Procedure for Regular Review and Amendment of 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 is to define the process for regular review of the Provincial Laboratory Formulary (PLF) and updating the PLF when changes are made, including the removal of outdated or redundant tests.

1.2 The overall objectives of PLF review are to:

1.2.1 Ensure that the tests in the PLF meet the needs for current standards of practice and clinical requirements;

1.2.2 Ensure redundant or outdated tests cannot be ordered;

1.2.3 Maintain control on test costs compared to clinical usefulness;

1.2.4 Direct clinicians toward ordering the most effective and appropriate tests for their patients;

1.2.5 Enhance responsibility and accountability in the test use process; and

1.2.6 Remove tests that are no longer considered useful based on standards of practice and evidence.

2.0 Policy Statements

2.1 The PLF laboratory test review is conducted on a yearly basis and organized by the Provincial Laboratory Formulary Advisory Council (PLFAC). Smaller test specific reviews will occur at greater frequency when new information becomes available on a test that requires immediate attention. Outdated and redundant tests will be identified by the PLFAC through the PLF review process. Other formal requests for changes to the PLF will also be considered during the review process.

2.2 Any changes to the PLF must go through a review process with appropriate evidence provided as to why change is necessary. The process may result in deletion of redundant or outdated tests. As part of the change process, stakeholders will be involved for review and comment prior to finalizing the change. Final approval for change will be given by PLFAC.

2.3 Once approved changes in the formulary list are completed, all stakeholders must be informed of the changes.

3.0 Scope

3.1 The annual PLF review will involve all orderable test entries.

4.0 Responsibility

4.1 PLFAC:

4.1.1 Ensures that test(s) identified for deletion is thoroughly reviewed before action is taken.

4.1.2 Ensures that, if a test is removed from the PLF, there is another test in the PLF that provides the same or similar results, when required.

4.1.3 Ensures laboratory tests in the PLF are the most cost-effective and safe tests available.

4.1.4 Ensures information on formulary listed tests are kept up to date.

4.1.5 Ensure review process is completed yearly or when new information becomes available requiring immediate action.

4.1.6 Obtain feedback from stakeholders when changes are required.

4.1.7 Implements changes and inform clinical staff when changes will take place.

4.1.8 Notifies Laboratory Services Advisory Group (LSAG).

4.2 PLFAC database maintenance working group:

4.2.1 Conducts a preliminary review of assigned tests and identifies any changes required to the PLF.

4.2.2 Appoints PLFAC database maintenance working group member to gather information and conduct intensive test reviews in content for the laboratory medicine sub-discipline.

4.2.3 Provides recommendations to PLFAC on changes to the PLF database

4.3 Stakeholders:

4.3.1 Reviews PLF items approved by the PLFAC and provides feedback.

4.3.2 Provides documentation/information relevant to decision making on PLF test status.

5.0 Procedure

5.1 The PLFAC database maintenance working group organizes an initial assessment of the PLF test list by a laboratory medicine specialist in order to determine tests requiring intensive review, and giving an initial 30 day

timeline for response. This initial review will involve an assessment to determine if any of the following criteria are still met for tests:

5.1.1 There are still clear clinical indications for testing**.**

5.1.2 The test result is required for patient management decisions.

5.1.3 The test fills a unique clinical niche not filled by less costly and/or more effective investigations.

5.1.4 The test provides the most cost-effective alternative available.

5.1.5 The test is available from accredited clinical laboratories and validated for clinical and non-research use.

5.2 Tests failing to meet one or more of the above will be communicated back to PLFAC and selected for more intensive review.

5.3 The co-chair of the PLFAC will compile a finalized list of tests requiring intensive review and direct back to the PLFAC database maintenance working group, which will assign specific members responsibility for gathering documentation on each test requiring further assessment. Consultation with other stakeholders will occur, as needed, at this phase and at the discretion of the PLFAC database maintenance working group. The information required to conduct a more intensive review will include, but will not be limited to, the following:

5.3.1 Identity of test requiring intensive review.

5.3.2 Information on availability of new or other tests providing benefit in the same clinical context.

5.3.3 The relative value of the test compared to other alternatives based on cost and diagnostic performance.

5.3.4 The frequency of test use.

5.3.5 Information on whether test is used appropriately on not.

5.3.6 Information on ordering frequency.

5.3.7 Information on changes in test availability, methodology and/or cost.

5.3.8 Information on new use or change in usefulness of the test. Information on change in standards of practice or new clinical requirements.

5.4 Following the intensive review, the database maintenance working group will provide a written recommendation to PLFAC on any other proposed changes.

5.5 The chair of the PLFAC database maintenance working group will present recommendations and any proposed changes to PLFAC for final decision. Recommendations by the formulary committee may include, but is not limited to, the following:

5.5.1 Removing or adding a test to the formulary;

5.5.2 Modification of test information and requirements in the formulary;

5.5.3 Restricting tests to specialized physicians;

5.5.4 Developing special order forms for specific tests; and

5.5.5 Informing physicians and staff on certain tests and when they should be ordered.

5.6 Proposed PLF changes accepted by PLFAC are communicated to stakeholders and giving 60 days to provide feedback on the proposed changes.

5.7 PLFAC reviews all feedback provided by stakeholders.

5.7.1 If no modifications to the proposal are warranted, communication of formulary update is issued with a minimum of 30 day notice of the impending change.

5.7.2 If further modification is required PLFAC will inform the database maintenance working group with the received critique and documentation for continued review and for further refinement of recommendations.

5.8 Finalized recommendations are reviewed by the PLFAC committee for approval.

5.9 Approved changes are accompanied by formal notification to stakeholders.

5.9.1 For tests approved for deletion:

5.9.1.1 Make changes to the formulary to indicate that the test is considered redundant and un-orderable.

5.9.1.2 Communicate changes to the LSAG so steps can be taken to ensure test is no longer orderable in the Laboratory Information System (LIS).

5.9.1.3 Remove test from any requisitions used for ordering the test.

5.9.1.4 If required, add the replacement test to the PLF (see procedure on adding new tests to the formulary).

5.10 Follow procedure *PLFAC Procedure for Dissemination of Provincial Laboratory Formulary Amendments to Stakeholders* to educate the clinical staff and the laboratory on any changes made to the formulary; the reasons as to why the changes were made; if there are replacement tests added to the formulary; and any other pertinent information concerning test changes.

6.0 Procedural Notes

Documentation reviewed and submitted for PLF change must clearly demonstrate the advantage of implementing the change which includes, but is not limited to:

- Improved effectiveness;
- enhanced safety;
- reduced potential for over-utilization; and/or
- Increased cost effectiveness.

7.0 Supporting Documents

7.1 *Manual for the Development and Maintenance of Hospital Drug Formularies*; Rational Pharmaceutical Management Project; April 1996.

7.2 *Lab Formularies: The Time is Now*; AACC Clinical Laboratory News; February 2015.

7.3 *Formulary Evaluation Using a Class Review Approach*; P & T Journal for Managed Care and Hospital Formulary Management; April 2013.

7.4 *Formulary*; Saskatchewan Ministry of Health Drug Plan; Sixty first Edition; October 2011-March 2012.

7.5 *Development and Maintenance of Hospital Drug Formularies*; Rational Pharmaceutical Management Project; April 1996.

8.0 Related Documents

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

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

8.3 *Procedure for Adding New Laboratory Tests to the Provincial Laboratory Formulary*

8.4 *Terms of Reference of the Provincial Laboratory Formulary Advisory Council-Database Maintenance Working Group*

9.0 Definitions and Acronyms:

- **PLFAC – Provincial Laboratory Formulary Advisory Council:** A provincial sub-committee of the Newfoundland and Labrador DHCS Laboratory Reform Team. The PLFAC assists and advises on laboratory test utilization and development of a lab test formulary.
- **PLF – Provincial Laboratory Formulary:** Continuously updated list of laboratory tests and related information that can be ordered by physicians to be performed in your lab, other labs in your system, or reference laboratories.
- **Stakeholders:** Physicians, Nurse Practitioners and others with test ordering privileges or others representing groups directly impacted.
- **LIS** - Laboratory Information System
- **LSAG** - Laboratory Services Advisory Group