



**Alberta Health
Services**

Calgary Health Region

Local Health Technology Assessment

Decision Support

Medical Services

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INTRODUCTION

Background

Health technology includes any method or intervention that is used to promote health; prevent, diagnose, or treat disease; or improve rehabilitation and long-term care. Technologies include drugs, devices, diagnostic agents, equipment, and medical and surgical procedures. The definition also includes organizational and service systems that provide health care, such as telehealth (Canadian Agency for Drugs and Technologies in Health (CADTH) 2007).

Health technology assessment (HTA) provides health care decision makers with a comprehensive, objective, evidence-based analysis of the clinical effectiveness, cost-effectiveness and broader impact of drugs, medical technologies and health systems. HTA examines technologies at all stages of their life cycle, from development through to maturity and obsolescence (CADTH 2007).

In Canada, federal and provincial agencies such as the CADTH, and in Alberta, the Alberta Heritage Foundation for Medical Research, and the Institute of Health Economics provide health care decision makers with HTA reports. However, HTAs conducted through international, national, or provincial HTA agencies do not usually consider factors that are critical for local decision makers. For example, an HTA report from a federal or provincial agency may not consider local population health needs, presence of local alternatives and trained personnel, local priorities, infrastructure implications, funding options, and consequent cost implications of the health technology. Furthermore, many local decision- and policy-makers do not have a consistent and transparent mechanism in place for the integration of clinical, cost, and resource evidence into the decision process. Therefore, a tool was developed for use at the local level when considering the introduction of new health technology or the replacement or discard of existing technologies. The tool is called the **Local HTA Program**, as it is based on the basic rationale involved in health technology assessment.

This form may be printed and submitted in hardcopy or sent as email attachment. The form may be found on the DOM Website.

PART A: TECHNOLOGY REQUEST FORM

To be completed by applicant

1. Name of Applicant: _____

Division: _____ Phone: _____

Email: _____ Pager: _____

2. Name (trade name if applicable) of proposed technology:

3. Product Manufacturer: _____

Distributor: _____

4. Health Protection Branch Approved:

- Yes
- N/A [note HPB approval can be different from FDA Approval]
- No [see Health Canada Special Access Request Form]

5. Type of Proposed Technology:

- Device Process of Care
- Medication (Currently P&T Committee is the avenue for request for new drugs. Maintain this process for now. September 2008)

6. Category of Proposed Technology: [check all that apply]

- Innovative/Experimental New [Little or no safety and effectiveness data is available AND/OR not presently an insured service AND/OR not approved by Health Canada.]
- Proven New [Clinical safety and effectiveness have been demonstrated, but technology has not been used in the local environment. AND/OR is not presently an insured service in Alberta.]
- Replacement of Existing Technology: [The old version is discarded and proposed version is adopted. Comparative evaluation may be needed.]
- Upgrade or addition of Existing Technology: [New features are added to existing technology. Comparative evaluation may be needed.]

7. **Description of proposed technology.** [Briefly describe the proposed technology including: 1) its important features, 2) its advantages and benefits, and 3) any potential for innovation in patient care services. If this is a replacement, upgrade, addition, or discard of an existing technology, (as checked in #6) please also **describe the existing technology** (comparison product) and the reason(s) for change.]

8. **Change from current practice:** [check one]

Minor change

Significant change

9. **Proposed location for use:**

Service(s): _____

Site(s): _____

10. Request for: Testing a limited number Permanent use

PATIENT CARE

11. **Population characteristics:** [Please describe the patient characteristics, approximate numbers and indications for use]

12. **Needs, benefits and advantages.** [Give a brief summary of the needs, benefits and advantages of the proposed technology over current practice.]

13. **Standard of Care/ Best Practice.** [Describe whether the proposed technology has the potential to establish a new Standard of Care/ Best Practice.]

INNOVATION

14. Innovation characteristics [Please describe the potential for innovation in patient care services]

TRAINING

15. Are there staff training implications? [If yes, please describe.]

Yes No

16. Are there nursing care implications? [If yes, please describe.]

Yes No

17. Are there physician/surgeon training implications? [If yes, please describe.]

Yes No

18. Will credentialing be required? [If yes, please describe.]

Yes No

SAFETY

19. Safety category: [check one]

a. **At least as safe as comparator procedure(s)** [A comparator procedure may be the current “gold standard” procedure, an alternative procedure, a non-surgical procedure or no treatment (natural history).]

b. **Unknown** [Safety has not been determined.]

20. Safety descriptions [Please provide a general description of the known safety of the technology, e.g. list possible complications and known complication rates and adverse events.]

EVIDENCE OF EFFECTIVENESS

21. Summary of clinical effectiveness

[Please summarize the relevant literature of clinical effectiveness of the proposed technology.]

22. Evidence for clinical effectiveness

[Give the best FIVE references for evidence of clinical effectiveness. For each, give the title and authors, the source and the level of evidence (Levels I-V as defined in **Appendix B**).

1	Reference: Source: <input type="checkbox"/> Medical Literature <input type="checkbox"/> Manufacturer <input type="checkbox"/> HTA Report Level of Evidence: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Unknown
2	Reference: Source: <input type="checkbox"/> Medical Literature <input type="checkbox"/> Manufacturer <input type="checkbox"/> HTA Report Level of Evidence: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Unknown
3	Reference: Source: <input type="checkbox"/> Medical Literature <input type="checkbox"/> Manufacturer <input type="checkbox"/> HTA Report Level of Evidence: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Unknown
4	Reference: Source: <input type="checkbox"/> Medical Literature <input type="checkbox"/> Manufacturer <input type="checkbox"/> HTA Report Level of Evidence: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Unknown
5	Reference: Source: <input type="checkbox"/> Medical Literature <input type="checkbox"/> Manufacturer <input type="checkbox"/> HTA Report Level of Evidence: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Unknown

23. **Outcome measures** [Describe what outcomes will be measured, if applicable.]

APPLICANT SIGNATURE: _____

PRINT NAME: _____ **DATE:** _____

Submit completed “**Part A: Technology Request Form**” to the Local HTA Coordinators by e-mail Kathy.Cassidy@calgaryhealthregion.ca or interoffice mail to Room 910 North Tower FMC.

PART B: LOCAL HTA RESOURCE IMPACT INFORMATION

To be completed by Clinical Director or Designate

1. **Will the technology impact resources or infrastructure?**
 Yes No

2. **Technical requirements and impact.**
[Please describe the practical requirements and impact of the proposed new technology such as space, equipment, regulatory restrictions, compatibility with existing equipment, and maintenance or cleaning routines, e.g., Scope Cleaning]

3. **Will this Technology “fit” with existing technologies:**
 Yes No Unknown

INFRASTRUCTURE COST

4. **Engineering Cost** [estimate engineering cost]
Completed by appropriate individual (or e-mailed)
Name: Manager, Clinical Engineering at affected site

5. **Planning Cost** [estimate planning cost]
Completed by appropriate individual (or e-mailed)
Name: Manager, Planning at affected site

6. **Maintenance Cost** [estimate maintenance cost]
Completed by appropriate individual (or e-mailed)
Name: Manager, Facilities at affected site

7. **Capital Cost** [estimate capital cost]
Completed by appropriate individual (or e-mailed)
Name: Manager, Purchasing Department

CLINICAL DIRECTOR/DESIGNATE SIGNATURE: _____

PRINT NAME: _____ **DATE :** _____

Submit completed “**Part B: Local HTA Resource Impact Information**” to the Local HTA Coordinators by e-mail Kathy.Cassidy@calgaryhealthregion.ca or interoffice mail to Room 910 North Tower FMC.

PART C: TECHNOLOGY REQUEST SUPPORT

To be Submitted to Division Head by Local HTA Coordinators

The designated CONTENT EXPERT (Division Head, designate or sub-committee of expert(s)) will review “Part A: Technology Request”, gather input (formal or informal) from other experts (internal such as division members or external) about this technology and support/not support the “Request”.

Support by the CONTENT EXPERT indicates that the majority of members agree that the requested technology:

- will improve patient care in the Calgary Health Region

1. CONTENT EXPERT support of Technology Request: [check ONE]

a. **NOT Supported.**

Do not proceed with remainder of application.

Please provide reasons for decision and return request to applicant.

b. **Supported.**

Please provide reasons for decision.

c. **Comments** [If there is anything that needs to be brought to the attention of the review committee that has not yet been addressed, please provide any additional comments on the request particularly in relation to the safety, effectiveness and potential innovation of the proposed technology].

CONTENT EXPERT SIGNATURE: _____
(designate or sub-committee chair)

PRINT NAME: _____ **DATE:** _____

Submit to the Local HTA Coordinators by e-mail Kathy.Cassidy@calgaryhealthregion.ca or interoffice mail to Room 910 North Tower FMC.

PART D: TECHNOLOGY REQUEST CHECK

To be Submitted to Contracts/Purchasing by Local HTA Coordinators

Contract/Purchasing Representative will determine:

- if there are any legal or contractual issues with this **Technology Request**
- if there are cost concerns
- whether a **Request For Proposal** (RFP) is required
- if the **Technology Request** information is sufficient (e.g. change of vendor)

If the Contract/Costing expert feels that further information is required, then the expert may recommend that the **Technology Request** be forwarded to the **Local HTA Advisory Committee** for possible Local HTA (See **Appendix A** guide).

1. **Are there any legal or contractual, issues with this request?**
 Yes No
2. **Are there significant cost concerns with this request?**
 Yes No
3. **Is the item or a similar item already on purchase contract?**
 Yes No
4. **Does the item require a Request For Proposal (RFP)?**
 Yes No

5. Comments

If anything needs to be brought to the attention of the Local HTA Coordinators that has not yet been addressed, please provide any additional information particularly in relation to the safety, effectiveness and potential innovation of the proposed technology.

CONTRACTS/PURCHAING SIGNATURE: _____

PRINT NAME: _____ **DATE:** _____

Submit to the Local HTA Coordinators by e-mail Kathy.Cassidy@calgaryhealthregion.ca or interoffice mail to Room 910 North Tower FMC.

PART E: LOCAL HTA CHECK

To be completed Local HTA Coordinators

The Local HTA Coordinators will check if a Local HTA process is required [Possible clinical and/or resources allocation impact – (see **Appendix A** guide)].

1. Which type of technology review is required?
 - a. **Technology Request is Approved** [Local HTA is NOT required; Technology Request information is sufficient.]
 - b. **EXPEDITED Local HTA is recommended** [The Local HTA Coordinators will review the *Technology Request* and may gather further information.]
 - c. **Further information required**

LOCAL HTA COORDINATORS SIGNATURE: _____

PRINT NAME: _____ DATE: _____

Submit to MSEC if required for final approval.

PART F: MSEC DECISION

To be completed by MSEC Committee

1. Decision of the Department Executive Committee

- Not approved**
- Approved** [No need for further assessment]
- Restricted approval - Audit**
[Approved under Audit conditions when not enough data are known. Conditions may relate to testing in a specific number of patients or may require minimum hours of surgeon's training.]
- Restricted approval – Clinical Trial**
[Approved as a Clinical Trial. Clinical and health research policies shall apply.]
- Request full HTA**
[A full HTA will be requested from federal or provincial HTA agencies]
- Request submission of new technology in region capital equipment list.**
[Technology is approved in principal, but is outside the Department budget.]

2. Conditions of approval [Describe conditions of approval. For example, how many cases are allowed, Timeline and conditions of annual update to Executive Committee.]

3. Comments

AUTHORIZING SIGNATURE: _____

PRINT NAME: _____ **DATE :** _____

Submit to the Local HTA Coordinators by e-mail Kathy.Cassidy@calgaryhealthregion.ca or interoffice mail to Room 910 North Tower FMC.

APPENDIX A: WHEN IS A LOCAL HTA REQUIRED? GUIDELINES

There are two main pathways for technology assessment:

1. Technology Request pathway

This pathway is used when the proposed technology is a small change of current practice (i.e. change of vendor, small upgrade of existing technology, etc). The major basic criteria to look for in this category are to ensure that clinical safety is clearly demonstrated and that the technology is affordable.

2. Local Health Technology Assessment (Local HTA) pathway

This pathway is used when there are significant uncertainties about the technologies. If any answers fall within **column 1**, then a Local HTA is likely required.

Guidelines		
Is this technology a change from current practice? If so, answer the following questions (some questions may not be applicable):		
Patient Impact Questions:	Column 1	Column 2
1. Has the clinical safety of this technology been clearly demonstrated?	No	Yes
2. Has the positive impact of this technology on patients been well described in scientific literature?	No	Yes
3. Has this technology been widely adopted elsewhere?	No	Yes
4. Is the quality of the technology (such as component materials) the same or better as that currently used?	No	Yes
Health Care Provider Impact Questions:		
5. Are other providers in the CHR also in agreement about adopting the technology?	No	Yes
6. Will the technology require new training for any health care staff?	Yes	No
7. Does the operation of the technology require certification or significant practice time?	Yes	No
Resources Impact Questions:		
8. Is the technology compatible with existing infrastructure?	No	Yes
9. Does the technology require new maintenance routines?	Yes	No
10. Does the technology require new cleaning routines?	Yes	No
Cost Impact Questions:		
11. Does the technology fit within the existing budget?	No	Yes
12. Will information regarding costing in other areas of health care be needed to determine whether the technology will or will not impact budget?	Yes	No

APPENDIX B: LEVELS OF EVIDENCE

Levels of Evidence for Primary Research Question ¹				
	Types of Studies			
	Therapeutic Studies— Investigating the Results of Treatment	Prognostic Studies— Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies— Investigating a Diagnostic Test	Economic and Decision Analyses— Developing an Economic or Decision Model
Level I	<ul style="list-style-type: none"> • High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review² of Level-I randomized controlled trials (and study results were homogeneous³) 	<ul style="list-style-type: none"> • High-quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review² of Level-I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference "gold" standard) • Systematic review² of Level-I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; multiway sensitivity analyses • Systematic review² of Level-I studies
Level II	<ul style="list-style-type: none"> • Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective⁴ comparative study⁵ • Systematic review² of Level-II studies or Level-I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective⁶ study • Untreated controls from a randomized controlled trial • Lesser-quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review² of Level-II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on basis of consecutive patients (with universally applied reference "gold" standard) • Systematic review² of Level-II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; multiway sensitivity analyses • Systematic review² of Level-II studies
Level III	<ul style="list-style-type: none"> • Case-control study⁷ • Retrospective⁶ comparative study⁵ • Systematic review² of Level-III studies 	<ul style="list-style-type: none"> • Case-control study⁷ 	<ul style="list-style-type: none"> • Study of nonconsecutive patients (without consistently applied reference "gold" standard) • Systematic review² of Level-III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; poor estimates • Systematic review² of Level-III studies
Level IV	Case series ⁸	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • No sensitivity analyses
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

1. A complete assessment of the quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g., with cemented hip arthroplasty) compared with patients treated another way (e.g., with cementless hip arthroplasty) at the same institution.
6. Study was started after the first patient enrolled.
7. Patients identified for the study on the basis of their outcome (e.g., failed total hip arthroplasty), called "cases," are compared with those who did not have the outcome (e.g., had a successful total hip arthroplasty), called "controls."
8. Patients treated one way with no comparison group of patients treated another way.

This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please see www.cebm.net.