biomarkers** that can provide information about an individual's specific tumor. A biomarker is a biological molecule in the blood, tissue, or other bodily fluids that signal a normal or abnormal process or condition of a disease. This is done to properly assess who may benefit from a specific anti-cancer treatment and who might be at an increased risk of side effects from other treatments, rather than administering standardized anti-cancer treatments to patients based on the location of the cancer.

Genomic testing also identifies DNA changes that may be causing certain cancer behaviours, such as growth, how aggressive it is, or whether it spreads to other body parts. Lastly, genomic testing may be helpful in finding a **clinical trial** that enrolls patients based on the biomarkers in their cancer.

What Does Genomic Testing Involve?

Unlike genetic testing which tests the individual, genomic testing involves testing the cancer. Genomic tests provide a snapshot of the molecular composition of the cancer at the specific time that it is tested and as the cancer cells change over time, the genomic test results will change as well.

In genomic testing a healthcare professional takes a sample of your cancer cells which can be done during surgery or from a biopsy. The sample is then sent to a laboratory that tests the cells for specific biomarkers and a lab report is created based on the findings. After the results are analyzed, you and your healthcare team can begin to make treatment decisions. Outside of using genomic tests for treatment decision-making, these tests can also be ordered for a variety of reasons, including for prognostic reasons or to monitor a patient's response to treatment.

Breast Cancer, Treatment Decisions and Genomic Testing

Genomic tests are available as both multi-panel tests and comprehensive genomic profiling (NGS) tests. Multi-panel tests only test for a pre-determined range of genes while comprehensive genomic profiling tests whole genomes. For example, **Foundation Medicine's** comprehensive genomic profiling tests "provide information about clinically relevant biomarkers and genomic alterations to help match patients to approved targeted therapies, immunotherapies, and clinical trial options". At this time these tests are not currently reimbursed throughout the country.

Below we outline a few of the multi-panel genomic tests that are used for breast cancer patients in Canada.

Oncotype DX

There are two types of Oncotype DX tests. The Oncotype DX Breast Cancer Recurrence Test is for early-stage, ER-positive, HER2-negative breast cancer and it analyzes the activity of 21 genes to predict the likelihood of the cancer growing and responding to treatment. It also provides information on risk of recurrence and whether the patient would benefit from chemotherapy. The Oncotype DX Breast DCIS Test is for DCIS breast cancer. It also provides information on risk of recurrence, the risk of a new cancer developing in the same breast, and whether the patient would benefit from chemotherapy. ^[1]

The Oncotype DX test is the most common test used in Canada. It is funded in all provinces for patients with early-stage node negative breast cancer and publicly funded in a few provinces for lymph node positive breast cancer based on specific eligibility criteria.

Prosigna Breast Cancer Prognostic Gene Signature Assay

The Prosigna Breast Cancer Prognostic Gene Signature Assay test is for early-stage, hormone-receptor-positive disease with up to three positive lymph nodes. It analyzes the activity of 50 genes to predict the risk of distant recurrence for postmenopausal women within 10 years of diagnosis and after 5 years of hormonal therapy. It provides a low-risk or high-risk score for recurrence which can be helpful in deciding whether 5 years or 10 years of hormonal therapy, such as Tamoxifen, is more ideal.^[2]

Prosigna is currently only funded in Alberta, British Columbia, and Ontario

EndoPredict

The EndoPredict test is for early-stage, hormone-receptor-positive, HER2-negative breast cancer that is either node-negative or has up to three positive lymph nodes. It analyzes the activity of 12 genes to predict the likelihood of distant recurrence. It provides a low-risk or high-risk score for recurrence which can be helpful in deciding whether chemotherapy or other treatments after surgery are necessary.^[3]

Ontario is the only province that publicly funds EndoPredict.

MammaPrint

MammaPrint is for stage I or stage II breast cancer that is hormone-receptor-positive or hormone-receptor-negative. It looks at the activity of 70 genes and predicts the risk of recurrence within 10 years after diagnosis of these types of cancers. It provides a low-risk or high-risk score for recurrence which can be helpful in deciding whether chemotherapy or other treatments after surgery are necessary.^[4]

MammaPrint is not yet publicly funded anywhere in Canada as it is currently under final review by the Ministry of Health.

When to Get Genomic Testing Done

Genomic testing can be done any time after a tissue sample (biopsy or resection) of cancer has been taken. When it comes to genomic testing, earlier is better than later to ensure that you have all your treatment options available to you from the beginning. Before taking these steps, it is important to first discuss with your healthcare team to confirm that genomic testing would be beneficial to you.

[1] Oncotype DX Genomic Tests. *Breastcancer.org*. https://www.breastcancer.org/symptoms/testing/types/oncotype_dx

[2] Prosigna Breast Cancer Prognostic Gene Signature Assay. *Breastcancer.org*. <https://www.breastcancer.org/symptoms/testing/types/prosigna>

[3] EndoPredict Test. *Breastcancer.org*. <https://www.breastcancer.org/symptoms/testing/types/endopredict-test>

[4] MammaPrint Test. *Breastcancer.org*. <https://www.breastcancer.org/symptoms/testing/types/mammaprint>

Advocating to Get Genomic Testing Done

Because publicly-funded genomic testing varies across the country, you may want to advocate for more equitable access to this testing. This is especially relevant if you live in a province or territory that does not cover genomic testing. Below we discuss avenues and actions you can take to advocate to get access to genomic testing.

Contact Your Provincial MPP/MLA

Depending on where you live, you can reach out to your MPP (Member of Provincial Parliament) or MLA (Member of Legislative Assembly) and detail your situation about not being able to access certain genomic tests because they are not covered in your province or territory. This is also a way to explore whether policy changes need to be made to ensure that other breast cancer patients who may need to access genomic testing can do so.

You can [find the contact information](#) for your elected official using your home address. In your correspondence to them, be sure to include what the importance of having access to genomic testing would mean to you.

Contact Your Ministry of Health

The Ministry of Health where you live is responsible for setting healthcare policies in your province. You can reach out to them to voice your concerns regarding access to genomic testing. If you reach out to your MPP/MLA, they can also reach out to your provincial Ministry of Health on your behalf. You can find the contact information for your Ministry of Health [here](#). In your correspondence to them, be sure to include what the importance of having access to genomic testing would mean to you.

You can also contact the Minister of Health of Canada and voice your concerns about not being able to access genomic testing and why it is important for yourself and other breast cancer patients to be able to access it. The contact information for the Minister of Health of Canada is:

Minister of Health
House of Commons
Ottawa, Ontario K1A 0A6
hcminister.ministresc@canada.ca

Contact Your Private Insurance Company

If you have private insurance, then you may be able to have your genomic testing covered if you are able to find a private clinic that offers this type of test. The first step would be to check what your current coverage is, or to call them directly to see if whether it can be covered. You can find a list of questions to ask your private insurance company regarding coverage as well as questions to ask if genomic testing is not covered [here](#). If you end up in a situation where your insurance does not cover genomic testing, you can take [these steps](#) to appeal.

Pay Out-of-Pocket

If you don't wish to contact a government official, don't have private insurance, or if your private insurance company is unable to cover these tests, the option to pay out-of-pocket is available. Simply visit the official website of the companies that offer genomic testing to see if you can buy it directly through them. Be sure to read through their terms and conditions and well as what the test results can and cannot guarantee. It is also advisable to speak to your doctor prior to buying any tests to ensure that you are getting the appropriate test for yourself which will help to ensure that the test results will be valuable to you.