

pCODR Expert Review Committee Deliberative Framework

March 2016

RECORD OF UPDATES

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INQUIRIES

Inquiries and correspondence about the pan-Canadian Oncology Drug Review (pCODR) should be directed to:

CADTH pan-Canadian Oncology Drug Review 154 University Avenue, suite 300 Toronto, ON M5H 3Y9

Telephone:	1-866-988-1444
Fax:	1-866-662-1778
Email:	info@pcodr.ca
Website:	www.cadth.ca/pcodr

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pERC Deliberative Framework

The pan-Canadian Oncology Drug Review (pCODR) was established by the provincial and territorial Ministries of Health to assess the clinical evidence, cost effectiveness and patient perspectives on cancer drugs and to use this information to make recommendations to the jurisdictions to guide their drug funding decisions.

A key aspect of this process is the work done by the pCODR Expert Review Committee (pERC). Committee members examine the clinical and economic information provided by the guidance panels, as well as patient advocacy group input and Provincial Advisory Group (PAG) input, to formulate a recommendation.

To help guide the pERC's deliberations, the pCODR Advisory Committee has endorsed the following framework (see Tables 1 and 2). The framework provides an outline of all the elements that should be considered by pERC during its review, and reinforces that no single element over-rides another, but rather that pERC uses the sum of all elements to formulate a funding recommendation. The framework can be applied to all oncology drugs and situations including situations such as rare cancers or end of life care. In addition, the framework reinforces that there is no threshold that must be met for any single element in the review; rather, it is the individual drug, disease and context that determine pERC's information needs for each element of the framework.

Table 1. Criteria Definitions and Sources of the pERC Deliberative Framework

Criteria	Definition	Sub-Criteria	Source
Overall Clinical Benefit	A measure of the <u>net</u> <u>health benefit</u> of using the drug to diagnose or manage a cancer related condition (e.g., lung cancer) or cancer care related issue (e.g., skeletal related events in metastatic disease)	 Effectiveness Safety Burden of Illness Need 	Clinical Guidance Report provided by Clinical Guidance Panel, which incorporates the pCODR systematic review and registered clinician input
Alignment with Patient Values	An assessment made after considering information on patient values	• Patient values	Patient advocacy group input sought at beginning of the review
Cost Effectiveness	A measure of the <u>net</u> <u>efficiency</u> of the drug and companion technology compared to other drug and non- drug alternatives (no cut-off threshold)	 Economic evaluation Costs, cost per QALY, cost per life year gained, cost per clinical event avoided Uncertainty of net economic benefits 	Economic Guidance Report, which incorporates the Economic Guidance Panel review of the pharmacoeconomic model.
Feasibility of Adoption into the Health System	An assessment of the ease with which the drug can be adopted into the overall health care and cancer care systems	 Economic Feasibility - Budget Impact Assessment Organizational Feasibility 	Provincial Advisory Group input Economic Guidance Report, which incorporates evaluation of budget impact assessment assumptions

Note: pERC Deliberative Framework adapted from Johnson, Sikich, Evans et al. Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario. International Journal of Technology Assessment in Health Care, 25, pp 141-150. 2009

Table 2. Detailed Description of Each Element of the pERC Deliberative Framework.

Criteria	Sub-Criteria	Sub-Criteria Definitions	
Overall Clinical Benefit	Effectiveness (systematic review in the Clinical Guidance Report)	The <u>potential health impact</u> of the drug compared to the other drug and non-drug alternatives, measured in terms of <u>relevant patient outcomes</u> such as mortality, morbidity, quality of life. <u>Magnitude, direction and uncertainty</u> of effect should be considered.	
	Safety (systematic review in the Clinical Guidance Report)	<u>Frequency</u> and <u>severity</u> of adverse effects associate with the new drug compared to other drug and non-drug alternatives.	
	Burden of Illness (Clinical Guidance Report, patient advocacy group input)	Incidence, prevalence or other measure of <u>disease</u> <u>burden on the population.</u>	
	Need (Clinical Guidance Report, patient advocacy group input)	<u>Availability of an effective alternative</u> to the drug technology.	
Alignment with Patient Values	Patient Values (patient advocacy group input)	<u>Patient based values</u> which bear on the appropriate use and impact of the drug.	
Cost effectiveness	Economic Evaluations (Economic Guidance Report and pharmaco- economic model review)	A measure of the <u>net cost</u> or efficiency of the drug and companion technology <u>compared to other drug</u> <u>and non-drug alternatives</u> . The <u>uncertainty</u> of results should be considered.	
Feasibility of Adoption into Health Systems	Economic Feasibility (evaluation of budget impact assessment in Economic Guidance Report)	The <u>net budget</u> impact of the new drug on other drug and health system spending, including companion testing technology.	
	Organizational Feasibility (Provincial Advisory Group input)	The <u>ease</u> with which the new drug can be adopted, with an assessment of health system <u>enablers</u> and <u>barriers</u> to implementation, inclusive of all elements: operational, capital, human resources, legislative and regulatory requirements	

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