pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pCODR PAG Input on a Review

July 2011

RECORD OF UPDATES

Update	Version	Reported on pCODR Website
Original	July 2011	July 21, 2011

INQUIRIES

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TABLE OF CONTENTS

1 ABOUT COMPLETING THIS TEMPLATE

As part of the pCODR Expert Review Committee (pERC) Deliberative Framework, when making a funding recommendation, pERC must consider the potential impact and feasibility of adopting into the health system the new drug or a new indication for a drug. Input provided by pCODR's Provincial Advisory Group (PAG) on a review is used to inform this component of pERC's deliberations and is important contextual information for a pERC recommendation. The *pERC Deliberative Framework* is available on the pCODR website, www.pcodr.ca.

Receiving PAG input early in the review process allows pCODR to use incorporate this information when establishing the plan (protocol) for conducting the review.

When providing input, PAG is asked to broadly consider the following questions:

- In your jurisdiction, what factors would you consider might impact the ease with which the drug might be adopted into the health system?
- What are potential enablers or barriers in the health system to implementing a funding recommendation for this drug? Generally, enablers/barriers could be operational, capital, human resources, legislative, or regulatory in nature.

The categories and questions outlined below are only examples, to guide identification of relevant implementation factors for pERC's consideration. For each factor identified, please note if there is information that could be provided in the Clinical and Economic Guidance Reports that would additionally explain an implementation process by jurisdictions (e.g. utilization data, supplemental issues, etc.). Please clearly indicate if the factor would be considered an enabler or a barrier in your jurisdiction.

2 PAG INPUT on a pCODR REVIEW

2.1 Category – Comparators

Example questions that may be relevant to the implementation of a pERC recommendation:

- Does the current standard of care impact how a new drug may be funded e.g., prior treatment?
- Have there been previous challenges in trying to implement funding for similar drugs?
- Are there any issues with the administration of relevant comparators that may be important to consider e.g. closed distribution systems, need for specific supportive care?

COMPARATORS		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**

2.2 Category - Patient Population

Example questions that may be relevant to the implementation of a pERC recommendation:

- Is there interest being expressed by clinicians for broader use than is currently under review or supported by existing evidence e.g. use in an adjuvant setting when data currently supports metastatic, use as first-line treatment options when submission is for second-line use?
- Are there potentially few/many patients who would meet the indication under review by pCODR? Would size of targeted patient population have any policy implications?

PATIENT POPULATION		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**

2.3 Category – Accessibility

Example questions that may be relevant to the implementation of a pERC recommendation:

- Would patients be able to easily access this treatment (or relevant comparators) in your jurisdiction (e.g. due to cost, availability, distribution, location)?
- Will patients have access to and funding coverage for other drugs in the treatment regimen?
- If companion molecular testing is required, will jurisdiction have access to it? Is the test funded?

ACCESSIBILITY		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**

2.4 Category – Dosing Issues

- Can the drug and/or treatment protocol be delivered in less central or rural locations or is tertiary care expertise required?
- Will there be challenges in implementing the proposed dose regimen (e.g., 7 day therapy for an IV drug where care settings operate on alternate cycle?
- Is there potential for dose intensification or de-escalation (e.g. frequency, duration of treatment)? Is there regional variation in use where different protocols are used?
- Do utilization data indicate trends in the doses used for comparators?

DOSING ISSUES		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**

2.5 Category – Implementation Costs and Cost Avoidances

- What space and human resource implications need to be considered (e.g. increase or decrease chemo unit chair time), taking into account factors such as the potential patient population to be treated and the duration of therapy?
- What health system costs (other than cost of the drug) will be incurred e.g. molecular testing, additional lab investigations, monitoring tests (e.g. ECHO/MUGA scans, bone mineral density), supportive care drugs that are required, additional drug costs that are part of a combination treatment protocol, infusion pumps, etc.?
- Are there additional costs that would be avoided with implementation of this drug?
- Could the recommendation of a less costly alternative still increase costs through overall market expansion or increases in utilization (e.g. 'me-too' drugs, because used as a sequential option and not a true alternative)?
- Is dose wastage an issue with administration of this drug or its comparator? (or any other administration/nursing / pharmacy issues)?

IMPLEMENTATION COSTS		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**

2.6 Category – Other

- Are there other factors (e.g. regulatory, policy, program design) that should be considered by pERC when making a recommendation that would impact on the feasibility of implementing a recommendation (e.g. dispensing requirements for drugs with controlled distribution)?

OTHER		
Jurisdiction	**Factor Identified**	**Enabler or Barrier**