

# pCODR: The Pan-Canadian Oncology Drug Review

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# Why pCODR?

- To assess uniform clinical, pharmacoeconomic, and guideline evidence for oncology drug submissions and provide recommendations re: funding
- To ensure all provinces/territories (except Quebec) have reasonable access to said evidence to support their own timely decision-making and planning

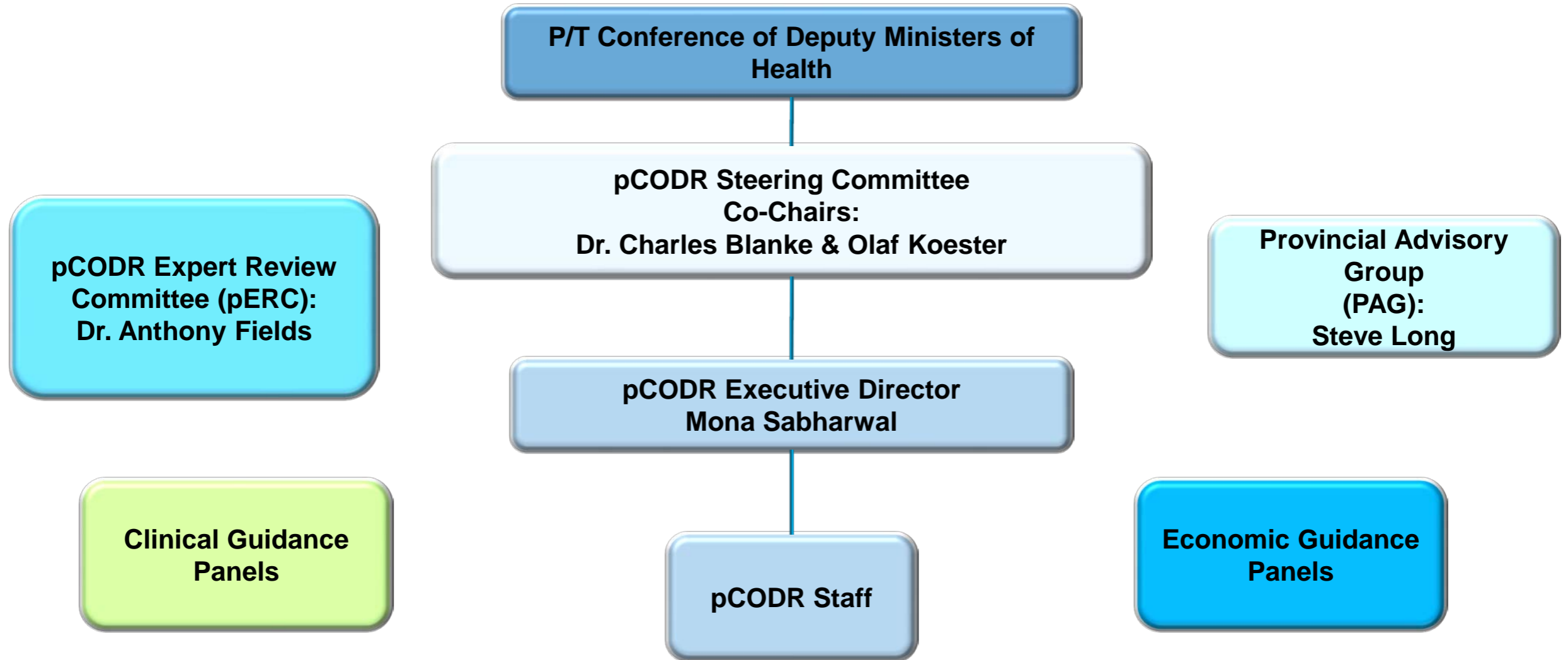
## Why pCODR? (cont.)

- Leverage limited existing P/T and national resources
- Reduce duplication of effort and facilitate cost efficiency and sustainability
- Improve clarity about decision-making for patients, health professionals and the pharmaceutical industry

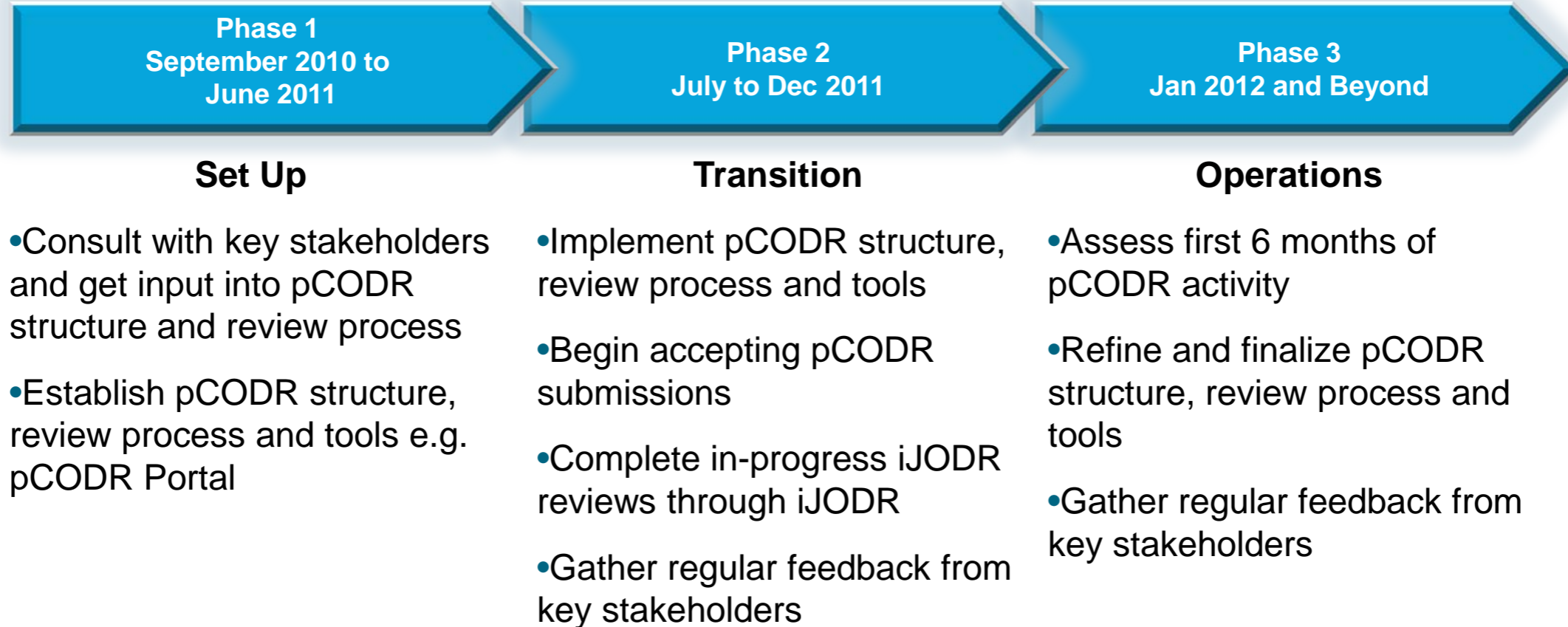
# pCODR Partners

- Provincial cancer agencies
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Canadian Partnership Against Cancer (CPAC)
- P/T Ministries of Health (excluding Quebec)

## *pCODR Structure*



## *pCODR Rollout*



## *pCODR Guiding Principles*

### Governance

- A review process with governance structures which are fair, objective, transparent and accountable to patients, payers and the public

### Representation

- A review process that is multidisciplinary, cross-jurisdictional and collaborative in nature with appropriate representation from diverse stakeholders and linked to other key national initiatives

### Efficient and Effective

- A review process that is cost-efficient, effective and streamlined (i.e. reduced duplication) to support timely decision-making

### Evaluation

- A review process with capacity for data capture and ongoing evaluation (decision monitoring/performance measurement) to support continuous process improvements. In addition, capacity for health outcomes and economic impact analysis to support decision-making and planning

## *pCODR Guiding Principles*

### Health System Focus

- Cancer drugs are evaluated within a review process and decision making framework that are consistent with those used for drugs for other diseases

### Evidence-based

- A review process with capacity for rigorous and consistent evidence-based clinical and pharmacoeconomic reviews to support evidence-based decision-making

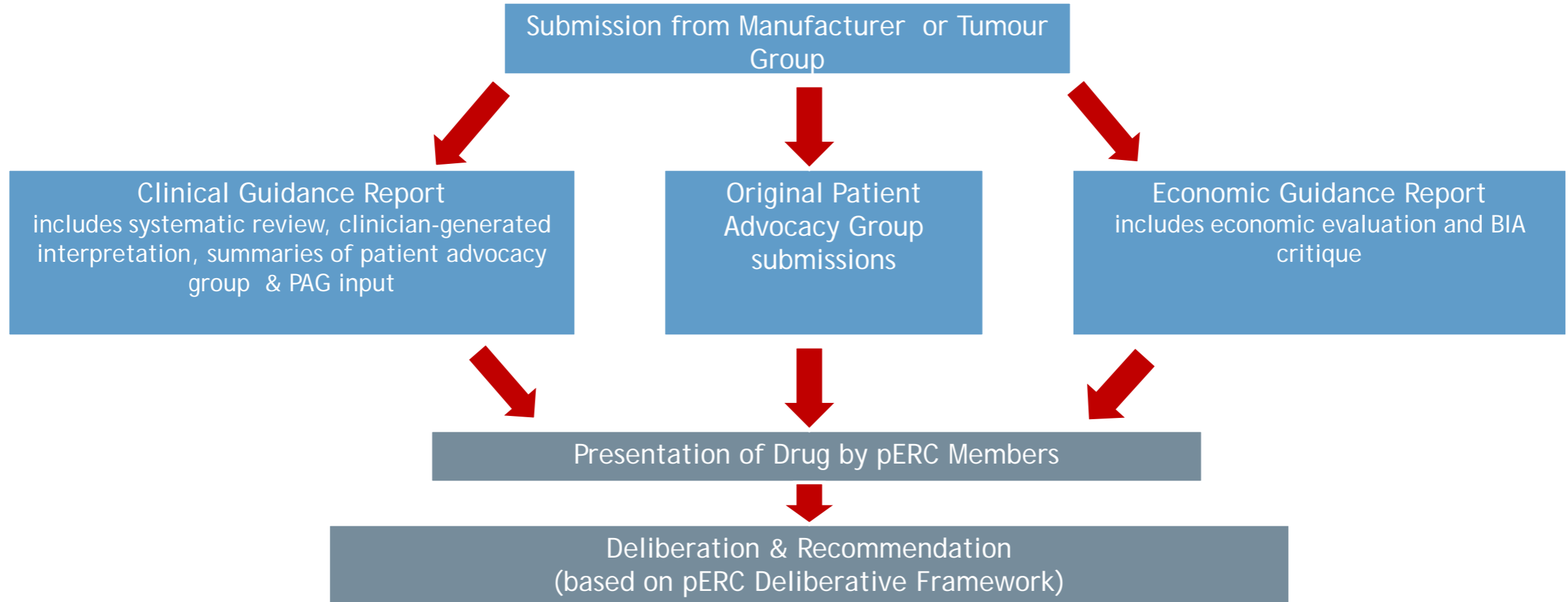
### Excellence

- A review process that reflects an ongoing commitment to excellence through incorporation of best practices in a spirit of continuous quality improvement

### Ethical Framework

- A review process that includes an ethical framework which balances the need for timely and quality cancer therapies with broader societal values

## How Does pCODR Work?



## Detailed Description of Each Element of the pERC Deliberative Framework (1)

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 and 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 burden on the population</u> .
	Need (Clinical Guidance Report, patient advocacy group input)	<u>Availability of an effective alternative</u> to the drug technology.

## Detailed Description of Each Element of the pERC Deliberative Framework (2)

Criteria	Sub-Criteria	Sub-Criteria Definitions
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 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

## *Three Categories of pERC Recommendations*

### 1.Recommend

- A drug with a clear clinical benefit and economic benefit

### 2.Consider with Conditions

- Provides context and describes conditions under which a specific jurisdiction may or may not want to fund the drug
- These conditions would relate to issues that directly change the efficacy or cost-effectiveness of the drug
- Factors or conditions to consider could include utilization patterns, funding of comparators, availability/accessibility of other options

### 3.Do Not Recommend

- No reason to recommend identified during pERC deliberations

## *How patients participate in pCODR review process?*

- Registered patient advocacy groups can provide written comments at two points in pCODR review process:
  - early in process for use in preparation of reports used by pERC to develop its recommendations
  - later in the review after pERC makes its initial recommendation

## *Role of PAG in Tumour Group Submissions*

- Tumour groups should work with their jurisdictional PAG member to bring forward their intention to make a submission
- PAG\* member will:
  - assist in determining if Submission is of local or national scope before a Tumour Group files a Submission
  - keep pCODR informed of upcoming tumour group submissions in their jurisdiction
  - act as liaison between tumour group and pCODR to facilitate initial contact
  - encourage co-ordination and collaboration amongst tumour groups on pCODR submissions
  - provide administrative support to tumour groups making a submission

\* PAG = Provincial Advisory Group

## *Role of Manufacturers in Tumour Group Submissions*

- pCODR will notify a manufacturer if a tumour group submission is underway
- Tumour group may seek support from manufacturer on clinical or economic requirements
- pCODR may provide tumour group with appropriate contact information for a manufacturer but is not responsible for coordinating interactions
- pCODR will neither facilitate nor limit manufacturer involvement in a submission

## *Procedural Review (AKA Appeal)*

- A procedural review can be requested within 10 business days of a pERC Final Recommendation being posted
- A request may be submitted on the basis that:
  - pCODR failed to act in accordance with its procedures in conducting review
  - pERC failed to apply its deliberative framework in formulating its recommendation
- Request may be made by: submitter, (manufacturer - if not submitter) PAG, or patient advocacy group who provided input on the review or feedback on pERC Initial Recommendation
- Further information is available in the pCODR Procedural Review Guidelines, available at:  
[http://www.pcodr.ca/portal/server.pt/gateway/PTARGS\\_0\\_5006\\_2139\\_549\\_5957\\_43/http%3B/ucm-vip/idc/groups/pcodr/documents/pcodrdocument/pcodr-procedural-review-guide.pdf](http://www.pcodr.ca/portal/server.pt/gateway/PTARGS_0_5006_2139_549_5957_43/http%3B/ucm-vip/idc/groups/pcodr/documents/pcodrdocument/pcodr-procedural-review-guide.pdf)

## *Resubmissions*

- pCODR may accept Resubmissions under following circumstances:
  - New Information becomes available during review process before Final Recommendation issued
  - New Information becomes available after the Final Recommendation issued
  - New Information becomes available that affects funding conditions and/or criteria recommended by pERC and accepted by P/T Ministries of Health or Provincial Cancer Agencies in their decisions to fund a Drug

# BCCA Questions/Problems

- Will we follow recommendations?
  - Ideally: NO means NO; YES means MAYBE
  - We have funded dozens of iJODR “NO’s”
    - Will we lose our “cutting edge”?
- Will there be one federal price negotiated per drug?
  - Will we lose our “special deals”?
- Will other P/T’s follow the rules?

# BCCA Questions/Problems

- Process: What does pCODR mean for PEC, and to a lesser extent iTEC and CAP?
- Could/should this lead to federal funding for cancer drugs?