Alberta Lab Formulary Committee Rapid HTA Prioritization Framework

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Prepared by:

Jeff Round, Chief Scientific Officer

Ken Bond, Director, Evidence Synthesis

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Corresponding Author/Project Lead

Please direct any inquiries about this report to Jeff Round, jround@ihe.ca or Ken Bond, kbond@ihe.ca.

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Declared Competing Interest of Authors

A competing interest is considered to be financial interest or non-financial interest, either direct or indirect, that would affect the research contained in this report or create a situation in which a person's judgement could be unduly influenced by a secondary interest, such as personal advancement.

The authors of this publication claim no competing interest.

Introduction

With the rapid growth in available laboratory tests, clinical laboratories are faced with two challenges: (1) adopting new laboratory tests available that are inaccurate or of little clinical benefit, and (2) denying access to cutting-edge diagnostics that are clinically beneficial or more precise compared to current diagnostic methods (Landaas et al. 2020). In addition to these challenges, the large number of potential tests and their uncertain value may raise concerns about their cost-effectiveness and system affordability, if adopted on a broad scale. The Rapid Health Technology Assessment (HTA) Prioritization Framework aims to formalize the existing provincial Lab Formulary Committee (LFC) decision process and integrate a rapid HTA component into the process to help steward precious health care resources by the adoption of only those laboratory tests that have demonstrated strong clinical and economic value. It is also hoped that a formalized process will help to avoid tests entering the system that have not had an appropriate assessment of benefit, costs, and provincial implementation issues, and to reduce the need for the cancellation of inappropriate test orders. The framework builds on the current LFC review process to provide a formalized process and decision rules to assess and approve new laboratory tests in a consistent, evidence-based manner, and in a way that ensures the tests will add value to the health care of Albertans.

The purpose of the framework is also to support the LFC in decision making in a way that accounts for important health system values by facilitating decision-making in a manner that is structured, transparent, consistent, relevant, and accountable, such that they promote the mission, aims, and values of Alberta Health Services (AHS) and its subsidiary Alberta Precision Laboratories (APL). *Structure* refers to the extent to which the LFC has formalized the test prioritization process. *Transparency* refers to the extent to which the reasons for decisions are or can be clearly discussed and communicated to all stakeholders. *Consistency* refers to the extent to which decisions have a similar process and outcomes that are similar when the considerations involved are relevantly similar. The *relevance* of a decision is the extent to which the decisions reflect the operational priorities of APL and the population it serves. All of these factors contribute to *accountability*, which is the extent to which the LFC can justify its decisions, all things considered.

Framework Development

The development and testing of the of the Framework and Rapid HTA process was conducted in two phases. Phase 1 was the development of a review process and decision framework to support the LFC identify lab test requests that require additional assessment, and the templates to support and record decisions. The process and criteria were developed using materials previously developed by IHE for prioritization process framework developments and through a review of the current LFC review process and relevant documentation, including the LFC test intake form, APL briefing note template, APL project placemat, and discussions with the LFC Chair, as well as members of the Alberta Laboratory Formulary Committee (LFC) and AHS Innovation, Evidence & Impact Team. The development of the process and framework was also informed by other HTA-informed laboratory test assessment processes such as that described by Landaas et al. (2020).

Phase 2 involved the development of rapid HTA methods that are specific for the needs of the LFC and feasible given decision-making demands and budgets in the Alberta setting. These rapid HTA methods will be tested and ongoingly refined via review and economic analysis of test request to

LFC where comprehensive reviews of clinical evidence and other information required for robust economic evaluation, model development and analysis, and development of a standard report format for the committee is required.

The LFC Rapid HTA Prioritization Process

The rapid HTA prioritization framework for the LFC is intended to help the LFC determine which laboratory tests under its review require more thorough evaluation of their potential costs and benefits, as well as implementation considerations, to inform the LFC decision about whether the test should be added to the provincial lab formulary. The prioritization framework describes the main factors that are considered by the committee in a particular decision, and provides a structured decision process to guide the consideration of and deliberation about these issues.

Laboratory Formulary Committee Review and Prioritization Process

The LFC review process receives three kinds of test request:

1. **New tests.** The vast majority of new test requests are for tests that are in use in another health system, are seen to be of value, and are desired by clinicians in Alberta. These tests are well validated and, generally, have known clinical and therapeutic value.

2. **Expanding indication.** These are tests currently in use, and clinicians are interested in expanding their use.

3. **Tests developed in Alberta.** These are tests invented in Alberta and the test developer would like to have the test listed on the provincial formulary. These tests have usually involved lengthy and sustained engagement with APL and the Alberta health-innovation ecosystem.

Figure 1 (below) depicts the LFC prioritization process including a step to identify those tests for which a rapid HTA may be needed. Because new tests (Category 1) often have well established value, they are least likely to require additional assessment.

When considering a request for a new test, the committee should refer to the AHS Innovation Pipeline Primer (https://www.albertahealthservices.ca/assets/about/scn/ahs-scn-so-innov-pipeline-primer.pdf). The Primer includes five steps of evidence development and describes the evidence needs at each stage. The steps are:

1. Idea Generation
2. Proof of Concept Testing
3. Implementation Test in Alberta (AB)
4. Implementation Work to Scale
5. Implement to Sustainment in Care

Placement of the test on this pathway establishes the evidence needs for the requestor. The Primer also includes details of the AHS Investment Request Intake Form which will need to be completed by the requestor and submitted by the LFC to the Sustainability Program Office (SPO) if a budget request is required.

The LFC review process (Figure 1) begins with a desirable or promising lab test identified by a physician or by laboratory staff (Step 1). The physician, in partnership with the medical/scientific lead in APL, completes the standard intake form and slide presentation template and submits them to LFC secretariat (Step 2). The LFC Secretariat then reviews the completed form and slide presentation (Step 3). If more information is required, this is requested (Step 4). Once the information package is considered complete, it goes to the LFC for review at its regular meeting. When the LFC reviews the test request (Step 5), it should consider several questions:

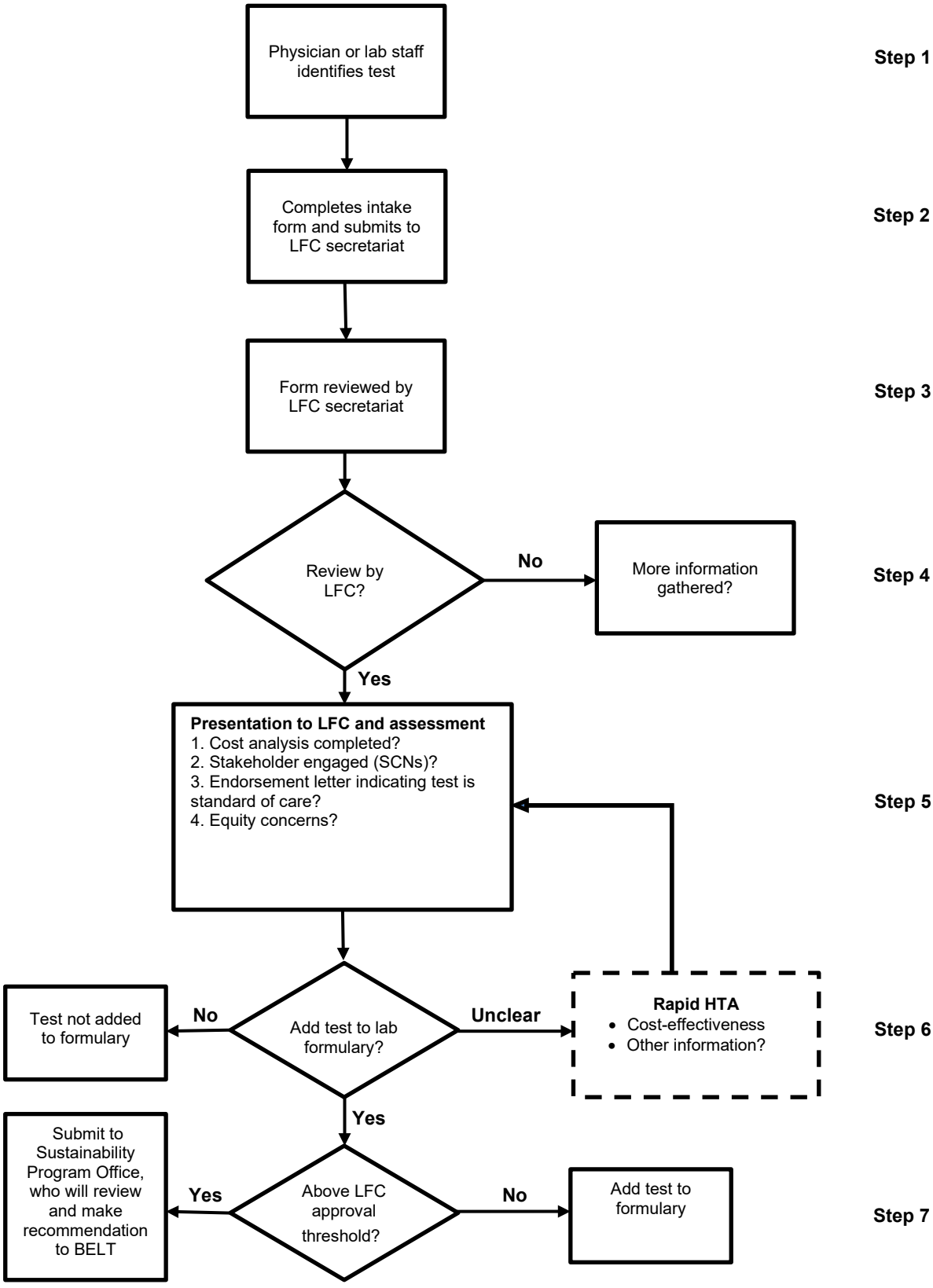
1. Why should the test be adopted and what is the need in Alberta (i.e. the size of the target population)?
2. Is adoption of the test feasible? For example, are there capital or staff investments required to administer or analyse the test?
3. Has a cost analysis been completed and can the cost of the test be absorbed?
4. Have the appropriate stakeholders and subject matter experts been engaged to ensure appropriate use and implementation?
5. Is the test considered standard of care by system stakeholders?
6. Have equity concerns been assessed and addressed?

The information with which to answer each of these questions needs to be provided in the test request information package. If the test is considered to be a standard of care, the relevant system stakeholders have been engaged, and the budget impact of adopting the test has been considered, it is it is likely to be recommended to be added to the provincial lab formulary, subject to budget considerations.

Equity concerns may be considered as well, though less regularly. If there is sufficient information and evidence to make a decision, yet the cost-effectiveness of the test is in question (for example, due to high cost of the test), a rapid HTA may be requested (Step 6). Once the rapid HTA is completed, this new information is submitted to the LFC for a second review of the test.

If the test is considered appropriate, it is approved and added to the formulary. If the cost is above the threshold for approval by the LFC, the related budget request is sent to AHS. These should be submitted to the Sustainability Program Office (SPO), which receives all requests for new investment and assesses these against the Pipeline, making recommendations to the Budget Executive Leadership Team (BELT) as to whether or not to fund (Step 7). The test review request does not return to the LFC if it is sent to BELT for budget approval review, if approved APL assumes responsibility for implementation and operationalization.

Figure 1. LFC Test Review and Assessment Process



Criteria for Assessing and Prioritizing Tests

The assessment questions described in Step 5 above indicate four distinct domains of concern to the LFC and a number of associated criteria within each domain. The domains and criteria are described in Table 1 below. The process and criteria proposed here are similar, in many respects, to a process proposed by Landaas and colleagues (Landaas et al. 2020) that applies HTA methods to the assessment and approval of laboratory tests. The HTA-supported process described by Landaas et al. involves five steps: (1) a new technology request from a clinician or department, (2) reviews of each request to determine it meets inclusion criteria, (3) an HTA report that includes nine dimensions of evidence and is reviewed by a clinical expert for accuracy, (4) a clinical committee specific to the technology reviews the HTA report and makes an adoption recommendation to the executive committee, and (5) an executive committee reviews the new technology and committee recommendations and makes the final adoption decision.

The value dimensions currently used by the LFC, and further refined here, are consistent with Alberta Health Services' four dimensions of value impact (Lewanczuk et al. 2020): (1) improvement in three of six dimensions of the AHS Quadruple Aim (effectiveness, appropriateness, and efficiency), (2) demonstrated economic benefit, (3) implementation feasibility, and (4) health equity.

The following **six principles** have been proposed to guide LFC decision-making using the prioritization framework:

1. Decisions should be made in a manner that is fair and transparent.
2. The decision-making process should be applied consistently across the tests reviewed. This does not mean the same decisions would be made if repeated, only that the process is consistently employed.
3. Decisions are to be made after considering the relevant evidence and information on the following four domains that were identified from APL and AHS documents and discussion with the LFC Chair:

   Test Appropriateness – The technical and clinical performance of the test, the recommendations of current guidelines, the clinical benefits of the test, and extent to which the test aligns with APL organizational goals.

   System Stakeholder Engagement – The extent to which the appropriate clinical leaders in the zones have been engaged and indicate support for adopting and implementing the test.

   Economic Impact – Total cost and the cost per unit of health benefit (efficiency) of the test compared to other alternatives, the affordability for APL/AHS budget, and an indication of what is displaced or foregone to adopt it (opportunity cost);

   Equity – The consideration of provincial utilization patterns and assessment of the extent which the test (its introduction or expansion) would create other and/or significant costs and/or have impact on co-morbidities or pose a risk to the population if it is no longer provided.
4. The evaluation of each domain draws on a wide range of information, including scientific and clinical evidence, economic evaluation and budget impact assessments, and expert input/opinion.

5. The decision-making process explicitly states the criteria being used in decisions and the relevant evidence and information that may be sought in order to assess how a test fares on each of the domains. The decisions take place within a deliberative process defined as one that involves the face-to-face (virtual or in person) interaction of the relevant LFC members.
6. Following deliberation on the evidence for each domain, LFC members come to consensus on a recommendation. A rationale for the decision is documented and a brief statement of the recommendation is sent to requestor.

The prioritization framework consists of four domains (test appropriateness, system stakeholder engagement, economic impact, and equity) each of which contain several assessment criteria. The development of the proposed assessment criteria was informed by the results of a comprehensive review by IHE of reimbursement criteria for HTA, the AHS Innovation Pipeline Evidence Placemat, which provides a framework and evidence requirements to support value-based decision making regarding innovative lab tests, and the current LFC documentation used for test request intake and assessment. Table 1 provides an overall description of each domain, identifies the criteria to be assessed, and lists considerations to be taken into account in the assessment.

Table 1. LFC Assessment Framework: Domains and Criteria

Domain	Criteria	Evaluation and Considerations
Domain 1: Test Appropriateness		
The assessment of test appropriateness should include consideration of the technical and clinical performance of the test, the recommendations of current guidelines, the clinical benefits of the test, and alignment with APL organizational goals.	Efficacy and Effectiveness	• There is evidence that the test has technical efficacy and acceptable diagnostic accuracy for the selected patient population. • There is evidence that the test supports therapeutic decision making that leads to improved patient outcomes compared with current testing for the selected patient population. • Test accuracy should be described relative to current standard of care
	System-Level Need	• There is evidence that the role of the test in clinical practice is well understood and established. • There is general agreement that the test is considered standard of care within the Alberta clinical community, for example, by relevant clinical societies.
	Alignment with APL Goals	• The test supports stated goals of APL, for example, by supporting the achievement of patient quality and safety goals.
Domain 2: System Stakeholder Engagement		
The assessment of the extent to which the appropriate clinical leaders in the zones have been engaged and indicate support for adopting and implementing the test.	Clinical Endorsement	• There is documentation indicating support for adopting the test by relevant clinical and laboratory groups and subject matter experts (e.g. SCNs, tumor teams, discipline councils)
	System capacity	• There is sufficient information provided to assess whether the current testing operations can accommodate, for example, the additional patients being tested, family members who may also be tested, etc. • Indication that any training required is available
Domain 3: Economic Impact		
The assessment of economic impact should include consideration of the product cost, the budget impact, cost-effectiveness and opportunity costs, overall health system value, impact on other health and non-health system partners, and direct costs to the patient, if any.	Affordability	• The costs of the test (operating and capital) arrived at by determining all relevant costs and savings to the health care system. • If test is expanding or replacing a current test, an indication of the incremental cost of transitioning to the new test. • Assessment of expected impact of test accuracy (eg does it change specificity or sensitivity and what happens in each case)
	Cost-effectiveness	• A measure of the net cost or efficiency of the health technology compared to available alternatives. • Ideally assessed by the appropriate economic evaluation including cost-effectiveness, cost-utility and any other relevant analyses.

Domain	Criteria	Evaluation and Considerations
	Financial risks	• Size of investment, likelihood of success
Domain 4: Equity		
The assessment should evaluate whether the test would lead to disproportionate impact on the most vulnerable patients and staff.	Equity	• Equity considers the impact on the health of vulnerable or marginalized populations where there is a known gap in health status, especially among those such as the elderly, low-income, indigenous, and people at end of life (palliative care). • It is also important to consider provincial utilization patterns. • If a test is being considered for removal, may consider whether removing this test would create other and/or later significant costs and/or have impact on co-morbidities or pose a risk to the population if it is no longer provided. • At the very least, the listing decision should not exacerbate existing inequities in test provision for vulnerable groups. At best, it would actively address social policy causes of inequality.
	Other considerations	• Other considerations that may influence whether the test is appropriate may include: societal concerns, policy concerns, or clinical/professional issues that will influence test use overall (for example, potential for misuse, resistance).

Sources of Evidence

It is important that evidence to support each of the criteria above be readily available. Table 2 outlines key sources of evidence and other information that should be available at the time of review to support LFC's recommendations.

Evidence to inform therapeutic advantage should be based on established scientific methods. While the scientific clinical evidence may be primary in order of evaluation, decision-making at the provincial level requires contextualizing this evidence. Therefore, there is a need for other forms of evidence, including budget impact, cost-effectiveness, engagement with appropriate system stakeholder and an assessment of equity issues and other issues. Evidence specific to the Alberta context can be developed as required. Expert opinion and experiential evidence should also be considered to help contextualize the scientific evidence.

In addition to formal reports, the LFC deliberations may provide the opportunity to identify and discuss relevant issues regarding organizational and patient values. As much information as possible on these aspects should be documented in advance of deliberation.

Patient Engagement and Patient-Based Evidence

There is universal agreement about the importance of incorporating patient perspectives and experiences within health technology assessments. Within the prioritization process described above, prior to a decision to request additional information in the form of a rapid HTA, the patient representative on the LFC plays a crucial role in helping to identify important perspectives and information pertaining to a test and the use of its results, particularly as they related to therapeutic effectiveness, cost-effectiveness, and equity. Rapid HTAs can help to address information gaps by conducting reviews of the patient-based evidence (usually consisting of the results of qualitative research) and in identifying and conducting additional patient engagement (for example, semi-structured interviews) to help provide important perspectives and experiences with Alberta. The LFC patient representative will play a crucial role here, as well, in helping to determine the scope and relevance of engagement activities.

Table 2. Examples of Sources of Evidence and Other Information by Domain

Domain	Criteria	Source of Evidence or Information
Test appropriateness	Efficacy, effectiveness, system-level need,	• Test validation studies, clinical studies, etc. • Clinical practice guidelines • Patient evidence
	Alignment with APL goals	• APL mission and goals
System stakeholder Engagement	Clinical endorsement, system capacity	• Letter from relevant clinical community indicating that use of test is supported.
	System capacity	• Strategic Clinical Network leadership (or equivalent) endorsement; AHS benefits realization team assessment
Economic impact	Affordability	• Budget impact assessment

	Cost-effectiveness	• Contextualized analysis (rapid HTA)
	Financial risk	• Budget impact assessment
Equity	Equity	• Health Equity Impact Assessment (eg ON Ministry of Health HEIA tool *https://www.health.gov.on.ca/en/pro/programs/heia/docs/template.pdf*)
	Other considerations	• Stakeholder letters of support

AHS: Alberta Health Services; APL: Alberta Precision Labs; BIA: budget impact analysis; LFC: Lab Formulary Committee; HTA: health technology assessment;

Assessment and Triggers for Rapid HTA

Assessment of the domains and criteria may provide a helpful starting point for deliberation by identifying different opinions and promoting structured and focused discussion. The evaluation of the four domains should be based on qualitative rating of the individual criteria. Committee members will score their degree of confidence in the evidence for each criterion using a qualitative rating (Acceptable, Not Acceptable, Not Applicable) to indicate the extent that each criterion is satisfied based on available information. These individual domain ratings can then be used by committee members in their deliberation and to better understand which criteria may be well addressed or not.

When there is sufficient uncertainty regarding the test cost and value, the committee may recommend a rapid health technology assessment to provide additional evidence regarding the potential clinical and cost-effectiveness of the test and to examine other aspects of the implementation of the test. Any HTA or evidence generation process should involve representatives from AHS, the relevant Strategic Clinical Network (SCN; or equivalent), APL, patient groups and Alberta Health as appropriate. Funding for evidence generation or assessment activities will need to be identified – APL does not have resources for supporting HTA requests.

HTA methods are well established, and there are several research groups in Alberta that routinely conduct systematic or rapid reviews, as well as economic evaluations. It is important as well that any evidence generation or health technology assessment activity consider patient input.

References

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Lewanczuk R, Chuck A, Todd K, Yiu V. Value in Healthcare: Designing an Integrated Value-Based Healthcare System. Healthc Pap. 2020 Feb;19(1):59-64. doi: 10.12927/hcpap.2020.26154. PMID: 32310754.

Appendix A: LFC Assessment and Prioritization Form

CRITERIA	EVIDENCE SOURCES USED IN ASSESSMENT	QUALITATIVE ASSESSMENT / COMMENTS
DOMAIN 1: Test Appropriateness		
Efficacy and effectiveness	☐ ☐ Other HTA reports ☐ Other (specify):	Note: Be clear about who has evaluated the evidence sources.
System level need		
Alignment with APL goals		
DOMAIN 2: System Stakeholder Engagement		
System Stakeholder Engagement		
System capacity		
DOMAIN 3: Economic Impact		
Affordability	☐ ☐ Health system partner input ☐ Other (specify):	
Cost-effectiveness	☐ ☐ Other (specify):	
Financial risk	☐ ☐ Other (specify):	
DOMAIN 4: EQUITY		
Equity	Specify:	
Other considerations	Specify:	

Institute of Health Economics
1200 – 10405 Jasper Avenue
Edmonton AB Canada T5J 3N4
Tel. 780.448.4881 Fax. 780.448.0018
info@ihe.ca

www.ihe.ca