Drugs Health Technologies Health Systems

Draft Reimbursement Recommendation

Pertuzumab

Reimbursement request: in combination with trastuzumab and chemotherapy for early stage HER2-positive breast cancer in the neoadjuvant setting

Requester: Public drug programs

Draft recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Pertuzumab?

The Formulary Management Expert Committee (FMEC) recommends that pertuzumab in combination with trastuzumab and chemotherapy, be reimbursed for the treatment of adults with early stage HER2-positive breast cancer in the neoadjuvant setting, provided certain conditions are met.

What Are the Conditions for Reimbursement?

Pertuzumab in combination with trastuzumab and chemotherapy may be initiated in adult patients for the neoadjuvant treatment of early stage HER2-POSITIVE breast cancer if all of the following conditions are met: there is locally advanced, inflammatory or early stage breast cancer (greater than 2 cm or node positive) and there is no evidence of metastasis. A price reduction for pertuzumab may be required.

Why Did CDA-AMC Make This Recommendation?

FMEC reviewed the CDA-AMC report, which included a review of the clinical evidence, specifically two randomized controlled trials (PEONY and NEOSPHERE) and 5 real world evidence (RWE) studies and a cost comparison of pertuzumab in combination of trastuzumab and chemotherapy versus other treatments used in Canada. FMEC also considered input received from 4 patient groups (Breast Cancer Canada, the Inflammatory Breast Cancer Network Foundation Canada, the Canadian Breast Cancer Network, and Rethink Breast Cancer, 4 clinician groups (Ontario Health (Cancer Care Ontario) Breast Cancer Drug Advisory Committee, the Breast Medical Oncology Group at the Juravinski Cancer Centre in Hamilton, Ontario, and the Research Excellence, Active Leadership Canadian Breast Cancer Alliance, Sunnybrook Odette Cancer Centre) and 1 industry group (Hoffman La-Roche Limited).

Based on the CDA-AMC assessment of the health economic evidence, which consisted of a cost comparison table, the reimbursement of pertuzumab in combination with trastuzumab and chemotherapy is associated with higher drug acquisition costs to publicly funded drug programs than relevant comparators based on publicly available list prices.

FMEC concluded that there was uncertainty in the clinical value demonstrated by pertuzumab in combination with trastuzumab and chemotherapy; however, pertuzumab in combination with trastuzumab and chemotherapy was considered to fill a significant unmet clinical need to minimize the risk of residual disease following resection, thereby avoiding exposure to adjuvant treatment with T-DM1 which is associated with more toxicities and monitoring requirements. The reimbursement conditions were further developed based on distinct social and ethical considerations, economic considerations, and impacts on health systems.

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Therapeutic Landscape

What Is Early Stage HER2-positive Breast Cancer?

Human epidermal growth factor receptor 2 (HER2)-positive breast cancer is a subtype of breast cancer characterized by overexpression of the HER2 protein, which is associated with more aggressive disease and a higher risk of recurrence. In Canada, breast cancer is the second most common cancer, with an estimated 30,800 new cases in 2024, of which approximately 15% to 20% are HER2-positive.

What Are the Current Treatment Options?

In patients with HER2-positive breast tumors, the availability of HER2 targeted therapy has changed the natural history of the disease. Most patients with a tumor greater than 2 cm or at least 1 positive lymph node should receive neoadjuvant HER2 targeted therapy in addition to taxane-based chemotherapy with or without anthracyclines. The standard of care in other international jurisdictions is to offer dual HER2 targeted therapies (e.g., pertuzumab in combination with trastuzumab) together with chemotherapy in the neoadjuvant setting. The rationale for this treatment strategy is to offer synergy as trastuzumab and pertuzumab have been reported to enhance apoptosis.

What Is the Treatment Under Review?

The treatment under review is dual HER2 blockade (pertuzumab-trastuzumab) plus taxane-based chemotherapy with or without anthracycline-based chemotherapy (with variable dosing and treatment frequencies) as a neoadjuvant regimen.

Pertuzumab is a monoclonal antibody that targets the extracellular dimerization domain of HER2, and blocks ligand-dependent heterodimerization of HER2 with other HER family members. This inhibits intracellular signaling, resulting in cell growth arrest and apoptosis. Health Canada recommends initial treatment with 840 mg as a 60-minute intravenous (IV) infusion and maintenance treatment with 420 mg ever 3 weeks as a 30- to 60-minute IV infusion.

Why Did We Conduct This Review?

The data protection of pertuzumab ended on April 2021. As such, this drug is eligible for a nonsponsored reimbursement review, per the <u>Procedures for Reimbursement Reviews</u>.

Pertuzumab, in combination with trastuzumab and chemotherapy, has previously been reviewed twice by CDA-AMC for the neoadjuvant treatment of patients with HER2-positive locally advanced, inflammatory, or early-stage breast cancer (greater than 2 cm in diameter or node-positive), in 2015 and 2022. Both reviews resulted in a do-not-reimburse recommendation. In 2015, a negative recommendation was issued as there was no demonstrated progression free survival (PFS) benefit and it was unclear whether pCR correlated with survival outcomes. In 2022, a negative recommendation was issued again, as available evidence did not show significant differences in PFS and disease-free survival (DFS), and other survival outcomes were either immature or not reported.

At the request of the public drug programs, a new review of the evidence for pertuzumab in the neoadjuvant setting was conducted. The request was prompted by emerging evidence suggesting potential efficacy and safety benefits and opportunities for cost minimization, particularly by reducing reliance on adjuvant T-DM1, which has notable toxicity concerns.

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Input From Interested Parties

- Breast Cancer Canada shared patient group input in support of the reimbursement review, citing that the use of pertuzumab in combination with trastuzumab and chemotherapy is supported by published guidance by Manna et al. in 2024 in Canada. Results of survey conducted in individuals diagnosed with stage 2 or 3 HER2-positive breast cancer were also submitted, highlighting their treatment experiences, their perspectives of benefits and side effects, as well as insights on treatment burden and financial impacts.
- The Inflammatory Breast Cancer Network Foundation Canada as a patient group submitted detailed feedback. The group shared members' concerns about inequitable access to neoadjuvant treatment with pertuzumab in Canada, citing that this treatment is readily accessible in other countries. The input also highlighted that diarrhea is a common adverse event of pertuzumab and highlighted other side effects (e.g. febrile neutropenia leading to hospitalization) related to other chemotherapies. In addition, this patient group highlighted the importance of having access to a treatment that reduces the risk of recurrence. Doing so also helps to avoid subsequent treatment such as T-DM1 which is more toxic and difficult for patients to tolerate. The financial impact of treatment was shared by some members as well. Overall, this group advocated for the reimbursement of neoadjuvant pertuzumab in early HER2-positive breast cancer.
- The Canadian Breast Cancer Network submitted detailed patient group input. In particular, survey results of HER2 positive patients were provided to highlight important considerations in treatment decision making. In particular, the patients highlighted that key considerations include efficacy of treatment and impact on the quality of life. Respondents' survey results also indicate that as high as 18% of all prescribed treatments were not publicly funded and among these unfunded treatments, pertuzumab was a treatment commonly prescribed by oncologists.
- Rethink Breast Cancer as a patient group shared insights about the disease, current
 available treatment options and survey results of outcomes important to breast cancer
 patients. These results indicate a high proportion of respondents rated maintaining quality of
 life and managing side effects as important outcomes. Two detailed testimonies were also
 submitted, highlighting their experiences and challenges with treatment access for
 pertuzumab due to cost or lack of public funding of this treatment in early HER2-positive breast
 cancer.
- The Ontario Health (Cancer Care Ontario) Breast Cancer Drug Advisory Committee provided clinician group input on the current treatments and treatment goals for early HER2-positive breast cancer. This clinician group highlighted important treatment gaps and unmet needs, specifically that dual HER-2 directed therapy with neoadjuvant pertuzumab with trastuzuamb is a standard of care in other jurisdictions. The input also shared the potential benefits of this treatment regimen in avoiding the use of T-DM1 in the adjuvant setting. The clinician group also highlighted the challenge of prescribing and supporting a combination treatment, where some treatments are administered and provided in publicly funded clinics and others (e.g. pertuzumab) would be supported by private infusion clinics.
- The Breast Medical Oncology Group at the Juravinski Cancer Centre in Hamilton, Ontario, submitted clinician group input, sharing various clinical evidence in support of the treatment of pertuzumab in combination with trastuzumab and chemotherapy in early HER2-positive breast cancer. This clinician group also discussed the value of patients achieving pCR and how it

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impacts on treatment decisions in the adjuvant setting (e.g., treatment option to lower the risk of toxicity). The clinician group also highlighted that the most important goals to patients are to increase the ability to achieve the best response and remain cancer free.

- The REAL Canadian Alliance shared clinician group input for the review by referencing the recent publication on expertise guidance. The group highlighted the following recommendation: For patients with HER2 early breast cancer with ≥cT2 or those with nodal disease (cN+), the standard of care is neoadjuvant therapy with trastuzumab plus pertuzuamb plus chemotherapy. The group also provided clinical evidence in support of this treatment. The group also highlighted other benefits such as reducing the adjuvant use of T-DM1 by supporting more patients to achieve pCR.
- Sunnybrook Breast Medical Oncology Team submitted a letter of support to advocate for the optimization of neoadjuvant therapy for HER2-positive early breast cancer patients. Specifically, the group strongly supports CDA-AMC to recommend the funding of this treatment. The group also shared key benefits of this treatment for patients, including improved breast cancer outcomes and potentially avoiding the need for adjuvant T-DM1.
- Hoffmann-La Roche Limited provided input to highlight the inequity of treatment access for neoadjuvant treatment in breast cancer. The industry group also provided information related to the latest treatment guidelines and evidence in support of the use of pertuzumab in combination with trastuzumab and chemotherapy in early breast cancer.

► Refer to the main report and the supplemental material document for this <u>review</u>.

Person With Lived Experience

A woman recounted her story of being diagnosed in her 40s with HER2-positive breast cancer after a routine mammogram. She was otherwise healthy with no predisposition to the disease. She was treated with combination chemotherapy that included neoadjuvant pertuzumab and trastuzumab which caused many difficult side effects such as nausea, hair loss, and severe diarrhea. She had radiation and surgery followed by 12 rounds of T-DM1. She worked full time throughout and paid out-of-pocket for many treatment-related costs. Family and friends were supportive but the onset of the COVID-19 pandemic restricted contact and made treatment isolating. She is now disease-free but thinks about cancer daily and deals with ongoing physical and emotional impacts of treatment. She has regular oncology follow-ups, is grateful for the high-quality care she received, and strives to live a balanced life.

Disclaimer: The perspectives shared by people with lived experience who present to the committee reflect their individual experiences and are not necessarily representative of all people with the same condition or course of treatment. Their insights provide valuable context about what a patient, support person or caregiver might go through when facing this condition or treatment, helping to inform the committee's deliberations. These narratives complement other forms of evidence and input and should be considered as part of a broader understanding of the condition and treatment under review. Where gender or gendered pronouns are used in these narratives, they are included with the permission of the individual.

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Summary of Deliberation

FMEC deliberated on all domains of value of the deliberative framework prior to developing their recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, please refer to the Expert Committee Deliberation at Canada's Drug Agency document.

FMEC considered the following key discussion points, organized by the five domains of value.



Clinical Value

- FMEC concluded that it is uncertain whether pertuzumab in combination with trastuzumab and chemotherapy demonstrates acceptable clinical value versus appropriate comparators in the Canadian setting.
- Through reflection on the input from patient groups or insights shared by the person with lived experience, FMEC
 members noted the following important patient values or perspectives: patients acknowledge the importance of
 tpCR as an outcome. In addition, survival outcomes, safety outcomes related to treatments and the quality of life
 are all important outcomes to patients.
- **FMEC** members highlighted the following discussion points:
 - FMEC discussed that PEONY plus all 5 RWE studies included tpCR as an outcome, while NEOSPHERE considered bpCR. pCR is an important patient outcome as it helps to determine the adjuvant treatment options. FMEC noted that pertuzumab resulted in clinically important and statistically significant improvements in pCR compared to no pertuzumab based on PEONY (OR 0.43, 95% CI 0.25 to 0.73), NEOSPHERE (absolute between-group difference of 16.82%, 95% CI 3.5 to 30.1, p = 0.0141) and 4 RWE studies. As such, FMEC discussed that, as there are higher portions of patients achieving pCR with the addition of pertuzumab to trastuzumab in the neoadjuvant setting leading to a decrease in residual disease, resulting in the less utilization of adjuvant therapy with T-DM1 which is associated with high rates of toxicity relative to adjuvant trastuzumab monotherapy.
 - o FMEC noted that based on the body of evidence from PEONY, NEOSPHERE and the included RWE studies, there is support that the addition of neoadjuvant pertuzumab may lead to increased tpCR rates. As an important outcome to patients, adding pertuzumab to trastuzumab and chemotherapy in the neoadjuvant setting offers overall benefits to them.
 - o FMEC also discussed further the additional benefits of achieving tpCR. Patients who can achieve tpCR tend to also benefit from other improved outcomes, such as having improved quality of life, avoiding more toxic downstream treatments (e.g., T-DM1), and having the ability to return to work sooner. These benefits are different and separate from the overall survival outcomes measured in clinical trials. Further, patients have voiced that they value these benefits and outcomes in the treatment journey.
 - o FMEC noted that while the 3-year and 5-year between-group difference in OS (6.0% and 3.9%) and the 5-year HR of 0.53 were not statistically significant in the PEONY trial, the guest specialists noted that a 4% absolute between-group difference in OS and the estimated hazard ratio were clinically meaningful. However, the evidence was very uncertain due to imprecision as the number of events was low, the confidence intervals were wide, and the lower bound of the 95% CI for the difference in OS included the possibility of little to no clinically significant benefit. In contrast, the RWE study by van der Voort et al

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reported an adjusted HR of 0.51 for 5-year overall survival, which was both statistically significant and clinically meaningful, this finding also has some uncertainty due to residual confounding and imprecision. FMEC also discussed some emerging evidence from a meta-analysis which suggests that pCR is an informative surrogate outcome for survival benefits, although a comprehensive appraisal of this topic is outside the scope of this review.



Unmet Clinical Need

- FMEC concluded that there is a significant clinical need arising from early breast cancer despite available treatments.
- Through reflection on the input from patient groups or insights shared by the person with lived experience, FMEC
 members noted the following important patient values or perspectives: patients want treatments that offer a better
 chance of cure and overall survival. Their treatment goals include achieving pCR, reducing the risk of recurrence
 and minimizing the toxicity and minimizing the need for additional treatments with additional adverse events. They
 also would like to maintain their quality of life.
- **FMEC** members highlighted the following discussion points:
 - FMEC noted that the alternative treatment options for HER2-POSITIVE breast cancer (over 2 cm or node positive) include chemotherapy in combination with trastuzumab, followed by adjuvant T-DM1 if a total pathological complete response (tpCR) is not achieved at surgery; otherwise, the adjuvant treatment is trastuzumab for patients who achieve tpCR.
 - o FMEC discussed that T-DM1 is associated with more toxicities as shared by guest specialists, the patient groups and the person with lived experience. As such, it would be preferable to achieve a tpCR and avoid T-DM1 if possible. Toxicities with T-DM1 are manageable however, in adjuvant setting in the Katherine trial, 18 % (n = 133) of patients from the T-DM1 group developed adverse events leading to discontinuation of treatment versus 2.1% (n=15) of patients from the trastuzumab monotherapy group. One guest specialist estimated a lower rate of discontinuation of T-DM1 in their clinical practice.



Distinct Social and Ethical Considerations

- FMEC concluded that pertuzumab in combination with trastuzumab and chemotherapy would potentially address a significant nonclinical need arising from early breast cancer despite available treatments.
- FMEC did not identify any important measures that would need to be implemented to ensure that the use
 of pertuzumab in combination with trastuzumab and chemotherapy addresses relevant social and ethical
 implications.
- Through reflection on the input from patient groups or insights shared by the person with lived experience, FMEC members noted the following important patient values or perspectives: The current access to neoadjuvant treatment of pertuzumab is inequitable due to its high cost. Additional treatment requirements include the administrative burden associated with financial assistance application and the need to navigate and access private infusion clinics.

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Many patients face additional challenges due to potential concerns for fertility, childcare coordination, financial burden and implications for career development.

- **FMEC** members highlighted the following discussion points:
 - FMEC discussed that many breast cancer oncologists value the benefits of neoadjuvant pertuzumab in combination with trastuzumab and chemotherapy and they also share the concerns for the toxicity and additional monitoring requirements associated with adjuvant treatment of T-DM1.
 - o FMEC noted that based on published guidelines, input from external partners and discussion with guest specialists that the use of neoadjuvant pertuzumab in combination with trastuzumab and chemotherapy has become a standard of care in early HER2-positive breast cancer management, both within Canada and outside of Canada. However, the lack of public funding of this treatment regimen has created inequity, where only a subset of patients can access the treatment if it is affordable through private insurance or pay out-of-pocket. The patients also need to have the means to coordinate the treatment and monitoring from multiple treatment centers as neoadjuvant pertuzumab is administered in private infusion clinics.



Economic Considerations

- FMEC concluded that there are economic considerations that are important to address when implementing the reimbursement of pertuzumab
- **FMEC** members highlighted the following discussion points:
 - The reimbursement of pertuzumab is expected to increase drug acquisition costs and total treatment costs,
 given that it is always added to current treatments for this population.
 - The total treatment cost calculation accounts for the known clinical benefit of increased pCR. Other clinical benefits (e.g. improved survival) remain uncertain, although evidence from observational studies suggests that EFS and OS are at least similar compared to regimens without pertuzumab.
 - A price reduction is warranted given the higher drug acquisition costs of pertuzumab coupled with uncertainty in outcomes.
 - There are currently no generic pertuzumab formulations under review by Health Canada.
 - o No Canadian cost-effectiveness studies were published since 2020.
 - Cost-effectiveness assessments from the 2022 CADTH review showed some scenarios under which pertuzumab in combination with trastuzumab and chemotherapy may be cost-effective compared to trastuzumab in combination with chemotherapy at an ICER threshold of \$50,000 per QALY gained, but this result was dependent on how pCR outcomes were assumed to translate into survival outcomes. Under the assumption of equivalent impact on EFS (HR=1), the economic model showed that pertuzumab in combination with trastuzumab and chemotherapy was more costly and less effective than trastuzumab in combination with chemotherapy.

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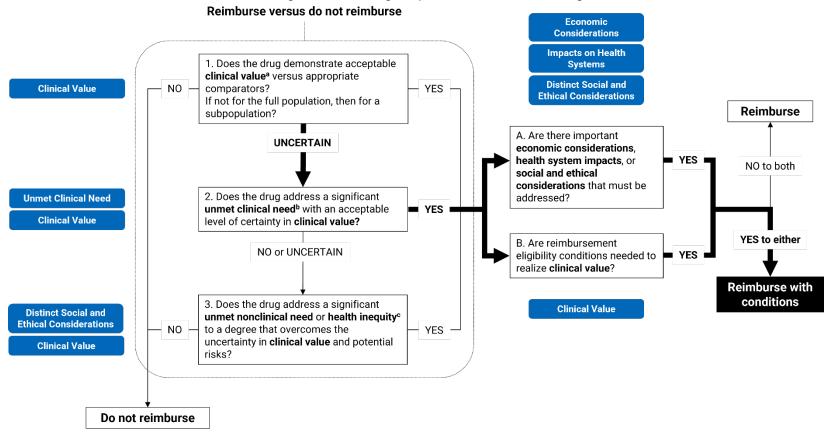
Impacts on Health Systems

- FMEC concluded that there are impacts on health systems that are important to address when implementing pertuzumab in combination with trastuzumab and chemotherapy.
- **FMEC** members highlighted the following discussion points:
 - o FMEC discussed that the use of neoadjuvant pertuzumab would increase the nursing and pharmacy resources required to prepare and administer this treatment for additional 3 to 6 cycles.
 - o FMEC also discussed that the subsequent resources required in the adjuvant setting differ, depending if the patients have achieved pathological complete response (pCR) or if they have residual disease. For patients who have achieved pCR, the adjuvant treatment of trastuzumab monotherapy is typically well tolerated for 14 cycles. For patients who continue to have residual disease following neoadjuvant treatment, the use of adjuvant T-DM1 is associated with more toxicities, frequent bloodwork investigations and clinic visits. FMEC noted that it is generally preferred for patients to achieve pCR so they can receive the adjuvant treatment of trastuzumab which is perceived to be better tolerated in comparison to patients who have residual disease and require adjuvant T-DM1.

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Figure 1: Recommendation Pathway

Alt-text: Flow chart indicating the steps used by the committee for this recommendation. The committee determined that it was uncertain whether the drug demonstrated acceptable clinical value versus relevant comparators. However, the committee also determined that the drug addresses a significant unmet clinical need with an acceptable level of certainty in clinical value. Therefore, the committee recommended reimbursement of the drug for the patient population under consideration. After deliberating on economic considerations, impacts on health systems, distinct social and ethical considerations, and whether reimbursement conditions are needed to realize clinical value, the committee determined that reimbursement of the drug should be contingent upon 1 or more conditions being satisfied.



^a Acceptable clinical value refers to at least comparable clinical value (if the drug is expected to be substitutive treatment) or added clinical value (if the drug is expected to be additive treatment) versus appropriate comparators.

^b Significant unmet clinical need depends on all of the following: severity of the condition, availability of effective treatments, and challenges in evidence generation due to rarity of the condition or ethical issues.

^c Unmet nonclinical need and health inequity are key components within the distinct and social ethical considerations domain of value..

Full Recommendation

With a vote of 7 to 0, FMEC recommends that pertuzumab in combination with trastuzumab and chemotherapy, for the treatment of early stage HER2-POSITIVE breast cancer in the neoadjuvant setting, be reimbursed if the conditions presented in <u>Table 1</u> are met.

Table 1: Conditions, Reasons, and Guidance

Re	imbursement condition	Reason	Implementation guidance
		Initiation	
1.	Pertuzumab in combination with trastuzumab and chemotherapy may be initiated in adult patients for the neoadjuvant treatment of early stage HER2-positive breast cancer if all of the following conditions are met:	The evidence suggests pertuzumab in combination with trastuzumab and chemotherapy resulted in a clinically important improvement in pCR compared to placebo with trastuzumab plus chemotherapy.	The exact number of cycles of pertuzumab neoadjuvant treatment depends on the chemotherapy backbone and may range from 3 to 6 cycles.
	1.1. There is locally advanced, inflammatory or early stage breast cancer (greater than 2 cm or node positive).	Further, patients who achieve pCR can avoid T-DM1, an adjuvant treatment which is associated with higher rates of toxicity relative to trastuzumab monotherapy in the adjuvant setting.	
	1.2. There is no evidence of metastasis.1.3. Treatment of pertuzumab should be limited to a maximum of 6 cycles in the neoadjuvant setting.	FMEC also noted that pertuzumab in combination with trastuzumab and chemotherapy is considered a standard of care in the management of early HER2-POSITIVE breast cancer, based on published guidelines ¹²³ , input from clinician groups and guest specialists consulted for this review.	
		Discontinuation and renewal	
2.	Treatment should be discontinued if there is any of the following: 2.1. disease progression 2.2. unacceptable toxicities	Consistent with clinical practice, patients discontinued treatment upon disease progression or unacceptable toxicities.	
		Prescribing	
3.	Prescribing should be limited to clinicians with expertise in the diagnosis and management of breast cancer.	This will ensure that appropriate treatment is prescribed for patients and adverse events are optimally managed.	-
Pricing			
4.	A price reduction may be required	The reimbursement of pertuzumab is expected to increase overall drug acquisition costs.	-
		No recent evidence was identified regarding the cost-effectiveness of pertuzumab relative to relevant comparators. A cost-effective analysis would be needed to determine whether pertuzumab is cost-effective.	
		Price reductions may be required, given that pertuzumab is associated with increased drug acquisition costs and likely clinical benefit.	

HER= human epidermal growth factor receptor; LVEF = left ventricular ejection fraction; pCR = pathological complete response; T-DM1 = trastuzumab emtansine

¹ Loibl S, Andre F, Bachelot T, et al. Early breast cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol. 2024;35(2):159182. doi:10.1016/j.annonc.2023.11.016 2Gradishar WJ, Moran MS, Abraham J, et al. Breast Cancer, Version 3.2024, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2024;22(5):331-357. doi:10.6004/jnccn.2024.0035 3 Manna M, Gelmon KA, Boileau J-F, et al. Guidance for Canadian Breast Cancer Practice: National Consensus Recommendations for the Systemic Treatment of Patients with HER2-POSITIVE Breast CPTexture of Patients with HER2-POSITIVE Breast CPTexture of Patients With HER2-POSITIVE Breast CREAT National Consensus Recommendations for the Systemic Treatment of Patients with HER2-POSITIVE Breast CPTexture of Patients With HER2-POSITIVE Breast CREAT National Consensus Recommendations for the Systemic Treatment of Patients with HER2-POSITIVE Breast CPTexture of Patients With HER2-POSITIVE Breast CPTexture

FMEC Information

Members of the committee: Dr. Emily Reynen (Chair), Dr. Zaina Albalawi, Dr. Hardit Khuman, Ms. Valerie McDonald, Dr. Bill Semchuk, Dr. Jim Silvius, Dr. Marianne Taylor, Dr. Maureen Trudeau, Dr. Dominika Wranik. Two guest specialists from British Columbia and Ontario participated in this review.

Regrets: One expert committee member did not attend the meeting.

Meeting date: July 17, 2025

Conflicts of interest: None

Special thanks: Canada's Drug Agency (CDA-AMC) extends our special thanks to the individuals who presented directly to FMEC and to patient organizations representing the community of those with or having had breast cancer, including the Canadian Breast Cancer Network, JK Miller, and Bukun Adegbembo.

Note: CDA-AMC makes every attempt to engage with people with lived experience as closely to the indication and treatments under review as possible; however, at times, CDA-AMC is unable to do so and instead engages with individuals with similar treatment journeys or experience with comparators under review to ensure lived experience perspectives are included and considered in Reimbursement Reviews. CDA-AMC is fortunate to be able to engage with individuals who are willing to share their treatment journey with FMEC.

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