IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 24, 2021

PACKET: 2106

DRUG: Palbociclib

USE: Malignant tumor of breast; Early, HER2-negative, hormone receptor-positive, in combination with adjuvant endocrine therapy

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C, L, S *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Mayer EL, Dueck AC, et al. Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study. Lancet Oncol. 2021 Feb;22(2):212-222.	This was a multi-center, open-label, randomized phase III trial that investigated palbociclib with standard adjuvant endocrine therapy in patients with HR-positive, HER2-negative early breast cancer. The risk of potential bias associated with randomization, allocation concealment, and reporting were deemed low. The risk of potential bias associated with performance and detection were deemed high due to the open-label nature of the trial without the use of central review. The risk of potential bias associated with attrition was deemed high because there was high attrition among the groups, and because the full survival analysis is not mature yet.	S
Loibl, S, Marme, F, Martin, M, et al: Palbociclib for Residual High-Risk Invasive HR-Positive and HER2-Negative Early Breast Cancer-The Penelope-B Trial. J Clin Oncol Apr 01, 2021; Vol Epub, p. Epub.	This was a multi-center, double-blind, randomized phase III trial that investigated palbociclib with standard adjuvant endocrine therapy in patients with HR-positive, HER2-negative early breast cancer. The risk of potential bias associated with randomization, allocation concealment, performance, detection, and reporting were deemed low. The risk of potential bias associated with attrition was deemed high because there was high attrition among the groups.	S
Mayer, EL, DeMichele, A, Rugo, HS, et al: A phase II feasibility study of palbociclib in combination with adjuvant endocrine therapy for hormone receptor-positive invasive breast carcinoma. Ann Oncol Sep 01, 2019; Vol 30, Issue 9; pp. 1514-1520.		3
Di Cosimo, S, Porcu, L, and Cardoso, F: CDK 4/6 inhibitors mired in uncertainty in HR positive and HER2 negative early breast cancer. Breast Feb 2021; Vol 55, pp. 75-78.		4

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Megan Smith	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Todd Gersten	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
IBM MICROMEDEX	Ineffective	Class III: Not Recommended		B
Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of Palbociclib in combination with endocrine therapy to treat early malignant breast cancer patients (HER2 -, HR +) does not show a benefit in a double blind study over placebo with that same endocrine therapy. The degree of disease free survival was the reference point for these trials. Perhaps the type of endocrine therapy used on these patients played a role in the trial outcome?	
Richard LoCicero	Ineffective	Class III: Not Recommended	Two phase III trials have failed to demonstrate the efficacy of palbociclib in the adjuvant treatment of early stage breast cancer. Its use in this setting cannot be recommended.	
Todd Gersten	Ineffective	Class III: Not Recommended	The available body of research on the use of Palbociclib, as an added adjuvant therapy to standard of care endocrine therapy, has not demonstrated an improvement in disease free survival versus the endocrine therapy alone.	