CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Palbociclib (Ibrance) for Advanced Breast Cancer Resubmission (pCODR 10093)

pERC Recommendation: Recommends

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: December 6, 2016

This information is current as of December 1, 2019.

Note: Funding criteria as listed on the decision date. Please refer to the provincial drug programs for the most recent funding criteria and program eligibility.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
BC	Funded	Apr 1, 2018	Post-menopausal women with ER-positive, HER2-negative advanced breast cancer with no prior systemic treatment (including chemotherapy) for metastatic disease. • Patients should not be resistant to prior (neo)adjuvant aromatase inhibitor therapy (patients must be a minimum of 12 months from last adjuvant aromatase inhibitor), nor have active or uncontrolled metastases to the central nervous system. • Good performance status • BC Cancer CAP approval Eligibility Updated Oct 1/18 Post-menopausal women and men with ER-positive, HER2-negative advanced breast cancer with no prior systemic treatment (including chemotherapy) for metastatic disease (including women with chemically induced menopause with LHRH agonists)
AB	Funded	May 8, 2018	In combination with an aromatase inhibitor as a first line treatment for postmenopausal women with ER positive HER2 negative advanced breast cancer (de novo stage IV or prior earlier stage and disease free for at least 12 months following completion of adjuvant non-steroidal aromatase inhibitor). Physicians may choose only one of the following combinations: palbociclib + AI first line, ribociclib + AI first line, or everolimus +exemestane second line for an individual patient. The following groups of patient would be included: pre-menopausal patients with chemically induced menopause, patients with bone only metastases, patients that are HER2 equivocal by FISH testing, or male patients.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Feb 23, 2018	In combination with an aromatase inhibitor (AI), for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer who have not received any prior treatment for metastatic disease. Treatment should continue until unacceptable toxicity or disease progression. Patients should have a good performance status and not be resistant to prior (neo)adjuvant aromatase inhibitor therapy, nor have active or uncontrolled metastases to the central nervous system. Eligibility Notes: Anastrozole or Letrozole are the approved aromatase inhibitors for use in combination with Palbociclib; other endocrine therapies (e.g. Tamoxifen, Exemestane, Fulvestrant) are not approved; Good performance status for Palbociclib eligibility is interpreted as ECOG <=2; Patients who received prior chemotherapy in the advanced setting are not eligible for Palbociclib; For patients who received Anastrozole or Letrozole in the (neo)adjuvant setting, a minimum disease free interval of twelve (12) months after stopping therapy is required for Palbociclib eligibility; there is no time restriction for patients who relapse after receiving Tamoxifen or Exemestane in the (neo)adjuvant setting.
MB	Funded	Apr 19, 2018	Palbociclib in combination with an aromatase inhibitor: For the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor 2 (HER2) negative advanced breast cancer who have not received any prior treatment for metastatic disease. Patients should have good performance status. Patients cannot be resistant to prior (neo)adjuvant aromatase inhibitor therapy, nor have active or uncontrolled central nervous system metastases. Treatment should continue until disease progression or unacceptable toxicity.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	Feb 20, 2018	Initial Criteria: For the treatment of post-menopausal women with estrogen receptor (ER) – positive, human epidermal growth factor receptor 2 (HER 2)-negative advanced breast cancer who meet the following criteria: -Patient has not received any prior systemic treatment for metastatic disease; AND -Palbociclib is used in combination with an aromatase inhibitor (e.g. letrozole, anastrozole, exemestane); AND -Has good performance status (ECOG 0 to 2); AND -Must be disease free for a minimum of 12 months following adjuvant therapy with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) Renewal Criteria: Renewals will be considered in patients who have not demonstrated evidence of disease progression or development of unacceptable toxicity requiring discontinuation while on palbociclib. Exclusion Criteria: -The patient's disease was resistant to prior (neo)adjuvant aromatase inhibitor therapy. -The patient has active or uncontrolled metastases to the central nervous system. -The patient's disease progressed while treated with Afinitor (in combination with exemestane) 1. Funding will be considered for patients who missed the opportunity to use Ibrance i.e. patients started on monotherapy with an aromatase inhibitor (e.g. letrozole, anastrozole, exemestane) for treatment of post-menopausal ER-positive, HER2-negative (ER+/HER2-) advanced breast cancer who have not received any prior systemic treatment for metastatic disease and who are not resistant to (neo)adjuvant aromatase inhibitor therapy. 2. Public funding will be considered for only one of Ibrance (in combination with an aromatase inhibitor) OR Afinitor (in combination with exemestane); no public funding for sequential treatment e.g. Afinitor then Ibrance (or vice versa).

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NS	Funded	Jul 31, 2018	In combination with an aromatase inhibitor (AI) (ie. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior treatment for metastatic disease. Treatment should continue until unacceptable toxicity or disease progression. Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy, without active or uncontrolled metastases to the central nervous system. Patients will be eligible for either Palbociclib plus an aromatase inhibitor in the first line setting or Everolimus plus Exemestane as a subsequent line of therapy, but not both therapies.
NB	Funded	Feb 12, 2018	In combination with an aromatase inhibitor (e.g., letrozole) for the treatment of estrogen receptor positive, HER2 negative advanced breast cancer in postmenopausal women who: • have not received prior therapy for metastatic disease, and • are not resistant to (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, and • do not have active or uncontrolled metastases to the central nervous system. Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes: 1. Patients must have a good performance status. 2. Resistance is defined as disease progression occurring during or within 12 months following (neo)adjuvant NSAI therapy. 3. Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: • Sequential use of palbociclib and everolimus will not be reimbursed. • Initial approval period: 1 year. • Renewal approval period: 1 year.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NL	Funded	May 4, 2018	IBRANCE (palbociclib) is recommended in combination with an aromatase inhibitor (e.g., letrozole) for the treatment of estrogen receptor positive, HER2 negative advanced breast cancer in postmenopausal women who: • have not received prior therapy for metastatic disease, and • are not resistant to (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, and • do not have active or uncontrolled metastases to the central nervous system. Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes: 1. Patients must have a good performance status. 2. Resistance is defined as disease progression occurring during or within 12 months following (neo) adjuvant NSAI therapy. 3. Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: • Sequential use of palbociclib and everolimus will not be reimbursed. • Approval period: 12 months
PEI	Under provincial consideration		

Under provincial consideration means that the province is reviewing pCODR's recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level. This may occur before or after the pan-Canadian Pharmaceutical Alliance negotiations. Please contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.