Procedure for Adding New Laboratory Tests to the Provincial Laboratory Formulary

Issued by:

Provincial Laboratory Formulary Advisory Council

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1.0 Overview and Purpose

1.1 The purpose of this policy and procedure is to describe the process for the addition of new and previously unfunded tests to the Provincial Laboratory Formulary (PLF).

2.0 Policy Statements

2.1 The Provincial Laboratory Formulary Advisory Council (PLFAC) uses an application process to assist with decision making activities for the addition of new not previously funded tests to the PLF.

2.2 All decisions for addition of new not previously funded laboratory tests to the PLF must receive endorsement from the Department of Health and Community Services (HCS) before final approval.

3.0 Scope

3.1 This policy and procedure applies to new, emerging and infrequently ordered, and not currently funded tests.

3.2 This policy does not apply to tests already on in-house laboratory test menus, available for ordering on laboratory information systems for referred out-of-province testing, and listed in the PLF.

4.0 Responsibility

4.1 PLFAC Committee Members – Reviews new PLF item requests and makes recommendations concerning whether these should be included in the new PLF.

4.2 Laboratory Services Advisory Group (LSAG) - Reviews new PLF item requests and makes recommendations as to which sites the items will be available or if the tests will be referred out of province.

4.3 PLFAC database maintenance working group – prepares documentation for new test entries reviewed by the PLFAC.

4.4 Stakeholders – review PLFAC approved PLF items and provides feedback for the decision making process.

4.5 HCS – will review and decide on new PLF items submitted for approval and funding.

5.0 Procedure

Step 1: All requests for new PLF item additions undergo an application process.
This process includes:

- Completion of the *Application Form for Additions and Modifications to the Provincial Laboratory Formulary*.

- Attachment of references to evidence-based and supporting documentation from:
  - peer-reviewed literature;
  - clinical practice guidelines;
  - standards of practice;
  - diagnostic decision trees;
  - and letters of support.

The completed application is submitted to the PLFAC Co-Chairs by email or fax for preliminary screening.

Step 2: Review of Submission

- On receipt, all applications *are* reviewed by a Chair or designate; to ensure all necessary application components are completed or provided.
- If the submitted application information is incomplete, a Chair, or designate will notify the applicant, in writing, of application deficiencies, including missing documentation. If the additional information is not received within one month of notice, the application will be archived, and a new submission will be required.
- Once the submission package is complete, a Chair or designate will distribute the application package via email to the PLFAC members for review. In addition, a Chair will assign one member of the PLFAC to oversee this new PLF item request.
- The PLFAC members will meet either at the next scheduled PLFAC meeting or a Chair will call a special meeting to review the application. The PLFAC member assigned to this new PLF item request will provide a brief presentation at the meeting and lead following discussion.
- The decision making framework for the addition of new items to the laboratory PLF includes consideration of the following criteria:
  - Clinical Significance/Relevance of New Item. The PLFAC members and identified stakeholders must review the clinical significance/relevance of the new item. Clinical practice guidelines, national standards, and evidence-based literature accompanying the application form will be reviewed. Consultation with stakeholders with pertinent clinical and technical expertise will occur to gain relevant insight.
  - Cost Assessment of New Item. The PLFAC members must review the associated cost for the development and implementing of new not previously funded PLF items.
  - Potential impacts on other tests and services. The PLFAC members must review the impacts of the new test entry on other tests and services to determine other necessary PLF changes.
- The PLFAC members must determine if the new test item will replace or impact other items currently in use within the PLF. If the new item will replace or impact

a current PLF item the cost assessment must be compared to the cost of the current item to determine financial implications.

- Any new items requiring new or additional funding must indicate the proposed source of the funding on the *Application Form for Additions and Modifications to the Provincial Laboratory Formulary*. If funding for the new item is not available through existing budgets, a formal submission must be made to HCS for approval of the new test and for funding.

Step 4: PLFAC Decision

- PLFAC decisions will normally be achieved through consensus. If consensus cannot be reached, decisions will be made through majority vote. Majority vote is defined as 75% of the members present at the time an item is tabled for decision. Five members plus the chair of PLFAC shall constitute a quorum.
- For non-approved tests a PLF entry will be prepared, by the PLFAC database maintenance working group, but indicating that the test is not available for ordering. This entry will contain the date of completion of the last review and decision. The PLF entry will contain:
    - Test Name
    - Aliases
    - LOINC Test Code (*if available*)
    - Tier *("Tier 4-Non-formulary test (Test not available*)")
    - Description and Primary Use (*Short statement indicating why test is not approved*)
    - Ordering Requirements (*Statement indicating that test is not available*)
    - Date added (*Date of entry*)
    - Last updated (*Date of last review*)
- For approved tests a PLF entry will be prepared, by the PLFAC database maintenance working group, and based on the accepted format. This entry will contain the date of completion of the last review and decision (see further details below).

Step 5: Submission to HCS

- All decisions on requests will be submitted to the Deputy Minister of HCS through the Provincial Director of Clinical Laboratory Services for endorsement and decision on funding.

Step 6: Location for Implementation of New Items

- Following notice of endorsement from HCS, the PLFAC, in cooperation with LSAG will define the locations where the new PLF test will be performed. Consideration will be given to approved budget and costs related to implementation of the new PLF item.

Step 7: Access to New Item

- For approved new items, the PLFAC database maintenance-working group will develop recommendations for this new PLF entry and is responsible for creating the guidelines and policies for how this test will be implemented. The three W's must be addressed:
    - WHO – Define what care groups require access to the new PLF item.
    - WHEN – Define ordering guidelines, special authorization or other ordering requirements.
    - WHERE – Define locations where the new items can be ordered.
- Once completed, guidelines and policies will be submitted to the PLFAC for review. Details regarding the technical specifics, test cost, site(s) where test will be developed and performed and how tests will be funded for development and clinical use should be included.
- The completed test information prepared by PLFAC database maintenance working group must include:

    a. Test Name
    b. Aliases
    c. Provincial Mnemonic
    d. LOINC Test Code
    e. Description and Primary Use
    f. Reorder interval
    g. TAT
    h. Test Cost
    i. Tier
    j. Ordering Requirements (Restrictions and Conditions)
    k. Required Consultations
    l. Algorithms and guidelines
    m. Special Patient Preparation
    n. Special Collection/Transport/Processing Requirements
    o. Criterial for rejection of test order
    p. Laboratory Service Area
    q. Performing Laboratory/Site
    r. Date added
    s. Last updated

- The PLFAC database maintenance-working group will submit completed test information documents to a PLFAC Chair or designate who will circulate to the PLFAC members via email for completion.
- PLFAC reviews the PLFAC database maintenance working group documentation at next scheduled meeting. Decisions from the follow-up review include: granting of approval for entry, or issuing a request for additional work/information to complete an acceptable entry into the PLF. If additional work is required,

documents will be circulated back and forth between the PLFAC and the PLFAC database maintenance-working group until approval of the PLF entry is given.

Step 8: Timelines for implementation of approved PLF items.

- Timelines from processing to implementation of requests will vary based on complexity of the new service but will be estimated in consultation with LSAG following endorsement of decisions by HCS.

Step 9: Dissemination on information on new PLF decisions:

- Information on new PLF decisions will be made based on the procedure on: *Procedure for Dissemination of Provincial Laboratory Formulary Amendments to Stakeholders*

6.0 Related Documents

6.1 *Procedure for Dissemination of Provincial Laboratory Formulary Amendments to Stakeholders*

6.2 *Application Form for Additions and Modifications to the Provincial Laboratory Formulary*

6.3 *Terms of Reference for the Provincial Laboratory Formulary Advisory Council*

6.4 *Terms of Reference for the Provincial Laboratory Formulary Advisory Council – Database Maintenance Working Group*

7.0 Definitions and Acronyms:

- **PLFAC – Provincial Laboratory Formulary Advisory Council :** A provincial committee of the Newfoundland and Labrador HCS Laboratory Reform Initiative. The PLFAC assists and advises on laboratory test utilization and development of a PLF.
- **HCS - Department of Health And Community Services**
- **IT - Information Technology**
- **LOINC – Logical Observation Identifiers Names and Codes**: A set of universal identifiers to standardize description of medical laboratory data.
- **PLFAC-database maintenance working group** -: A laboratory specialty sub-group of PLFAC tasked with preparing information for updating of the PLF.
- **LSAG - Laboratory Services Advisory Group**
- **PLF – Provincial Laboratory Formulary:** Continuously updated list of funded laboratory tests and related information that can be ordered by physicians.
- **TAT – Turnaround time**