

WAITING

FOR

TIMELY EQUITABLE ACCESS TO DRUGS
FOR METASTATIC BREAST CANCER



TREATMENT:

ACKNOWLEDGEMENTS

THE CANADIAN BREAST CANCER NETWORK WOULD LIKE TO ACKNOWLEDGE EVERYONE WHO CONTRIBUTED TO THIS REPORT.

Thank you to the women living with metastatic breast cancer and their caregivers who participated in our survey. We appreciate the time you have taken to share your experiences. Your voice has focused the need to raise awareness and address metastatic breast cancer drug access in Canada. Thank you to the many partner organizations and groups across Canada who shared the survey.

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The Canadian Breast Cancer Network stands in solidarity with Canadians affected by metastatic breast cancer. This report is dedicated in loving memory to breast cancer advocate Geraldene Whyte, and to the many Canadians we have lost to metastatic disease.

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EXECUTIVE SUMMARY

Metastatic breast cancer affects thousands of Canadian women and their families. Close to 1,200 Canadian women will receive an initial diagnosis of metastatic breast cancer this year.¹ Many more women who had an initial diagnosis of an earlier stage of breast cancer will go on to develop metastatic breast cancer.² Metastatic breast cancer occurs when the cancer spreads to other areas of the body from the original cancer site, most often to the bones, but also to the liver, lungs, brain and skin.

The Canadian Breast Cancer Network (CBCN) has identified metastatic breast cancer as a priority issue and provides resources and support for women living with metastatic breast cancer and their families. CBCN is taking the lead on raising awareness of the need for equitable access to drug treatments for metastatic breast cancer in all regions of Canada. Drug access is a matter of life and death for women living with metastatic cancer. Drugs often lose their effectiveness over time and treatment must switch to other drugs or combinations of drugs to keep ahead of tumour growth. Timely access to drugs is crucial.

The treatment landscape for metastatic breast cancer varies depending on which of the four main types of breast cancer you have and on where you live in Canada. Each province and territory has its own list of cancer drugs (the formulary) for which it will cover part or all of the cost through publicly-funded drug plans. A determining factor in access to needed drugs is the time elapsed after drugs have gone through the required levels of review by the federal government and the provinces until the provinces provide coverage by listing them on their formularies.

1 Canadian Partnership Against Cancer. The 2014 Cancer System Performance Report, March 2014. Available at http://www.cancerview.ca/idc/groups/public/documents/webcontent/sp_report_2014.pdf

2 Unfortunately at this time we cannot give an accurate number of the women how had an earlier breast cancer diagnosis who go on to develop metastatic breast cancer as there are no current Canadian statistics available.

OBSTACLES TO ACCESS: WAIT TIMES FOR LISTING ON PROVINCIAL FORMULARIES AND FORMULARY RESTRICTIONS

Delays in formulary listings result from the lack of firm deadlines for the provinces to list a drug on their formulary once a drug has been approved and an agreement has been reached on pricing with the drug manufacturer. As a result, there is often a two-year time lag or longer between provinces in making formulary listing decisions, resulting in inequitable access across the country. For Canadians living with metastatic breast cancer, waiting two years for a drug has a profound effect on quality of life for patients and their families and can make the difference between survival or not.

Delays can occur at any of the four main stages during the approval process, with the most significant ones happening at the pan-Canadian and provincial levels. The four stages are:

1. Review by Health Canada to approve a drug for sale in Canada.
2. Review by the Pan-Canadian Drug Oncology Review (pCODR). Following Health Canada approval, pCODR reviews clinical and economic data for new treatments and makes recommendations to the provinces and territories (except Quebec which is not a member) on whether they should consider listing the drug to their formularies.
3. Negotiations by the pan-Canadian Pharmaceutical Alliance (pCPA), which is a collaborative effort of the provinces to reach an agreement with the drug manufacturer on the drug price that will be available to all provinces that belong to pCPA.
4. Decision by each province and territory about whether they will list the drug on their formulary.

This lengthy review process often leaves patients waiting for long periods. Even patients with private insurance are

impacted by waits, particularly if their insurance plans only cover those treatments listed on the provincial formulary.

The provincial disparities in wait times can be illustrated by the experience with four metastatic therapies – Halaven, Afinitor, Perjeta and Kadcyra. The review process for these drugs at the pCPA level took between four and six months, while approval at the provincial level varied greatly. In the case of Halaven, the first province to list the drug took three months and the latest province to list it took 35 months, while two provinces still do not list it on their formularies.

As of September 2015 wait times for listing on provincial formularies for Afinitor varied between seven and 18 months and one province still does not list it. The delay in provincial listing for Perjeta took from three to 23 months, and for Kadcyra the delays ranged from three to 10 months, with two provinces and one territory still not covering it.

These lengthy and inequitable wait times cause enormous physical, emotional and financial strain on women and their families at a time when they are trying to slow the progression of the disease and maintain the best possible quality of life. The pattern of long delays is especially pronounced in Quebec and the Atlantic provinces.

A further limitation on access is created by the restrictions that provincial formularies place on when drugs can be used in the course of treatment. Many provincial formularies restrict certain drugs to initial treatment or later phases of treatment (referred to as first line treatment, second line, etc.). Formularies often cover older drugs that are less costly, particularly if the drug is no longer covered by patent and is available in generic form. It is a challenge to secure coverage of newer therapies. This has an impact on women who may run out of treatment options on older drugs and who face hurdles in getting access to newer, more effective therapies that may prolong their lives. Women also discover that the choices they made for their initial treatment can restrict their choices as the disease progresses.

VOICES OF WOMEN AFFECTED BY METASTATIC BREAST CANCER

To learn more about women's experiences with access to treatment for metastatic breast cancer, CBCN conducted an online survey and key informant interviews during spring 2015. The following quotes sum up the experience of many women.

I was shocked at the cost of Faslodex [and eventually found a way to get coverage]. I developed two more tumours this year. It frightens me – will the drugs I need be covered? Will I have to fight all the time? It's scary.

There's a two-level system. You get better drugs if you pay for them yourself. A woman I know goes from Alberta to Toronto for clinical trials.

The BC Cancer Agency has been very helpful – they completed forms for me so I could get Faslodex free of charge for almost nine months.

In our province, Perjeta is covered for first line treatment only. It is denied for second line treatment. I had it as a first line treatment. When I needed it again, I had to go back on chemo to satisfy the restrictions. I lost my hair and got nauseated all over again just to get Perjeta. I'm willing to put up with [side effects]. I have two young children and want to be alive to see them through school.

ACHIEVING EQUITABLE ACCESS

The Canadian Breast Cancer Network has identified four strategic pillars for improvement in the area of equitable access to treatment for all Canadian women living with metastatic breast cancer.

1. Support efforts toward faster and more equitable access to treatment drugs
 - CBCN will engage provinces that are slow to list drugs on their formularies and will advocate for them to list within a defined time period.
 - CBCN will advocate for all provinces to consider patient input submissions to ensure that the patient voice is heard and contributes to decision-making.
 - CBCN will engage the pCPA to advocate for more clarity in the deliberation process and will encourage the development of deadlines for decision-making.
 - CBCN will advocate for a fast-track review mechanism to expedite access to new treatments for patients with urgent care needs.
 - CBCN will support efforts to achieve a national pharmacare program, collaborating with partner organizations.
2. Increase knowledge and raise awareness
 - CBCN will advocate for more precise statistics on the number of Canadians affected by metastatic breast cancer.
 - CBCN will continue its initiatives to educate women about treatment options, treatment sequencing and differing provincial standards of care.
3. Work with navigators in the health care system
 - CBCN will engage drug access navigators and other patient navigators within cancer care.
4. Engage partners
 - CBCN will engage partner organizations that share the goal of equitable access to cancer treatment drugs for all Canadians.
 - CBCN will invite new partners to join us, including organizations representing family caregivers who have a growing voice and are deeply affected by women's access to treatment drugs.

• CBCN will continue to help women learn the advocacy skills they need to stand up for their right to knowledge, choices and access.

• CBCN will make full use of social media to extend the reach of the strategy and engage new supporters. We will work with media partners to raise awareness through coverage containing solid facts and personal stories.

3. Work with navigators in the health care system

• CBCN will engage drug access navigators and other patient navigators within cancer care.

4. Engage partners

• CBCN will engage partner organizations that share the goal of equitable access to cancer treatment drugs for all Canadians.

• CBCN will invite new partners to join us, including organizations representing family caregivers who have a growing voice and are deeply affected by women's access to treatment drugs.

The Canadian Breast Cancer Network invites all women living with metastatic breast cancer, their families, friends, clinicians, researchers and allies to join our call to action and make equitable access a reality for all.

INTRODUCTION

Many Canadians are shocked to learn that drugs approved for sale in Canada with demonstrated efficacy are often not covered by provincial public drug plans. Instead, payment for drugs is often the patient's responsibility. Where you live in Canada, not your health needs, determines how long you may have to wait and the extent of coverage you receive.

In 2012, the Canadian Breast Cancer Network (CBCN) identified metastatic breast cancer as a priority issue, and has been actively working to raise awareness of metastatic breast cancer and advocate for the development of more resources, information, support and access to new therapies for Canadians afflicted by metastatic breast cancer.

In 2013, CBCN published a report on the experience of metastatic breast cancer patients and their caregivers, in partnership with Rethink Breast Cancer. The report, *Metastatic Breast Cancer in Canada: The lived experience of patients and caregivers*, details the experience of dealing with quality of life, access to treatment and support, access to new therapies and the financial impact of living with metastatic breast cancer.³

Since launching the metastatic breast cancer campaign, CBCN has trained numerous Canadians living with metastatic breast cancer in self-advocacy for increased drug access and has successfully led advocacy campaigns to expedite metastatic drug coverage in Ontario, British Columbia, Manitoba, Prince Edward Island, Nova Scotia and Quebec.

The Canadian Breast Cancer Network champions the issues of Canadians living with metastatic breast cancer to decision-makers and the general public. In 2014, CBCN launched its Living Legacy campaign to raise awareness of metastatic breast cancer. The campaign features a dedicated advisory committee of women living with metastatic breast cancer, who shared their stories in an online video and at the launch reception on Parliament Hill attended by over 30 parliamentarians. The Living Legacy campaign highlights the urgent need to ensure that the voices and experiences of Canadians living with metastatic breast cancer are being leveraged to inform health care decision-making at all levels.

In this paper we focus on the need for equitable access to medications for women with metastatic breast cancer. We describe how drugs are approved for sale and granted public funding in Canada. We also highlight the inequitable wait times that exist within the multi-staged drug review system and provincial formulary listings, which result in variable coverage in each province and territory. Throughout the report, we feature women living with metastatic breast cancer who share their experiences of trying to access drug treatments. Their voices are expressed in italics.

A call to action outlines the advocacy initiatives that CBCN will lead in partnership with others.

THE CANADIAN PUBLIC WOULD BE SHOCKED TO KNOW THAT ACCESS IS SO INEQUITABLE ACROSS THE COUNTRY

³ *Metastatic Breast Cancer in Canada – The lived experience of patients and caregivers*. Canadian Breast Cancer Network and Rethink Breast Cancer 2013. Available at <http://www.cbcn.ca/index.php?pageaction=content.page&id=7951&lang=en>

WHAT IS METASTATIC BREAST CANCER?

Metastatic breast cancer, also known as advanced, secondary or Stage IV breast cancer⁴ is the spread of cancerous cell growth to areas of the body other than where the cancer first formed, often with increased severity. This may happen before or after treatment of the cancer in the breast, or it may result from a recurrent breast cancer (breast cancer that grows back in the same location, perhaps a number of years later). Though breast cancer cells can spread to almost any part of the body, they most commonly spread to the bones. Other common sites include the lungs, liver, brain and skin. It is this new cancer that is called a metastasis.

Treatment for metastatic breast cancer are often categorized by the receptor status of the tumor. The receptor status is broken down into four main types, and each type requires its own set of treatment drugs. The four types are:

- Hormone receptor positive (HR+). When a tumour is not HR+, it is referred to as Hormone receptor negative (HR-).
- Human epidermal growth factor receptor 2 positive or negative (HER2+ or HER2-).
- A tumour can be HR+ and HER2-; this is the most common form of breast cancer.
- A tumour can be both HR- and HER2 -, also known as Triple-Negative Breast Cancer

Different drugs are used to treat different breast cancers and the metastases that may occur in the bones, liver, lung, brain and other sites in the body. Appendix B provides details about the different types of breast cancer and the most common

4 Breast cancer is divided into five main stages, 0 through IV. The stages are based on the size of the tumor, the number of lymph nodes involved, and how much the cancer has spread.

drugs used to treat metastatic breast cancer in Canada. An estimated 25,064 Canadian women will be diagnosed with breast cancer in 2015. This represents 26 per cent of all cancers in women.⁵

Approximately 5 per cent of these women will have an initial diagnosis of metastatic breast cancer⁶ and more women diagnosed initially with earlier stages of breast cancer will go on to develop metastatic breast cancer.

We can estimate the number of women with metastatic breast cancer in Canada, but we do not have exact figures. This is because there is no clear statistical category for metastatic breast cancer. Clinical practice in cancer care classifies cancer cases according to the stage at initial diagnosis. For example, if a woman is initially diagnosed with Stage II breast cancer that is treated but then recurs years later and has spread to the bones, the cancer is recorded as Stage II with bone metastasis, not Stage IV cancer. We do know that approximately 1,200 women have an initial diagnosis of metastatic breast cancer each year. Added to this is the cumulative number of women who progress to metastatic breast cancer from an initial diagnosis at an earlier stage.

Many women living with metastatic breast cancer find it frustrating to not know more precisely how many other women in their region or in Canada are facing metastatic breast cancer, and they are further frustrated with the challenges of access to treatment and support.

5 Canadian Cancer Statistics 2015. Canadian Cancer Society. Available at <http://www.cancer.ca/en/cancer-information/cancer-101/canadian-cancer-statistics-publication/?region=on>. An estimated 200 men will be diagnosed with breast cancer in 2015.

6 Canadian Partnership Against Cancer. The 2014 Cancer System Performance Report, March 2014. Available at http://www.cancerview.ca/idc/groups/public/documents/webcontent/sp_report_2014.pdf

THE ISSUE

I've had to go across the country to workshops just to meet other women with metastatic breast cancer. We need accurate data Canada-wide about the burden of this illness so that patients and governments can make informed decisions about the costs of drug coverage. Right now we have to fight for drug access in isolation- we have to rally for each other.

Thousands of Canadian women are living with metastatic breast cancer. One of their greatest challenges is getting access to the drugs they need to treat the disease and keep ahead of it as it develops drug resistance, requiring a switch to new medication or combinations of medication. Where you live in Canada determines whether or not you can get drugs at a price you can afford.

Although Canada has publicly-funded medical care for essential health services under the *Canada Health Act*, this is restricted to medical services. Pharmaceutical coverage differs by province and territory, resulting in unequal access to essential medications across the country.

Drugs that are paid for in part or in full by provincial benefit plans are often referred to as being listed on the provincial/territorial drug formulary. The drugs that are listed on provincial/territorial formularies vary with each jurisdiction, as does the amount of the total drug cost that is paid by the province or territory.

For women living with metastatic breast cancer, a formulary listing can be a question of life or death. If a required drug is on the provincial or territorial formulary, it is probably affordable. If it is not on the formulary, patients must pay for the drug themselves or through private insurance. A further challenge is getting access to new drugs once the disease has developed a resistance to the drugs currently being used. To counter disease progression, timely access to new treatments is crucial for metastatic patients.

Since wait times for listing new drugs on formularies vary widely from province to province, this creates a situation in which a patient in one province has coverage for a treatment while a patient in another jurisdiction continues to wait for the drug to be covered and accessible. This inequity in access can limit a patient's treatment options and result in further disease progression.

Almost 70 per cent of Canadians have private insurance that covers part or all of the cost not covered by publicly-funded drug plans. The amount that private insurance will cover varies according to the insurance plan. Many private insurance plans will cover only drugs listed on the formulary of the patient's province of residence. For those without private insurance, the total cost not covered by a publicly-funded drug plan is the responsibility of the patient.

If the patient cannot pay, they do not get the drug. The cost of a new drug can be as high as several thousand dollars a month. When this cost is beyond the means of the patient, treatment is affected. The woman's physician may not tell her about, and may not prescribe, drugs that are not affordable for her. In this case, her treatment will rely on older, possibly less effective drugs. Treatment options and often treatment effectiveness will be reduced.

This has serious consequences because drug combinations and new drugs help women keep ahead of the cancer progression and can prolong life.

The Canadian Breast Cancer Network believes that it is the right of every person living with metastatic breast cancer in Canada to have timely access to the most effective treatment and that survival and quality of life should not be determined by the lottery of where you live.

HOW DRUGS ARE APPROVED AND FUNDED IN CANADA

My doctor just doesn't tell me about drugs and treatments he knows I can't afford.

The following is a brief overview of how drugs are approved for sale and granted public funding in Canada, demonstrating why drug access is variable across Canada.

Patients hoping to access new treatments must first wait during the Health Canada approval process, which occurs before drugs can be marketed in Canada. A drug manufacturer applies for approval to Health Canada, whose review examines health, safety and quality of the drug, including data from clinical trials. As seen in Figure 1, this process can take up to two years but a Priority Review Process may make drugs available more quickly for diseases such as cancer for which there are few effective therapies already on the market.

Treatments reviewed and approved for sale by Health Canada are not automatically guaranteed coverage by provincial formularies. Instead, treatments must go through the various stages of the Canadian drug approval process to become eligible for coverage in each jurisdiction.

Following approval by Health Canada, the pan-Canadian Oncology Drug Review (pCODR) evaluates an approved cancer drug and makes a recommendation to the provinces and territories (except Quebec which is not a member of pCODR) to guide decisions in their jurisdictions about whether to publicly fund the drug. The pan-Canadian Oncology Drug Review analyzes clinical, economic and patient evidence and uses this evaluation to provide recommendations and advice to the provincial/territorial drug plans and provincial cancer agencies about reimbursement to patients. Non-oncology therapies are reviewed in a similar process by the Common Drug Review.

These review processes can take up to a year. Organizations representing patients are invited to provide input to pCODR reviews, which the CBCN has done on several occasions.

After pCODR issues a positive recommendation, called a Notification to Implement, the process focuses on drug costs. The provinces and territories have formed a partnership to conduct joint negotiations with pharmaceutical manufacturers for brand name drugs and to achieve better value for generic drugs. The pan-Canadian Pharmaceutical Alliance (pCPA) is an initiative of the Council of the Federation, which is comprised of Canada's 13 provincial and territorial Premiers. The pan-Canadian Pharmaceutical Alliance aims to achieve lower prices and consistent pricing for all jurisdictions through joint negotiations and bulk buying and thereby aims to increase access to treatment options and improve consistency of coverage criteria across Canada. While Quebec is considering joining, that province and the territories do not currently participate in the pCPA. Once pricing negotiations with the manufacturer have been concluded, a Letter of Intent is signed with the manufacturer by the lead province in the negotiation (Ontario is the lead for brand name drugs; Nova Scotia and Saskatchewan are the lead for generic drugs). The agreed price is available to all provinces that are members of pCPA. The pan-Canadian Pharmaceutical Alliance negotiation is an open-ended process with no set timelines and limited transparency during negotiations.

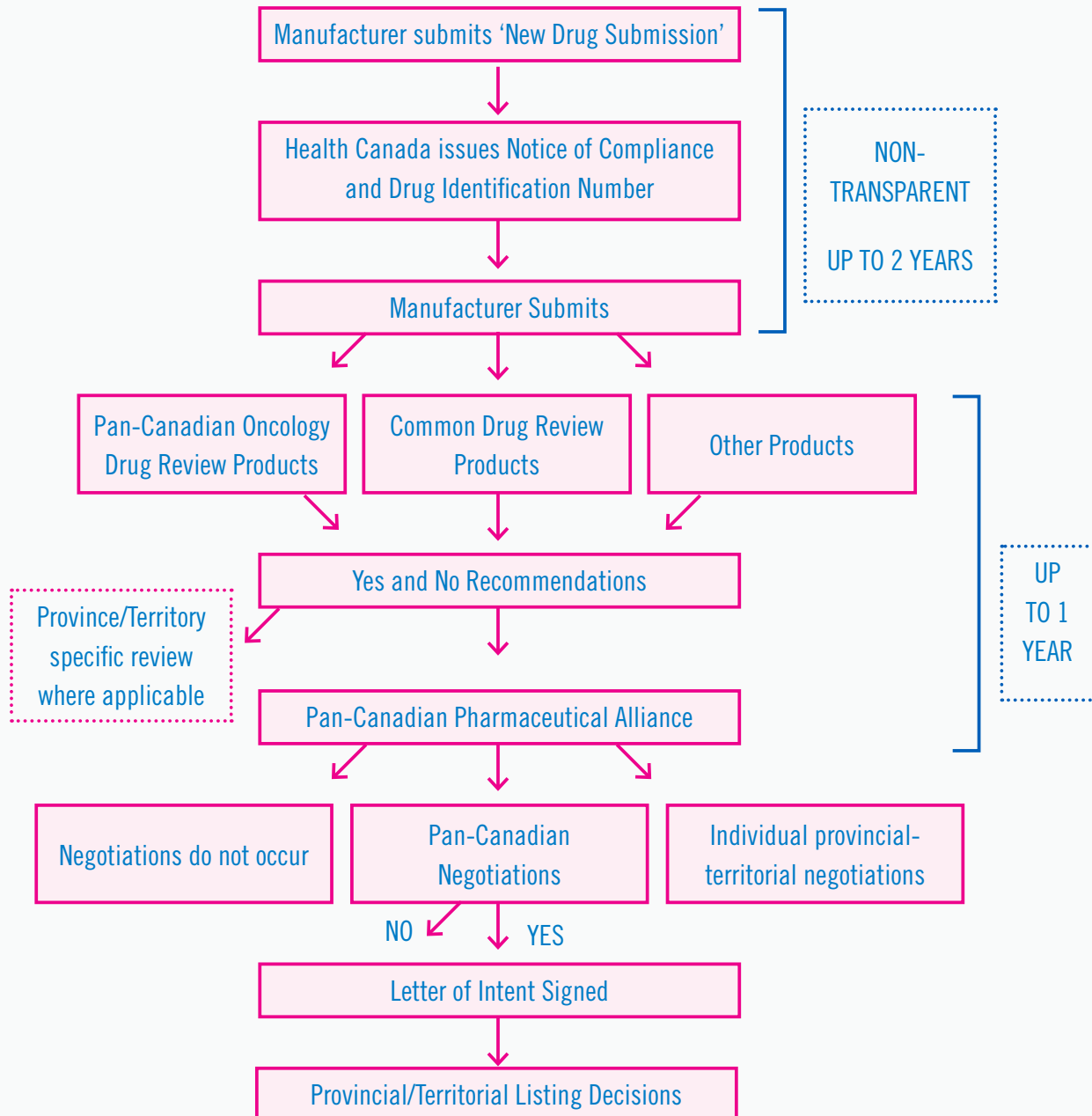
There is currently no obligation on provinces to make a firm commitment to list a drug on their formularies once the pricing negotiations are completed. This creates inequitable access because some provinces list the drug quickly while others delay for up to two years or more before listing. For a patient waiting for access to a drug, a two-year delay can make the difference between life and death.

Individual jurisdictions make their own coverage and reimbursement decisions based on recommendations made by pCODR and on the price negotiated with the drug manufacturer through the pCPA. Provincial/territorial decisions also take into account other factors such as program mandates, priorities and budgets. It appears that each

province may do its own clinical review, even though thorough clinical reviews have already been done by Health Canada and pCODR. This may explain why provincial formularies have differing clinical restrictions on how a drug may be used.

Provincial and territorial publicly-funded drug plans also vary widely. Details of these plans are found in Appendix A.

FIGURE 1:TIMELINE OF DRUG REVIEW AND APPROVALS PROCESS IN CANADA



THE WAIT FOR DRUG COVERAGE VARIES ACROSS CANADA

Since each Canadian province and territory decides whether and when it will list a cancer drug on its formulary and whether or not it will cover the full or partial cost of the drug, the result is vastly different coverage for metastatic treatments in each Canadian province or territory. Provinces have varying delays as to when they decide to list a drug that has been through all the levels of approval and pricing negotiation. It must be noted that listings on formularies change often and that the formulary of each province should be checked for up-to-date information. Cancer drug formularies for all provinces and territories are available online except for Manitoba.

Patients with private insurance are less affected by formulary listings and the proportion of the drug cost that is publicly covered. However, different private insurance plans may provide widely different coverage and many private insurance plans base their drug coverage plans upon the provincial formulary listings. As a result, if a treatment is not covered by the provincial formulary, it is also not eligible for coverage under the private insurance plan. This creates a situation where many patients are forced to forego essential treatments due to inability to afford the cost of treatments whether or not they have private insurance.

As a result of Canada's multi-stage drug review process, patients are often left waiting indefinitely for treatments. The following case study of four metastatic therapies, which have all gone through the pCODR, pCPA and provincial drug review processes, provides an informed example of the current drug coverage system. The case study highlights the processes in the system causing the greatest lags, the vast differences in wait times for new treatments by province and the jurisdictions most affected by wait time delays.

Afinitor (everolimus): a patented drug manufactured by Novartis that is used in combination with exemestane for HR+ and HER2- metastatic breast cancer

Halaven (eribulin mesylate): a patented drug manufactured by Eisai that is used to treat metastatic breast cancer for patients who have previously received at least two chemotherapy regimens

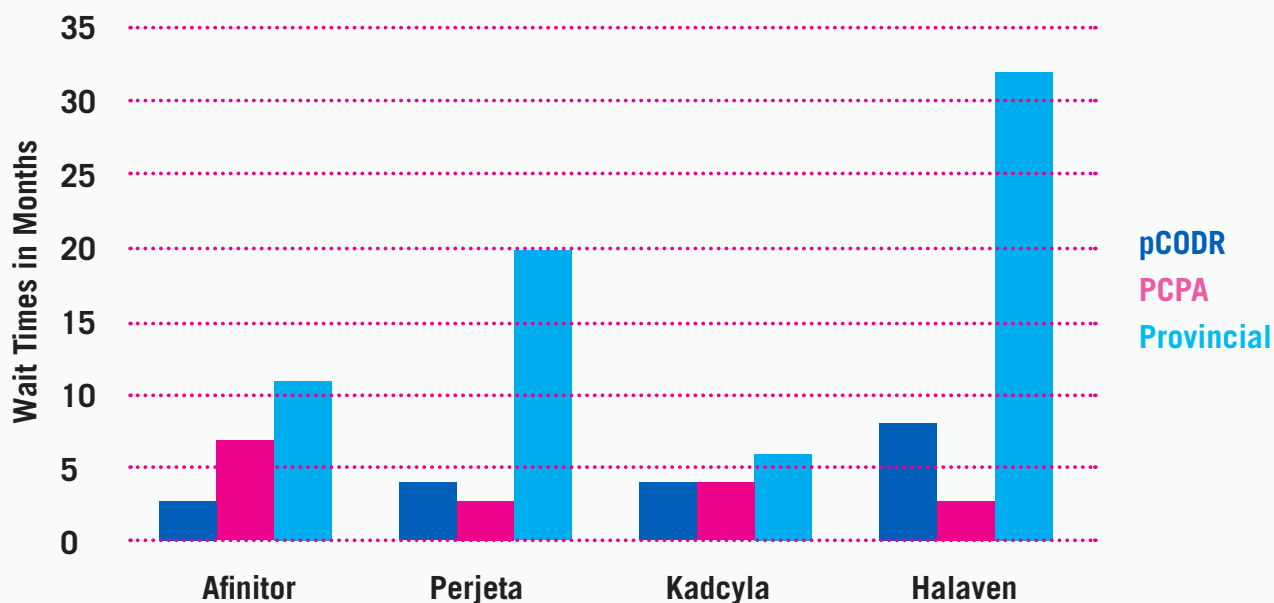
Kadcyla (trastuzumab emtansine): also known as TDM1, a patented drug manufactured by Roche Canada targets HER2+ metastatic breast cancer

Perjeta (pertuzumab): a patented drug manufactured by Roche Canada that is used to treat HER2+ metastatic breast cancer. It is usually taken in combination with Herceptin (trastuzumab).

SYSTEMIC DELAYS IMPACTING METASTATIC DRUG ACCESS

After waiting one to two years for drugs to be approved for sale in Canada, Canadian patients must endure further delays in access through the pCODR, pCPA and provincial drug assessment processes. For these patients, the longest and most problematic delays in the metastatic drug review system occur at the post-pCODR stage.

FIGURE 2: DRUG REVIEW PROCESS WAIT TIMES DIFFERENCE



As Figure 2 illustrates, the pCPA negotiations and the provincial formulary deliberations have the greatest impact on wait times for new treatments. Based on the available listing information, the pCODR wait time was calculated as the time elapsed between the issuing of the Notice of Compliance from Health Canada to the Notification to Implement issued by pCODR, which varied between three and eight months for the four metastatic therapies. Similarly, the pCPA data was calculated from the difference between the date of the Notification to Implement issued by pCODR and the date of the first provincial listing.

These calculations are limited because the pCPA does not publicly disclose the dates by which their decisions are finalized. Since pCPA deliberations are focused around pricing negotiations, the process can carry on for an indeterminate length of time and is dependent on the ability of the manufacturer and the provinces to come to an agreement. As a result, pCPA wait times for the four metastatic therapies differ widely from 3-4 months for Halaven, Kadcylla and Perjeta and up to 8 months for Afinitor.

But the greatest variances clearly occur at the provincial level. Wait times were calculated by examining only those provinces that have decided to list the treatment, and then measuring the time difference in months between the date that the first and last provinces listed the drug.

At the provincial level, the wait time discrepancies are staggering, varying from a 6-month difference for Kadcylla, 11 months for Afinitor, 20 months for Perjeta and 32 months for Halaven. It is important to note, particularly in the case of Kadcylla, which is the newest drug to enter the market, that these drugs are still undergoing review in several provinces and that these wait times are therefore just a snapshot of the total overall wait time variances across the country for the treatments. These wait time figures will continue to increase until more provinces list these treatments.

The post-pCODR process is also the period with the least transparency and certainty for patients. Because pCPA negotiations and provincial deliberations are open-ended and lack clear deadlines for decision-making, patients are not informed about when a drug is being considered for reimbursement by their province or when their province will make a final decision on the listing status of a therapeutic product. Furthermore, only Ontario, Quebec and British Columbia accept patient input submissions during their provincial reviews and therefore patients and patient advocacy organizations often do not have the opportunity to provide evidence or feedback to influence the decision-making process in any way. As a result, after the pCODR review process, drug reimbursement decisions enter an indefinite waiting period wherein drugs are considered for provincial reimbursement with minimal transparency or accountability for timely decision-making.

WAIT TIME DIFFERENCES AMONG PROVINCES

Further comparison of the approval and funding data for these four metastatic therapies reveals the stark differences in wait time delays between provinces for metastatic breast cancer patients hoping to access emerging treatments.

Halaven Even though pCODR issued the Notification to Implement for Halaven in August 2012, delays in listing it on provincial formularies varied between three and 35 months.

While Quebec funded Halaven within just three months, Manitoba and Ontario took 11 months to fund this therapy. Newfoundland and Labrador funded it within 13 months. Alberta and Saskatchewan listed within 14 months, while British Columbia listed after 17 months. Nova Scotia, the most recent province to fund this treatment, listed the treatment after 35 months, nearly three years after pCODR recommended the treatment for reimbursement. New Brunswick and Prince Edward Island still do not fund it.

Afinitor Wait times to have Afinitor listed on provincial formularies varied between seven and 18 months after pCODR issued its Notification to Implement in April 2013 recommending listing on formularies. Ontario, British Columbia, Alberta, Saskatchewan and New Brunswick listed Afinitor within seven to eight months. Quebec, Newfoundland and Labrador and the Yukon Territory

listed it within 10- 12 months, Manitoba after 15 months⁷ and Nova Scotia after 18 months. Prince Edward Island has not yet listed it.

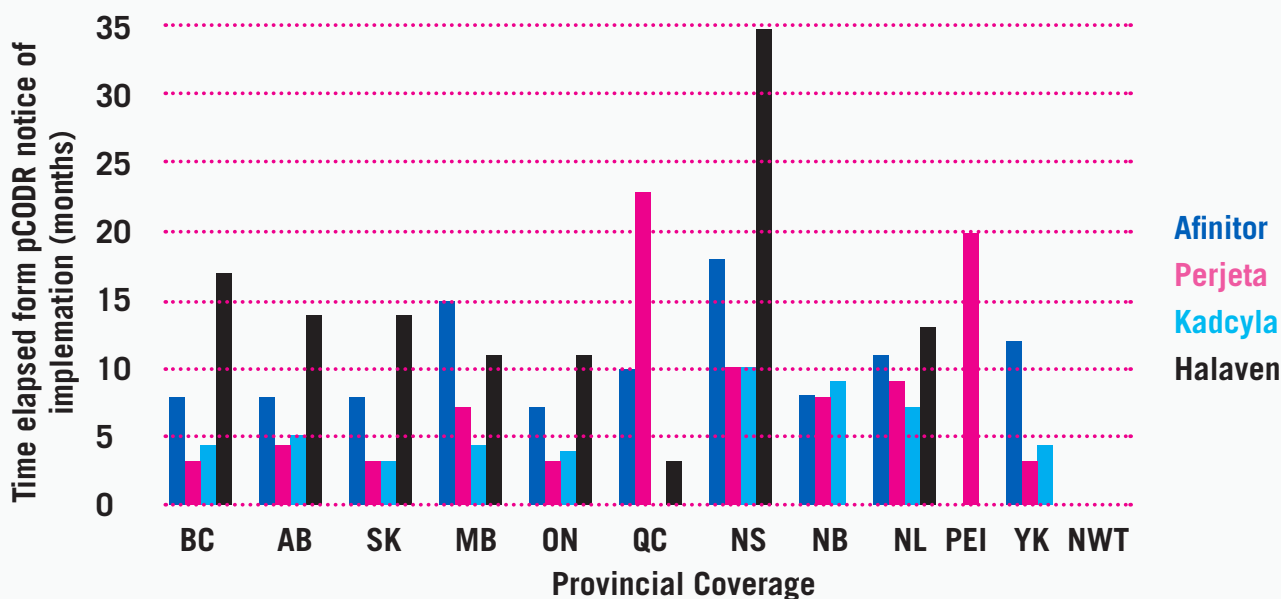
Perjeta The delay in listing by the provinces after the pCODR Notification to Implement in August 2013 varied from three to 23 months. British Columbia⁸, Alberta, Saskatchewan and Ontario listed it within three to four months. While Manitoba listed it within seven months, New Brunswick and Newfoundland and Labrador listed within eight to nine months and Nova Scotia within 10 months. Both Prince Edward Island and Quebec only decided to fund Perjeta in 2015, at 20 and 23 months respectively, or nearly two years after the pCODR Notification to Implement was issued.

Kadcyla Delays in listing Kadcyla after pCODR issued its Notification to Implement in January 2014 varied between three and 10 months. Saskatchewan was the first province to fund Kadcyla after 3 months. British Columbia, Manitoba and Ontario listed it to their formularies within four months, and Alberta funded it within 5 months. Newfoundland and Labrador and New Brunswick listed it within seven to nine months respectively, and Nova Scotia funded it within 10 months. Kadcyla remains under deliberation in Prince Edward Island, the North West Territories and Quebec.

7 In the case of Afinitor, sources indicate that in the province of Manitoba and the Yukon Territory, this treatment was available to patients before it was formally listed to the provincial formulary.

8 In the Yukon Territory, patients are often treated for oncology issues in Vancouver by the BC Cancer Agency (BCCA). As a result, both Perjeta and Kadcyla were available in the Yukon Territory upon approval by the BCCA.

FIGURE 3: WAIT TIMES FOR TARGETED THERAPIES BY PROVINCE



LAGGING BEHIND: THE IMPACT OF REGIONAL DISCREPANCIES ON ACCESS TO TREATMENTS

As depicted in figure 3, wait times to access new metastatic treatments vary substantially between provinces and within regions. As a result, a system of inequitable access has been established whereby patients in Ontario, British Columbia, Alberta, Saskatchewan and Manitoba are able to access treatments in almost half the time taken by Quebec, the Atlantic provinces and the territories.

Even a three or four month delay in provincial listings can have a profound impact on the health and lives of metastatic patients. In the case of provincial listing delays, the wait for patients is compounded at this point, after they have endured lags and delays at previous stages of the approval and review system.

Closer inspection of the listing data uncovers some concerning trends. In provinces with shorter overall wait times, such as Ontario, it is generally the case that wait times for listing decisions are reduced over time as new treatments enter the market. In Ontario, for example, Halaven entered the market first and took 11 months to be listed, followed by Afinitor which took seven months, Perjeta which took three months and Kadcylla which took four months. This pattern of decreasing wait times for drug listings is also evident in British Columbia, Alberta, Saskatchewan and Manitoba.

In Quebec, however, this pattern is reversed. While Halaven was listed by Quebec after only three months, Afinitor was funded after 10 months, Perjeta within 23 months and Kadcylla remains unfunded. This negative trend suggests that wait times for metastatic treatments are on the rise in Quebec and that there may be underlying policy issues delaying access to these treatments.

Similar concerns are evident in the Atlantic region. While Nova Scotia has some of the longest wait times for patients in the country and New Brunswick has delayed funding decisions on Kadcylla, metastatic patients in Prince Edward Island particularly suffer from a lack of access to treatment options. Prince Edward Island has only approved a single treatment for metastatic breast cancer, Perjeta, which was funded after a 20-month delay.

It should be noted that even in western and central provinces with shorter overall delays, wait times for the same treatment differ markedly from province to province.

It is evident from the case study data presented above that for metastatic patients in Canada hoping to access innovative and effective new therapies, systemic wait time delays create a significant barrier to receiving optimal treatment and care. On average, Canadian metastatic patients and their families are forced to endure wait time delays of two to four years before they are able to access new treatments. These delays occur at nearly every stage of the approval process, with the greatest waits occurring at the provincial level.

Furthermore, increased wait times for treatments create a situation of inequitable access across the country, whereby patients in certain provinces and regions have limited or no access to treatment options and are kept in the dark about whether new treatments will ever be approved in their province.

The lags in treatment access across the country likely also have an impact on standards of care, because patients in provinces where new treatments are approved quickly have access to more treatment options than those in provinces where patients must wait for new treatments to be added to the formulary.

The case study data also raises serious concerns about new and emerging metastatic therapies that are set to go through the drug approval system within the next five years. In the short term, these could include key therapies for the treatment of HR+ breast cancers, such as Faslodex (fulvestrant) manufactured by Astra Zeneca, and Ibrance (palbociclib) developed by Pfizer, as well as other new therapies currently being tested in clinical trials.

These lengthy wait times for new treatments have enormous implications for the prognosis of Canadian metastatic breast cancer patients. Slowing the progression of their disease and maintaining a better quality of life is of critical concern for these patients. Since timely access to treatment is paramount for effective patient care, metastatic patients with urgent treatment needs do not have the luxury of being able to wait for new treatments to become accessible on public formularies. Rather, for these patients, expedited access to a wide variety of treatment options can make all the difference in ensuring optimal health outcomes and improved quality of life.

LINE SEQUENCING TREATMENT ACCESS DELAYS

Not only is it essential to know whether a drug is listed on a provincial formulary, but also whether the drug is covered for initial treatment or later treatment when the first treatment loses its effectiveness. First, second or third line treatments refer to the sequence of treatments chosen by a woman and her oncologist. If drug A, B, and C are potential treatments, the choice may be made to start treatment with any one of them. This choice may restrict later treatment choices because, if the first drug becomes less effective, it may or may not be possible to switch to one of the other treatments if a formulary restricts their use to first line treatment only. Similarly, the choice of a third line treatment may be limited by restrictions imposed on which drugs were used for the first and second line treatments. Standards of care for first and subsequent lines of treatment may vary from one province to another. Most formularies also restrict the use of some drugs to their use in combination with other therapies and some require that a woman's health status be good before coverage is approved.

We will use four drugs as examples of how coverage differs across Canada due to treatment restrictions after they are listed on a formulary. Because clinical restrictions are decided by each province, this creates a situation in which women have varying access to treatments depending on where they live.

Aromasin (exemestane) is an aromatase inhibitor used to treat HR+ breast cancer in post-menopausal women. It is available in generic form because the patent held by the original manufacturer, Pfizer, has expired.

In British Columbia, formulary coverage of exemestane is provided for metastatic breast cancer as a first or second line hormonal treatment for post-menopausal women. In Saskatchewan exemestane may be used after failure of either anastrozole or letrozole (both generic aromatase inhibitors), which means that exemestane must be a second or third line treatment, not a first line treatment. Saskatchewan will not approve the use of letrozole if the patient has had an earlier failure with anastrozole. This makes initial drug choices important and stressful for women dealing with the shock of a metastatic diagnosis.

Ontario covers exemestane only for early breast cancer (not metastatic) after 2-3 years of tamoxifen therapy. Newfoundland and Labrador require special authorization for coverage of exemestane. Several jurisdictions (Alberta, Quebec, Northwest Territories) do not list restrictions on their formulary.

Faslodex (fulvestrant) is a drug manufactured by Astra Zeneca which is used to treat HR+ breast cancer. It is not yet on the formulary in Canadian jurisdictions but is available for sale in Canada. Women in Canada who can pay for Faslodex have access to it and some who cannot afford it have secured it through compassionate access programs. Other women who could not get access to Faslodex are going without it. For those who can access Faslodex, there are no treatment line restrictions because it is not yet listed on any provincial formularies.

Kadcyla (trastuzumab emtansine) is a drug manufactured by Roche Canada that is used to treat HER2+ breast cancer. Formulary restrictions on the use of Kadcyla depend on whether Herceptin has been used in an earlier line of treatment and how the cancer responded to it.

In British Columbia, Kadcyla will be covered if the woman has had prior treatment with Herceptin plus chemotherapy for metastatic breast cancer. Only two lines of anti-HER2+ therapy for metastatic breast cancer will be approved. In Alberta and Saskatchewan, Kadcyla is covered as a second line treatment for patients in relatively good health (an ECOG [Eastern Cooperative Oncology Group] performance status of zero or one).⁹ Patients must have been treated earlier with Herceptin plus chemotherapy or have had a disease recurrence during or within 6 months of completing therapy with Herceptin plus chemotherapy with or without Perjeta.

Manitoba has similar restrictions and requires an ECOG score of two or less and adequate heart, bone marrow, kidney and liver function. Ontario covers Kadcyla as a second line treatment for patients with an ECOG performance status of zero or one who have had prior treatment with Herceptin and chemotherapy and who have a disease recurrence during or within six months of completing that therapy. Thanks to advocacy efforts by CBCN on behalf of metastatic patients in Ontario, the province will cover Kadcyla during the period from

⁹ Patients with a performance score of 0 or 1 on the ECOG (Eastern Performance Oncology Group) performance scale are able to function well. The scale is used to assess how the disease is progressing and how it affects quality of life and daily living abilities. 0 is fully active with no restrictions on activity. 1 is restricted for strenuous activity but able to do light work. 2 is unable to work but up and about more than 50% of waking hours. 3 is confined to bed; 4 is completely disabled and 5 is dead.

October 2014 to October 2017 for those with a performance status of zero or one who have completed at least two lines of HER2 therapy prior to October 2014 and who have not previously received Kadcyla.

Nova Scotia restricts Kadcyla to second line therapy. Quebec, New Brunswick, Prince Edward Island and Newfoundland and Labrador do not cover Kadcyla.

The current drug TDM1 (Kadcyla) I am on, my oncologist believed I would not have funding for, but in consulting with peers I found out the funding for this drug changed and I could be on it. It is ridiculous that drugs needed are withheld when people could benefit from them. I know someone who was initially denied the second or metastatic treatment after she had an allergic reaction to the first line treatment for her type of cancer. They were not going to fund the next line of treatment because her cancer was not bad enough yet (emphasis added).

Perjeta (pertuzumab) is a promising newer drug manufactured by Roche Canada for treating HER2+ breast cancer. In Ontario it can be used in combination with Herceptin and chemotherapy (taxanes). In British Columbia it can be used as first-line treatment with Herceptin and docetaxel (chemotherapy). In Saskatchewan it can be used with Herceptin and a taxane chemotherapy drug for those who have not received prior therapy for HER2+ metastatic breast cancer; further restrictions apply.

Prince Edward Island recently listed Perjeta on its formulary to be used in combination with trastuzumab (Herceptin) and a taxane (a class of chemotherapy drugs) for patients with HER2+ metastatic breast cancer, with the restriction that the patient has not received prior HER2 therapy or chemotherapy for metastatic disease or has not relapsed within six months of receiving Herceptin.

Xgeva (denosumab) is a patented drug manufactured by Amgen that helps prevent bone damage when breast cancer has metastasized to the bones. It has been approved for sale by Health Canada and is currently being reviewed by the Common Drug Review. The Canadian Breast Cancer Network has submitted patient input as part of the review process. Saskatchewan covers Xgeva for prostate cancer only. Quebec covers it where an alternate drug is not tolerated. Its use appears to be restricted in other provinces to those with osteoporosis (not for cancer). Women with metastatic breast cancer who are able to pay for the drug have access to it and special access has been obtained by some women from the manufacturer.

As we have demonstrated for these metastatic treatments, treatment availability for a patient varies from province to province even when the drugs have been listed on provincial formularies. This creates barriers to access. As a result, patients once again do not have equal access to all treatment options and can be disadvantaged simply by their geography. After waiting for new treatments to go through the various drug approval and funding processes, patients often experience an additional waiting period to access important treatments while they explore alternative access options such as compassionate care, private insurance or participation in clinical trials.

RECOMMENDATIONS FOR CHANGE

In response to these inequalities in drug access across provinces coupled with the long wait times for drug approval at the provincial level, the CBCN has developed the following recommendations and will advocate for these changes:

SUPPORT EFFORTS TOWARD FASTER AND MORE EQUITABLE ACCESS TO TREATMENT DRUGS

Commitment by provinces to list drugs within defined deadlines:

Some provinces, notably Quebec and the Atlantic provinces, are slower to list drugs on their formularies even after all the steps of approval and pricing have been concluded. This results in women in other provinces having access to drugs sometimes up to three years earlier than women in Quebec and the Atlantic region. Three years is a long time for metastatic breast cancer patients – it can mean the difference between life and death.

- CBCN will engage provinces that are slow to list drugs on their formularies and will advocate for them to list within a defined time period.
- CBCN will advocate for all provinces to consider patient input submissions to ensure that the patient voice is heard and contributes to health care decision-making.

Increased transparency and accountability within the pan-Canadian Pharmaceutical Alliance: The pCPA negotiation process lacks transparency and accountability to patients waiting to access treatments. Without clear deadlines for decisions, patients are left in the dark regarding when drugs are eligible to be added to the provincial formularies.

- CBCN will engage the pCPA to advocate for more clarity in the deliberation process and will encourage the development of deadlines for decision-making.

Accelerated review and approval: Canada needs a quick review process to approve drugs for sale and compassionate access for patients with urgent care needs. For example, since 1992, the United States has had an Accelerated Approval Program for cancer drugs for patients in need. Health Canada's Priority Review Process needs to be enhanced to provide faster review and approval.

- CBCN will advocate for a fast-track mechanism to expedite access to new treatments for patients with urgent care needs.

Canadian pharmacare program: There appears to be growing support for serious discussion of a national pharmacare program. Ultimately, a national pharmacare program would remove the inequities caused by provincial/territorial differences in drug coverage as long as timely access to gold standards of care is maintained across the board. The Canadian Medical Association held a consultation in 2011 on health care transformation. Their town hall meetings across Canada revealed strong support for a national pharmacare program governed at the federal, not the provincial, level.¹⁰

A recent roundtable discussion on national pharmacare was hosted by Dr. Eric Hoskins, Ontario Minister of Health and Long-Term Care. The roundtable was attended by ministers of health or their representatives from British Columbia, Saskatchewan, Manitoba, Newfoundland and Labrador and Northwest Territories.¹¹ The Canadian Pharmacists Association has just launched a multi-phased consultation called Pharmacare 2.0 to develop a national consensus for a pan-Canadian pharmacare framework.¹²

- CBCN will support efforts to achieve a national pharmacare program, collaborating with partner organizations.

10 The report is available at https://www.cma.ca/Assets/assets-library/document/en/advocacy/HCT_townhalls-e.pdf

11 <http://news.ontario.ca/mohltc/en/2015/06/ontario-hosts-roundtable-discussion-on-pharmacare-1.html>

12 <http://www.pharmacists.ca/index.cfm/news-events/news/canadian-pharmacists-association-launches-pharmacare-20/>

LONG WAIT TIMES AND INEQUITABLE ACCESS: THE IMPACT ON WOMEN AND THEIR FAMILIES

Discussion of drugs and approval processes is informative, but it does not express the importance of access to drug treatments for women living with metastatic breast cancer and their families. In this section, women from across Canada share their experience of access to the drugs they need in order to stay alive and function as well as possible.

The 2013 report *Metastatic Breast Cancer in Canada: The lived experience of patients and caregivers* was based on a survey of women with metastatic breast cancer, which focused on quality of life, access to new therapies and the financial impact of treatments.

Neupogen, Zoladex and Aromasin are expensive and aren't totally covered, so this hits the budget.

The delay for drug approval for my private insurance sometimes takes weeks.

For the present paper, CBCN hosted a bilingual survey during spring 2015 that focused on access to treatment drugs across Canada. Ninety eight women responded to the survey from all Canadian jurisdictions except Yukon. Seventy one people responded to the survey in English and 27 in French. Most responses were from Quebec (32 responses) and Ontario (26 responses), followed by British Columbia, Alberta, Saskatchewan, and Manitoba, with a small number of responses from other jurisdictions. 46% of the respondents were between 46-60 years of age. The majority (54%) of

respondents were diagnosed with metastatic breast cancer within the last two years.

Perjeta has just been added to our provincial formulary.

Neupogen is on the formulary, but not for metastatic breast cancer – for those with metastases (mets), the doctor just cuts the dose of cytotoxic chemotherapy.

The availability of treatments varied among survey participants. Respondents told us that most chemotherapy drugs were available to them; these tend to be administered in hospital and are covered by public health care. Hormonal treatment drugs were not universally covered especially Aromasin (exemestane), Faslodex (fulvestrant), and Lupron (leuprolide). Drugs for HER2+ breast cancer that were not universally available were Afinitor (everolimus), Kadcyla (trastuzumab), and Perjeta (pertuzumab). Drugs used to mitigate the effects of chemotherapy, treat bone metastases or boost blood cell counts were not universally covered, especially Aranesp (darbepoetin), Neulasta (pegfilgrastim), Neupogen (filgrastim), and Xgeva (denosumab).

I pay for Xgeva. It's not covered under my provincial plan.

I have help from the makers of Xgeva to get it.

Neupogen was accessed through compassionate care.

As stated earlier, even when a drug is on the formulary, its use may be restricted in ways that deny it to women with metastatic breast cancer or to those whose treatment sequence does not fit the formulary restrictions. This has the result of creating inequitable delays in treatment for women. When treatment is restricted due to delays in approval for provincial coverage or line restrictions, women are faced with the unenviable task of having to seek alternative funding and/or advocate for themselves. This takes time and focused effort at a critical juncture in their treatment and may have negative consequences for their treatment and disease progression.

Women who participated in the 2015 survey did not report exceptionally high monthly drug costs (very few paid more than \$500 per month out of pocket whether or not they had private insurance) although many spoke of the hurdles they had to overcome to have expensive drugs covered. Some said that they went without drugs that they could not afford and 67 per

cent had private insurance (89 per cent in Quebec). Of the women that did not have private insurance coverage, the vast majority (60 per cent) were reliant on a provincial/territorial drug plan to pay for treatments. This has the consequence of creating frustrating delays or restrictions on receiving much needed and timely treatment.

A major concern expressed by survey respondents was access related either to prohibitive cost or denial because of treatment sequence restrictions. We did follow-up interviews with 11 women who participated in the survey and who indicated they would be willing to speak further with us. They represent a range of regions, age groups and types of breast cancer. Many women spoke of the frustration and effort required to get access to treatment drugs and how fatiguing and frightening it is to have to work so hard trying to find the right person to talk to in order to prolong your life.

EXPENSE IS A BARRIER THAT REQUIRES DETERMINATION TO OVERCOME

There's a two-level system. You get better drugs if you pay for them yourself. A woman I know goes from Alberta to Toronto for clinical trials.

A friend of mine travels to the United States to get palbociclib treatment because it is not available in Canada.

The BC Cancer Agency has been very helpful – they completed forms for me so I could get Faslodex free of charge for almost nine months.

I've only started having problems this year since I started Faslodex. Now I've also been told that my private insurance will charge me \$25 if I continue to use the company brand drug instead of the generic brand for Aromasin.

I am currently still working and have benefits through my employer as well as through my husband's employer so my meds are covered 100 per cent. When I become unable to continue working, I will only have 80 per cent coverage through my husband's employer. My meds are very expensive. I will likely need to set up an online fundraising campaign to finance those meds as my income will also be greatly reduced when I lose my benefits.

My 35-year-old daughter died of breast cancer- she had been on Avastin in a clinical trial because the drug cost \$2,700 every 21 days. We could not raise the money to keep her on it after the trial. The drug was stopped and she died.

I recently lost my access to private health insurance because my employer fired me while on long term disability because I am not well enough to return to work. When I had insurance, it covered \$7,000 per month for me to access Afinitor (before it was covered by the government). Being on Afinitor gave me the best results I've ever had on a treatment. Although even with the private insurance it took me a full month of daily paperwork/calls, etc. to get it accepted. I was even off treatment for a bit due to delays of people completing the forms at my hospital. It was beyond stressful--a nightmare. In 2014 my private insurance was covering my access to Faslodex-- but my access was cut off when I was fired. The three weeks' notice they gave me was not enough time to get approval from the provincial plan for my medications (Faslodex, Xgeva, and pain meds).

I was shocked at the cost of Faslodex. My parents were going to help me out. My dad encouraged me to speak out. I did. I talked to my doctor who realized I wasn't covered. He linked me with a company called Faslocare. They covered the portion that private insurance doesn't pay. I was reimbursed for what I had paid out of pocket. They are angels. I developed two more tumours this year. It frightens me – will the drugs I need be covered? Will I have to fight all the time? It's scary.

STRATEGIES FOR GETTING ACCESS WHEN A DRUG IS NOT ON THE PROVINCIAL FORMULARY

I have a story about getting coverage for Perjeta. I did it all through letter writing. When I was diagnosed two years ago with metastatic breast cancer, my doctor recommended a new drug, Perjeta for HER2+ breast cancer. He thought my private insurance would cover it. Then one treatment in, I got a call from my insurance company – they changed the policy and no longer covered drugs not on BC Pharmacare. I wrote to my union, my employer, the BC Cancer Agency, the province and sent letters asking for compassionate funding. It was my only option. No one would fund it. The drug company would only pay 25 per cent. My friends found out and had a fundraiser for me. They raised \$50,000. We got in the newspaper. Someone sent the article to the cancer agency and then the cancer agency approved coverage within two months for everyone. I'm still recovering from all the energy this took.

It is extremely frustrating that Kadcylya is not covered in our province. It should not be the case that one has to fight for drug coverage at a time when you discover that you have a recurrence. You shouldn't be in a position to have to shame the government by going to the media with your personal story at a time when you need your strength to cope with your illness. Luckily, I haven't progressed on Herceptin – targeted treatment for HER2+ cancer has made the difference. I was told at diagnosis that I had six to nine months to live. I've been living with metastatic breast cancer for more than six years.

I'm triple positive (HR+ HER2+) and only get treatment for HER2+ (Prince Edward Island). In other provinces a triple positive gets hormone receptor and HER2 receptor treatment. It scares me because we have a 28 per cent higher mortality rate than other provinces. Neupogen is not given to metastatic patients because of cost.

WAITING TO ACCESS TREATMENTS CAN LEAD TO WORSE HEALTH OUTCOMES

Gerri's Story

For Gerri Whyte-Devine, her metastatic breast cancer meant a constant fight to get the treatment that she needed to stay alive.

The Ajax, Ontario resident was initially diagnosed with Stage III breast cancer in 2005 when she found a lump near her collarbone. She took a year off from her job at Air Canada for surgery, chemotherapy and radiation, and then returned to work.

Gerri was cancer-free for three years until a mammogram in April 2009 revealed calcium deposits in her breast. She went for day surgery to remove a lump. It turned out her breast cancer had come back.

Over the next two years, Gerri endured more chemotherapy, Herceptin, Taxol, and an infection in her left breast, for which she was given antibiotics. The Herceptin made her heart rate plummet, and treatment was therefore discontinued.

Then, in October 2011, after a suspicious mammogram and core biopsy, Gerri underwent a mastectomy. Tests revealed that she had HER2-positive metastatic breast cancer.

In July 2013, she connected with an oncologist at Sunnybrook Hospital in Toronto who told her about a new drug, Kadcylla. She understood that it boasted promising results with minimal side effects and was a potential life-saver. "To say I was elated would be an understatement," said Gerri.

But there was a catch: Kadcylla wasn't listed on the Ontario formulary and was very expensive. So Gerri began a year-long battle to have the province pay for the drug. She launched a petition on the Internet, wrote to her MPP, and

contacted Cancer Care Ontario, the Exceptional Access Program, the Minister of Health, the Ontario Ombudsman's office, and the Canadian Breast Cancer Network. CBCN helped her get a meeting with the Ontario Provincial Drug Program on July 30, 2014.

In July, Gerri suffered another setback: in addition to complications with her cancer diagnosis, she developed shingles and a major fracture to the sixth rib on her left side. Her right arm remained swollen and painful, and her rib was painfully sore.

Due to her arm situation, Gerri couldn't wait for provincial funding to start on Kadcylla; therefore, her mother helped and paid for her five intravenous infusions of the drug, which she received in June, July, and August of 2014 at a cost of \$18,000. On October 17, the province announced that it would temporarily fund Kadcylla for HER2+ metastatic breast cancer patients who had initiated or completed at least two lines of HER2-targeted therapy and who had not received Kadcylla in previous lines of therapy. Ironically, Gerri, who led the fight for this outcome, was not eligible because she had already started on Kadcylla as a third-line treatment.

Gerri passed away in early 2015, but her story is one of resilience and strength and serves as a poignant reminder of the impact of wait time delays on breast cancer patients and the need to continue advocating for better treatment outcomes for Canadians living with metastatic breast cancer.

TREATMENT SEQUENCE CAN RESTRICT ACCESS AND LEAD TO HARD CHOICES

My doctors are in a very awkward position ethically: If I need to switch treatments anytime soon, it is possible that they will have to avoid mentioning certain treatment options to me as I no longer have private insurance and many of my remaining options are NOT covered by our government plan! My family cannot afford something like \$7,000 a month. Nonetheless those drugs might be my only options to remain alive. I am only 39.

In our province, Perjeta is covered for first line treatment only. It is denied for second line treatment. I had Perjeta as a first line treatment. When it looked like I needed it again, my doctor had to put me on a taxane (chemotherapy) to

satisfy the restrictions. I had to go back on chemo and lose my hair and get nauseated all over again just to get Perjeta! You shouldn't have to do that. I have two young kids in elementary school and I want to be alive to see them through school. The chemo gives me neuropathy, but I'm willing to put up with it.

I live in the moment. Our provincial formulary has restrictions on first, second and third lines of treatment. What will happen to me as my disease progresses? They don't give you enough information at the beginning so you can make choices about treatment sequence.

FINDING ALLIES

When I was diagnosed with Stage IV cancer, they didn't tell me what that meant but they advised palliative care. Palliative my ass! Attitude is important. I fought for treatment and got it. I've had brain, chest and liver mets and am still alive five years later. The cancer doesn't kill you unless it's in a vital area. The drug access navigator put me in touch with the pharmaceutical companies to get funding.*

Our lives are at stake. If you have money, you live. If you don't have money, you die. I've changed drugs three times with a bit of progression on each drug, and then they change to another one. It's never good news. I was lucky to get Afinitor covered. Another woman in our group was paying full cost for it. I told her how to get reimbursed and she did.

It is confusing when you are processing bad news and at the same time being told you need a med that is not covered by provincial Medicare. My experience to date has been good because an experienced medical team

made compassionate care come through for me. It was a frightening time when my chemo was delayed because of low blood counts. It felt like both my body and the Medicare system were failing me. I have now been living with metastatic breast cancer for more than 10 years.

* Drug access navigator is a term used in the Ontario cancer care system. Approximately 50 drug access navigators work in cancer care in Ontario as staff members of a cancer care team. Their job is to help those without drug coverage make application to provincial plans and exceptional access programs. They can also help with application to Health Canada's Special Access Program for drugs not yet approved for sale in Canada and not funded by the province. They help patients find funding to pay for drugs. For those with private insurance, they help with renewals of authorization, appeals to the insurer and negotiations about coverage for drugs not on the formulary. They are the patient's advocate and helper in navigating drug access options. For more information, see the Oncology Drug Access Navigators of Ontario: www.odano.ca and Cancer Care Ontario – Cancer Drug Benefits Navigator https://www.cancercare.on.ca/ontariocancernewsarchives/200812/index_844.htm. Several other provinces have equivalent cancer drug patient navigators.

RECOMMENDATIONS FOR CHAMPIONING THE VOICE OF WOMEN LIVING WITH METASTATIC BREAST CANCER

“Fight on our behalf for equitable access – don’t make individuals fight this battle in isolation.”

Our strategy to raise awareness of the need for timely equitable access to treatment drugs for metastatic breast cancer is paramount to the work of the CBCN. We are committed to advocating for the following recommendations to ensure that the issues facing women with metastatic breast cancer are addressed:

INCREASE KNOWLEDGE AND RAISE AWARENESS

Better statistics: Our research shows that we need better information on the number of women living with metastatic breast cancer in order to have informed dialogue with governments about the impact of making drugs accessible. Currently it is not clear how many women are affected and what the impact of extending out-of-hospital drug coverage would be.

CBCN will advocate for more precise statistics on the number of Canadians affected by metastatic breast cancer.

Continue to educate women with metastatic breast cancer, their families and their care teams about treatment options and the impact of treatment choices: Many women told us how frustrating and exhausting it is for them to learn about treatment options and to fight for access to the drugs they need to survive. Many find the array of treatment choices confusing to learn and make decisions about while they are dealing with the emotional impact of a diagnosis, a recurrence or a failure of their current drugs. Knowing about treatment options is important for empowering patients. They have told us they need full information on treatment drugs and options and the consequences of choosing first, second and third line treatments because of the restrictions in their provincial formularies.

- CBCN will continue initiatives to educate patients about treatment options, treatment sequencing and differing standards of care in different provinces.
- CBCN will continue to help women learn the advocacy skills they need to stand up for their right to knowledge, choices and access. As one woman told us: *Don’t take no for an answer.*

Engage the Canadian public:

- CBCN will make full use of social media to extend the reach of the strategy and engage new supporters. We will work with media partners to raise awareness through coverage containing solid facts and personal stories.

WORK WITH NAVIGATORS IN THE HEALTH CARE SYSTEM

Women told us how helpful drug access navigators in cancer care teams have been. Although drug access navigators work within individual provinces, collectively they have valuable knowledge and advice to share about drug access issues.

- CBCN will engage drug access navigators and other patient navigators within cancer care. Potential partners are drug access and patient navigators in provincial cancer care systems.

ENGAGE PARTNERS

- CBCN will engage partner organizations that share the goal of equitable access to cancer treatment drugs for all Canadians

We will invite new partners to join with us:

- CBCN will engage with organizations representing family caregivers who have a growing voice and are deeply affected by women’s access to treatment drugs

CBCN invites all women living with metastatic breast cancer, their families, friends, clinicians, researchers and allies to join our call to action and make equitable access a reality for all.

CONCLUSION

The physical, financial and psychosocial toll of wait times delays and inequitable access to treatments is clearly evident in the stories shared by metastatic breast cancer patients and their families. For these Canadians, access to essential treatments is critical to prevent disease progression and ensure a longer life as well as better quality of life. However, in spite of their urgent care needs, Canadians living with metastatic breast cancer are enduring two to four year wait delays to access new treatment options. These delays, occurring at the post-pCODR level, have led to a system of inequitable access to treatments across the country, whereby patients in certain provinces and jurisdictions have little to no access to innovative new therapies for their condition. This situation is also likely to have a significant impact on the standard of care for metastatic patients, as patients in certain provinces have more treatment options available to them than patients residing in provinces that are slow to list new treatments on their formularies.

A further complicating factor for access to new metastatic treatments is the restriction of therapies to specific line settings, or treatment

sequence, by provincial formularies. Line therapy settings are not consistent across provinces, which further limits the treatment options for metastatic patients and creates unequal standards of care for metastatic patients across the country.

With such significant access barriers facing Canadians living with metastatic breast cancer and their families, CBCN stands up for women with metastatic breast cancer across Canada. The Canadian Breast Cancer Network will lead an advocacy and awareness-raising strategy with the goal of achieving equitable access to treatment drugs for metastatic breast cancer for all regardless of where they live in Canada. The Canadian Breast Cancer Network believes that equitable access is achievable because it is strongly rooted in the basic Canadian value of fairness.¹³

13 The University of Waterloo's Faculty of Applied Health Sciences has developed the Canadian Index of Wellbeing based on extensive consultation on core consensus values which include fairness, equity, inclusion and health: <https://uwaterloo.ca/canadian-index-wellbeing/about-canadian-index-wellbeing/reflecting-canadian-values>

APPENDIX A: PROVINCIAL AND TERRITORIAL PUBLICLY- FUNDED DRUG PLANS

All provinces and territories have publicly-funded drug coverage plans with varying amounts that must be covered (co-pay) by the patient. Provinces with cancer agencies often have a separate drug plan to cover cancer drugs. A few examples will illustrate the range of public drug coverage.

The Patented Medicine Prices Review Board, a federal agency, ensures that the prices of patented medicines sold in Canada are not excessive by monitoring prices on an ongoing basis. Drug manufacturers are not required to obtain approval of the price before a drug is sold.

BRITISH COLUMBIA

The general public drug plan is BC PharmaCare which covers BC residents and is income-based (Fair PharmaCare). Other aspects of PharmaCare cover specific populations such as those in residential care, those receiving provincial income assistance, and palliative care. The BC Cancer Agency has a separate benefit drug list for cancer drugs. A woman with metastatic breast cancer would access cancer treatment drugs through the BC Cancer Agency and may receive other drugs through BC PharmaCare (e.g. pain medication). PharmaCare sets a maximum price it will cover for each drug. If the drug costs more than the maximum price, the patient pays the additional cost.

Cancer drugs on the BC Cancer Agency Benefit Drug List are reimbursed for use under approved indications. Drugs not on the Benefit List are not reimbursed and must be paid by

the patient. The BC Cancer Agency Compassionate Access Program considers applications for coverage when drugs are not on the Benefit List.

ALBERTA, SASKATCHEWAN AND MANITOBA

Alberta has a number of publicly-funded supplementary drug benefit programs that include coverage for those under or over 65, palliative care and specific diseases. The Outpatient Cancer Drug Benefit Program provides a number of cancer drugs on its formulary at no cost to patients.

The Saskatchewan Prescription Drug Plan provides general drug benefits. The Saskatchewan Cancer Agency funds 100 per cent of the cost of cancer drugs on the formulary and also provides a list of drugs not funded by the Agency.

General drug benefits are provided by Manitoba Health's Pharmacare Program; this is an income-based program with an annual deductible based on family income. The Manitoba Home Cancer Drug Program covers 100 per cent of the cost of outpatient oral cancer and specific supportive drugs that are included on its formulary.

ONTARIO

Ontario has six core publicly-funded drug programs, including special provisions for seniors and those with high drug costs relative to income. One of the six programs is the New Drugs Funding Program for Cancer Care, which may pay for

many of the newer intravenous cancer drugs. Cancer Care Ontario administers three drug plans through Provincial Drug Reimbursement Programs. Drugs administered in the community (not in hospital) and listed on the formulary are covered by the Ontario Drug Benefit and exceptional access programs. Seniors, those on social assistance and those with no or limited private insurance have special eligibility provisions. In some situations, patients pay directly for drugs that are not publicly funded or may use private insurance.

QUEBEC

Quebec requires that all residents be covered by prescription drug insurance, either through private plans or the public plan, the Public Prescription Drug Insurance Plan. Only those who do not have a private plan may register for the public plan. There is an annual premium payable by all persons covered by the public plan whether or not they purchase prescription drugs. Cancer drugs that are reimbursable are listed on the general provincial drug formulary.

ATLANTIC PROVINCES

The New Brunswick Prescription Drug Program covers cancer drugs listed on the provincial formulary. The Drug Program beneficiary groups include seniors and those with specific conditions and needs. Cancer patients are not a specifically designated beneficiary group. Private insurance is needed to pay for drugs not on the provincial formulary and for those residents not in designated beneficiary groups. An estimated 25 per cent - 30 per cent of New Brunswick residents do not have private insurance. As of April 2015, all New Brunswick residents without private insurance were required to join the New Brunswick Drug Plan. All private plans are also required to be at least as effective as the New Brunswick Drug Plan.

Nova Scotia Pharmacare provides prescription drug benefits to eligible residents for drugs listed on the Nova Scotia formulary. The Family Pharmacare Program is income-dependent and the Seniors' Pharmacare Program is available to those without private insurance. The Drug Assistance for Cancer Patients provides assistance for those whose annual income is less than \$15,720.

The Prince Edward Island Pharmacare program offers a number of coverage programs for specific diseases and conditions. Cancer is not a designated program but the province has a Catastrophic Drug Program and a High Cost Drug Program, both of which are income-related. The High

Cost Cancer Program includes those with metastatic breast cancer. Only drugs listed on the provincial formulary are covered by these programs.

The Newfoundland and Labrador Prescription Drug Program covers prescription drug costs for drugs listed on the formulary for those without private insurance under five plans, including plans for those on low incomes and seniors. The Assurance Plan provides assistance for high cost drugs or the combined cost of different drugs and is income-dependent.

TERRITORIES

Eligible First Nations and Inuit populations throughout Canada receive drug benefits under the Non-Insured Health Benefits Program provided by the First Nations and Inuit Health Branch of Health Canada (FNIHB). These plans often cover cancer drugs that are not listed on provincial or territorial formularies. Territorial drug coverage often references FNIHB benefits which cover a significant proportion of their populations. For non-Aboriginal individuals, private insurance or a territorial benefit program may cover the cost of cancer drugs.

The Yukon Pharmacare and Extended Health Benefits program assists seniors and pays total costs of the lowest priced generic drugs listed in the formulary. There is no specific plan for cancer drugs. Many patients in the Yukon Territory are often treated for oncology issues in Vancouver by the BC Cancer Agency (BCCA) and as such breast cancer patients in the territory are ostensibly able to access new treatments upon their addition to the BC provincial formulary.

Northwest Territories provides extended health benefits for seniors that include drugs. Extended health benefits for specific diseases do not include cancer drugs, but several cancer treatment drugs are included on the territorial formulary.

Nunavut provides Extended Health Benefits for individuals not covered by First Nations and Inuit Health Branch benefits, seniors and those on low incomes. Some cancer drugs are included on the formulary.

APPENDIX B: BREAST CANCER TYPES AND SPECIFIC TREATMENT DRUGS

Breast cancer is not a single disease. There are four common types of breast cancer and each type requires its own treatment drugs. The genetic makeup of the tumour determines the type of breast cancer.

HR positive (HR+) breast cancer is hormone receptor positive. This means that the tumour contains either estrogen or progesterone receptors, or both. When these hormones, particularly estrogen, attach to hormone receptors, the cancer cells are stimulated to grow. These tumours can be treated with hormone therapy drugs that lower estrogen levels or block estrogen receptors. HR+ cancers are more common in women after menopause. HR- breast cancers do not have hormone receptors and require different treatment drugs. HR- cancers are more common in pre-menopausal women.

Tumours that test positive for human epidermal growth factor receptor-2, a protein which promotes the growth of cancer cells, are called HER2+. These tumours can be treated with drugs that specifically target HER2. Tumours that do not test positive for HER2 are called HER2-.

The most common form of breast cancer is HR+ and HER2-, accounting for 65 per cent of all breast cancers. This type of cancer is usually treated with hormone therapies that prevent the tumour from getting the estrogen that feeds its growth. These tumours can sometimes become resistant to hormone therapy, which requires a change in drug treatments.

Breast cancer that is both HR+ and HER2+ is treated with multiple types of drugs, including hormone therapy and targeted HER2 therapies.

Breast cancer that is HR- and HER2+ is treated with chemotherapy and targeted HER2+ drugs, but not hormonal therapies.

Breast cancer that is HR- and HER2- is referred to as triple negative breast cancer (negative for estrogen, progesterone and HER2). It cannot be treated with hormonal therapies or HER2 targeted drugs. Treatment usually consists of chemotherapy and drugs to counteract the side effects of chemotherapy. This type of cancer occurs more often in younger women and those with the BRCA1 mutation. Recent research indicates that there are seven sub-types of triple negative breast cancer, which may hold promise for future targeted therapies for each sub-type.

These are the most common drugs used to treat metastatic breast cancer in Canada:

CYTOTOXIC CHEMOTHERAPY

Chemotherapy drugs kill or prevent the growth of cancer cells, usually while a cell is dividing, and may be used in combination with other treatments. They kill healthy cells as well as cancer cells and are therefore likely to have side effects. Chemotherapy drugs can be administered in liquid form through a needle or in pill form. Those administered in liquid form are often provided in hospital at no charge to the patient. Prescription pills taken outside the hospital setting may involve a charge to the patient if their cost is not covered by public or private plans.

In Canada, the most commonly used chemotherapy drugs for metastatic breast cancer are listed below, by the original brand name, chemical name, mode of administration and whether a generic version is available.¹⁴

14 A generic version of a drug can be made by several manufacturers once the original manufacturer's patent has expired. Generic drugs are cheaper than brand-name drugs and are often the versions listed on provincial/territorial formularies.

Brand name	Chemical name	Administered	Generic available
Abraxane	paclitaxel	Injection	
Adriamycin	doxorubicin	Injection	
Adrucil	fluorouracil	Injection	Yes
Camptosar	irinotecan hydrochloride	Injection	
Cytosan	cyclophosphamide	Injection	Yes
Doxil	doxorubicin liposomal	Injection	Yes
Ellence	epirubicin	Injection	Yes
Gemzar	gemcitabine	Injection	Yes
Halaven	eribulin mesylate	Injection	
Ixempra	ixabepilone	Injection	
Rheumatrex, Trexall	methotrexate	Injection or tablet	Yes
Mutamycin	mitomycin-C	Injection	Yes
Navelbine	vinorelbine tartrate	Injection	Yes
Novantrone	mitoxantrone	Injection	Yes
Paraplatin	carboplatin	Injection	Yes
Platinol	cisplatin	Injection	Yes
Taxol	paclitaxel	Injection	Yes
Taxotere	docetaxel	Injection	Yes
Temodal	temozolomide	Capsule	Yes
Xeloda	capecitabine	Tablet	Yes

HORMONAL THERAPIES

Hormonal therapies are used to treat breast cancer cells that are hormone receptor-positive (HR+). These drugs either reduce the production of hormones in the body or block hormones from attaching to cancer cells and thereby prevent the stimulation of cancer cell growth. Drugs that stop

estrogen production can have the side effect of causing bone thinning, which means that a bone-strengthening drug will be prescribed at the same time.

The most commonly used hormonal therapies in Canada are:

Brand name	Chemical name	Administered	Generic available
Arimidex	anastrozole	Tablet	Yes
Aromasin	exemestane	Tablet	Yes
Faslodex	fulvestrant	Injection	
Femara	letrozole	Tablet	Yes
Halotestin	fluoxymesterone	Tablet	Yes
Lupron	leuprolide	Injection	Yes
Megace	megestrol acetate	Tablet or liquid by mouth	Yes
Nolvadex	tamoxifen	Tablet	Yes
Various names	testosterone	Various forms	Yes
Toremifine	fareston	Tablet	
Zoladex	goserelin	Injection	

TARGETED THERAPIES

Targeted therapies act on specific genes that make the proteins that stimulate cancer cell growth. Targeted therapy causes less harm to healthy cells than chemotherapy and has potentially fewer side effects. These drugs block molecules in

or on a cancer cell that help the cells grow and divide. These drugs may be used for HR+, HR+ HER2+ and HR-HER2+ breast cancer.

The most commonly used targeted drugs in Canada are:

Brand name	Chemical name	Administered	Generic available
Afinitor	everolimus	Tablet	
Avastin ¹⁴	bevacizumab	Injection	Yes
Herceptin	trastuzumab	Injection	
Kadcyla	trastuzumab emtansine	Injection	
Perjeta (also sold as a combination with Herceptin)	pertuzumab	Injection	
Tykerb (also sold as a combination with letrozole)	lapatinib	Tablet	

15 Health Canada withdrew its authorization from Avastin for use against metastatic breast cancer in 2011 because the risks outweighed the benefits. It is still approved for use against some other forms of cancer.

OTHER MEDICATIONS

These medications are often used to offset the side effects of other drugs, particularly for patients undergoing chemotherapy or with bone metastases. Bisphosphonates (e.g. Aredia (pamidronate) and Zometa (zoledronic acid)) may be prescribed to counter bone thinning associated with hormone-reducing therapies.

The most commonly used drugs in Canada are:

Brand name	Chemical name	Administered	Generic available
Aranesp	darbepoetin – boosts red blood cell production	Injection	
Aredia	pamidronate - reduces risk of bone fracture due to bone metastases	Injection	Yes
Evista	raloxifene – strengthens bones	Tablet	Yes
Neulasta	pegfilgrastim - boosts white blood cell count	Injection	
Neupogen	filgrastim - boosts white blood cell count	Injection	
Procrit/Epex	epoetin – treats anemia caused by chemotherapy	Injection	Yes
Xgeva	denosumab - reduces bone fracture risk due to bone metastases	Injection	
Zometa	zoledronic acid - reduces risk of bone fracture due to bone metastases	Injection	Yes

RESOURCES

Cancer organizations

Canadian Breast Cancer Network: www.cbcn.ca;
metastatic breast cancer page: <http://www.cbcn.ca/index.php?pageaction=content.page&id=125&lang=en>

Canadian Cancer Society: www.cancer.ca; breast cancer page: <http://www.cancer.ca/en/cancer-information/cancer-type/breast/breast-cancer/?region=pe>

Canadian Cancer Action Network: <http://www.cccanceraction.ca>

Cancer Advocacy Coalition of Canada: <http://www.canceradvocacy.ca>

CanCertainty: <http://www.cancercertaintyforall.ca>

Best Medicines Coalition of Canada: <http://www.bestmedicines.ca>

Rethink Breast Cancer: <http://rethinkbreastcancer.com>

American Cancer Society - breast cancer: www.cancer.org/acs/groups/cid/documents/webcontent/003090-pdf.pdf

Breast Cancer.org (USA) metastatic cancer page: http://www.breastcancer.org/symptoms/types/recur_metast

Advanced BC.org (USA) – descriptions of drugs used to treat metastatic breast cancer:

A-G: <http://www.advancedbc.org/content/treatments-common-use-metastatic-breast-cancer-g>; H-Z: <http://www.advancedbc.org/content/treatments-common-use-metastatic-breast-cancer-h-z>

Drug approval and pricing

Health Canada – How drugs are reviewed in Canada: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php

Pan-Canadian Oncology Drug Review: <https://www.cadth.ca/pcodr>

Pan-Canadian Pharmaceutical Alliance: <http://www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>

Patented Medicine Prices Review Board: <http://www.pmprb-cepmb.gc.ca/home>

Provincial/Territorial cancer drug formulary information

Formularies are updated often. Check for most recent versions.

British Columbia: http://www.bccancer.bc.ca/systemic-therapy-site/Documents/Benefit%20Drug%20List_1Feb2015.pdf

Alberta: Outpatient Cancer Drug Benefit Program: <http://www.albertahealthservices.ca/assets/programs/ps-1025651-drug-benefit-list.pdf>

Saskatchewan- Saskatchewan Cancer Agency Drug Formulary: <http://www.saskcancer.ca/Formulary%2001-05-2015>

Manitoba: Cancer Care Manitoba does not provide its formulary online

Ontario- formulary search page: <https://www.healthinfo.moh.gov.on.ca/formulary/>

Quebec – list of covered medications: https://www.prod.ramq.gouv.qc.ca/DPI/PO/Commun/PDF/Liste_Med/Liste_Med/liste_med_2015_04_24_en.pdf

New Brunswick Drug Plans Formulary: http://www.gnb.ca/0212/pdf/NBPDP_Formulary-e.pdf

Nova Scotia Pharmacare formulary: <http://novascotia.ca/dhw/pharmacare/documents/formulary.pdf>

Prince Edward Island Pharmacare Formulary: http://www.gov.pe.ca/photos/original/hpei_formulary.pdf

Newfoundland and Labrador Prescription Drug Program search page: <http://www.health.gov.nl.ca/health/prescription/newformulary.asp>

Yukon – Drug Formulary search page: <http://apps.gov.yk.ca/drugs/f?p=161:9000:516009234183358>

Northwest Territories Interchangeability Formulary: <http://www.nwticformulary.com/Default.aspx>

Nunavut – drug benefits available under the Non-Insured Health Benefits Program of Health Canada for First Nations and Inuit populations: <http://www.hc-sc.gc.ca/fniah-spnia/nihb-ssna/provide-fournir/pharma-prod/med-list/index-eng.php>

Pharmaceutical manufacturers

Rx&D Canada's Research-Based Pharmaceutical Companies: <http://www.canadapharma.org/en/home>. Contact information is provided on the website for the more than 50 member corporations of Rx&D. All of the major cancer drug manufacturers are members.

Drug access navigators

Oncology Drug Access Navigators of Ontario: This organization has begun inviting drug access navigators in cancer care in other provinces to affiliate with them. www.odano.ca

Patient navigators within provincial cancer agencies and programs – information can be found on provincial cancer care sites.

Clinical trials

A list of current clinical trials in Canada for treatment of metastatic breast cancer is available at: http://www.canadiancancertrials.ca/Default.aspx?dsEndecaNav=Ntk:Main_en%7cmetastatic+breast+cancer%7c1%7c,Ro:0,Nrc:id-30-dynrank-disabled%7cid-130-dynrank-disabled%7cid-131-dynrank-disabled%7cid-132-dynrank-disabled%7cid-619-dynrank-disabled%7cid-620-dynrank-disabled%7cid-621-dynrank-disabled%7cid-622-dynrank-disabled&lang=en&fromsearch=true



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