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Out of Province/Out of Country Laboratory and Genetic Testing Policy and Guidelines

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MINISTRY OF HEALTH AND PROVINCIAL HEALTH SERVICES AUTHORITY

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Introduction

The *Out of Province/Out of Country Laboratory and Genetic Testing Policies and Guidelines* are intended to guide the work of Provincial Health Services Authority (PHSA) by describing the criteria and processes used when considering public funding for out of province/out of country (OOP/OOC) laboratory and genetic testing.

Authority

Under authority of the *Laboratory Services Act* (the Act) and Regulations (the Regulation) the Minister of Health (the Minister) is responsible for the administration and provision of insured laboratory services to British Columbians.

On June 1, 2018, the Minister delegated the powers, duties, and functions of the Minister to PHSA for the OOP/OOC program for laboratory and genetic testing:

(a) Under section 7 of the *Laboratory Services Act*, and section 18.1 of the Laboratory Services Regulation, B.C. Reg. 52/2015
(b) As those provisions relate to the receipt, assessment, and approval of applications for elective, non-emergency laboratory services that are provided outside British Columbia

Program Overview

In special cases, ordering physicians require specialized laboratory and/or genetic testing that is not performed by BC laboratories and must be performed elsewhere. PHSA received the responsibility to consider, and where appropriate, approve funding for laboratory and genetic services, as well as to provide advice and assistance to the Ministry of Health (the Ministry) related to the funding and provision of the laboratory and genetic testing services performed outside BC.

PHSA assesses funding requests submitted by ordering physicians on behalf of their BC patients for medically necessary laboratory and/or genetic testing services that are not performed in BC. Under the *Laboratory Services Act* and its Regulation, if a beneficiary requires a laboratory service to be performed outside BC because it is not available within BC, the beneficiary may apply for public funding prior to sending the sample to the performing laboratory located elsewhere in Canada or internationally.

Roles and Responsibilities

PHSA is responsible for assessing the funding requests submitted by ordering physicians, performing assessments, communicating funding decisions, and managing the payment process when laboratory specimens are sent to laboratories outside BC. In addition, under its mandate to develop an integrated provincial laboratory system, PHSA may also make recommendations for future laboratory and genetic service delivery based on OOP/OOC utilization. PHSA provides additional information relating to coverage decisions, client communication, and administrative support as needed.

The Ministry oversees the OOP/OOC laboratory and genetic testing program (OOP/OOC program), reviews policy as required, and works jointly with PHSA to manage utilization/resources, improve service and program delivery.

Funding Approval Process

For each funding request, the OOP/OOC program conducts an assessment to determine whether the test should be publicly funded and identifies the most appropriate testing facility to bring the maximum value from a perspective of quality, timeliness, and cost. The OOP/OOC program then issues a letter of decision which may a) authorize the sample to be tested outside of BC, and the performing laboratory to receive payment through the OOP/OOC program, or b) deny public funding. It is important to note, however, denial of public funding from the OOP/OOC program based on the established assessment process does not prevent ordering physicians from acquiring the tests through a different payment mechanism (e.g., patient-pay through private laboratories).

Background and Historical Context of the OOP/OOC Program: Medical Services Commission OOP/OOC Medical Care Guidelines

The *Medical Services Commission OOP/OOC Medical Care Guidelines* provide guidance for medically necessary care obtained by a Medical Services Plan (MSP) beneficiary OOP and/or OOC. These guidelines are under the authority of the Medical Services Commission (MSC), in accordance with the *Medicare Protection Act* (MPA), the Health Care Services Regulation, the *Hospital Insurance Act,* and the Hospital Insurance Act Regulations. The OOP/OOC laboratory and genetic testing program was originally administered through the MSC, and therefore followed these guidelines. However, due to the large volume of requests and the specialized nature of the laboratory and genetic testing requests of the OOP/OOC laboratory and genetic testing program, it was delegated to PHSA on June 1, 2018 (as outlined above in the Authority section).

Consequently, these *OOP/OOC Laboratory and Genetic Testing Policies and Guidelines* are now the designated guidelines for the OOP/OOC program. They have been written to reflect the guidance provided in the *Medical Services Commission OOP/OOC Medical Care Guidelines*, and to provide additional clarity on the criteria for OOP/OOC laboratory services and genetic testing, including the application process and assessment of applications.

Definitions

The following terms are used throughout the Policies and Guidelines.

Access and **accessibility** means or refers to a beneficiary's ability to secure access, within a reasonable period of time, to medically required laboratory services that are benefits under MSP.

Application means the request for approval of public funding prior to the procurement of diagnostic laboratory and/or genetic tests that are performed outside BC.

Approval means that the PHSA OOP/OOC program has performed an assessment of the submitted application and has approved public funding prior to the samples being sent to laboratories outside BC.

Beneficiary means a person enrolled as a beneficiary under the *Medicare Protection Act.*

Benefits are laboratory services that are a benefit under section 4 *[what are benefits]*, of the *Laboratory Services Act.*

Genetic test is a laboratory test performed on genetic material such as chromosomes, genes, or DNA.

Foreign disclosure laws means any laws, statutes, by-laws, treaty, directive, policy having force of law, order, judgement, injunction, award, decree or other similar matter of any government, legislature (or similar body), court, governmental department, commission, board, bureau, agency, instrumentality, province, state, territory, association, county, municipality, city, town, or other political or governmental jurisdiction, whether not or in the future constituted, outside of Canada, that may require, request, or otherwise demand access, use or disclosure of personal information, whether to intercept or obstruct terrorism, or for any other reason.

Informed consent in the context of this document and the OOP/OOC program is outlined in policy 3.1.

Laboratory means the area of the hospital or out-patient facility that provides laboratory services.

a) **Referring laboratory** means the laboratory that collects the specimen and refers it to the performing laboratory for testing.
b) **Performing laboratory,** also known as a referral laboratory, is the laboratory identified to perform the approved laboratory or genetic test.

Laboratory service, subject to the Laboratory Services Regulation means

a) the taking or collecting, or the analysis, of specimens for the purpose of preventing, diagnosing, or treating human injury, disease, or illness, or
b) a prescribed service.

Medical consultation note is part of the patient's medical record that supports the funding application.

MSP is the acronym for *Medical Services Plan,* BC's public health insurance which covers the cost of medically necessary insured medical and laboratory services.

OOP/OOC is the acronym for *out of province/out of country*.

OOP/OOC program is the shortened form for the *Out of Province/Out of Country Laboratory and Genetic Testing Program.*

Ordering physician means the physician who has direct contact with, and is responsible for the patient, and is making the funding request for OOP/OOC laboratory and/or genetic services.

Personal information means recorded information about an identifiable individual other than contact information (**see:** The *Freedom of Information and Protection of Privacy Act)*.

PHN is the acronym for *Personal Health Number.*

Part 1 - Guiding Principles and Process

POLICY 1.1 – Program Principles and Objectives

PURPOSE

To articulate the principles that guide the work of PHSA in administering the OOP/OOC program.

POLICY

OOP/OOC program personnel perform their duties and functions with transparency, fairness, consistency, and timeliness.

PHSA, in exercising its delegated powers, operates in accordance with and advances the intentions of the *Laboratory Services Act.*

The OOP/OOC program will:

a) assess every case on its own merits,
b) make established policies and guidelines transparent,
c) make the consideration processes and funding decisions transparent,
d) scrutinize applications to ensure requests are valid,
e) explain why an application is denied, and
f) provide opportunity for appeal or reapplication.

GUIDELINE

The OOP/OOC Program may:

a) liaise with ordering physicians and performing laboratories as needed during the performance of duties.

POLICY 1.2 – Policy Review and Approval Process

PURPOSE

To articulate how new and revised polices will be drafted.

POLICY

Policy review timelines

OOP/OOC Program policy will be updated on a regular basis. The Ministry of Health and PHSA will review the Out of Province/Out of Country Laboratory and Genetic Testing Policy and Guidelines:

a) yearly, as of date of implementation September 1, 2021, and
b) as needed, to ensure OOP/OOC program improvement and functionality.

All changes to policy will be communicated on the PHSA OOP/OOC Program Website.

Part 2 - Applications for Funding Approval

POLICY 2.1 – Requirements for Application

PURPOSE

To articulate that OOP/OOC funding requires an application to be submitted, and approval provided, prior to the test being procured. Applications are subject to clinical review by the OOP/OOC program and must be medically necessary.

POLICY

When laboratory services, including genetic tests, are required for patient care and the service and/or test is not performed in a BC laboratory, ordering physicians may apply to the OOP/OOC program for funding, if the requested services **meet all of the below criteria**:

a) are medically necessary,
b) results would create a new medical treatment plan, and
c) results would significantly alter current medical treatment for the patient.

LIMITATIONS/EXCEPTIONS

The OOP/OOC program does not fund tests that meet any of the below criteria:

a) are not standard of care and cannot influence patient care or management,
b) do not significantly alter the management of the beneficiary's medical condition,
c) are experimental or developmental where the efficacy of the test is unknown,
d) are insured benefits in BC (OOP/OOC program will provide a list of insured benefits upon request),
e) are ordered on a person who is not an MSP beneficiary and/or is not eligible for MSP coverage,
f) meet the limitations/exceptions for genetic testing outlined in policy 4.3,
g) is available in an accredited laboratory in BC,
h) can be, or has been, performed in another Canadian province or territory on an MSP-covered BC resident and covered under interprovincial reciprocal agreements,
i) is funded as an inpatient hospital service under a regional or provincial program budget,
j) is funded or available as an inpatient or outpatient service through other provincial agencies or program budget, or
k) beneficiaries who are out of province and receive medical care outside of BC that includes laboratory services, without prior approval through the OOP/OOC program.

POLICY 2.2 – MSP Eligibility Requirement

PURPOSE

To articulate the requirement of being an MSP beneficiary, to be eligible and approved for the OOP/OOC program.

POLICY

The OOP/OOC program is responsible for approving funding only for patients who are beneficiaries under MSP. The beneficiary must be eligible for MSP benefits on the date of service (when the test is performed) in addition to the date the funding request is processed.

A PHN eligibility check will be performed at the time of funding approval and retrospectively when the invoice for the service is received.

LIMITATIONS/EXCEPTIONS

The OOP/OOC program does not cover patients who are not beneficiaries of MSP. For example, those who are insured under different plans or federal programs, such as:

a) Interim Federal Health Program recipients who are not beneficiaries of MSP,
b) Canadian Armed Forces (medical coverage for military personnel), or
c) Public Service Health Care Plan (eligible dependants of RCMP and Canadian Armed Forces) who are not beneficiaries of MSP.

GUIDELINE

Genetic Testing of Non-Beneficiaries

The OOP/OOC program may provide funding for genetic testing of non-beneficiaries when the non-beneficiary is a family member of the beneficiary, and family member genetic testing is a prerequisite for understanding the beneficiary's genetic test. In this circumstance, it is the beneficiary who is approved for OOP/OOC funding.

POLICY 2.3 – Ordering Physicians Eligible to Apply

PURPOSE

To articulate who may submit an application for OOP/OOC program funding.

POLICY

In order to apply for OOP/OOC funding, the ordering physician must meet all of the below criteria:

a) an active registrant of the BC College of Physicians and Surgeons,
b) entitled to practice in BC,
c) assigned a BC Ministry of Health MSP billing code,
d) working in a position that is delivering medical care to BC patients insured for benefits, and
e) practicing in a specialty that is relevant to the request.

GUIDELINE:

Physician Expertise

The OOP/OOC program may consider the ordering physician's area of expertise during the evaluation of the funding request to determine whether the ordering physician has the suitable knowledge base to deal with the test results or provide appropriate counselling for the results obtained.

POLICY 2.4 – Requests for Retroactive Reimbursement

PURPOSE

To articulate responsibility for payment for unapproved testing.

POLICY

a) if authorization is not provided before the sample is collected and submitted for testing it is ineligible for funding approval,
b) if testing is performed by a laboratory outside BC without authorization, the ordering physician is responsible for payment to the performing laboratory, and
c) ordering physicians and performing laboratories are unable to pursue retroactive payment from the OOP/OOC program.

POLICY 2.5 – Required Information

PURPOSE

To articulate the information required in an application for OOP/OOC program funding.

POLICY

Complete Applications

It is the responsibility of the ordering physician to submit the appropriate application and supplemental documentation (if applicable) through the established OOP/OOC program intake process to support the application review.

Only complete applications will be reviewed by the OOP/OOC program. Incomplete applications will be rejected, and a letter will be issued to the ordering physician. Completed resubmissions will be considered without prejudice.

Required Information for the Application

The following information is required in a complete and legible format:

a) Patient information:
    i. Surname, first name, valid BC Personal Health Number (PHN), date of birth
    ii. Signed OOP/OOC laboratory test patient consent form (see policy 3.1).

b) Ordering physician information:
    i. Surname, first name, MSP number, specialty, mailing address, phone number, fax number
    ii. Ordering physician's signature or ordering physician's delegated authority's signature (ordering physician must provide prior approval of delegate to OOP/OOC program).

c) Responses to the questions in the application form, either embedded within the form or included in the medical consultation note:
    i. Clinical diagnosis, clinical need, or additional rationale to support the medical necessity of the laboratory or genetic test
    ii. Explanation as to how the test result will create a new medical treatment plan or significantly alter the current medical treatment plan
    iii. Name of the specific laboratory service or genetic test to be funded.

Application Submission

a) Applications are to be submitted via the OOP/OOC program's online application process or via paper application through fax or mail.

GUIDELINE

Additional Information

A fully completed application form may be insufficient to initially approve funding. The OOP/OOC program evaluates requirements on a case by case basis, and may request additional information, evidence, and/or documents when required. The request of additional documentation may be conducted in consultation with the Ministry of Health and other expert areas.

Requests for a Specific Performing Laboratory

The ordering physician may request that a specific laboratory perform the test. In such cases, the OOP/OOC program will require the correct name and location of the proposed performing laboratory, as well as the rationale for requesting the identified laboratory.

Requesting a specific performing laboratory does not guarantee approval of that performing laboratory. The OOP/OOC program has the discretion to select a performing laboratory that demonstrates maximum value with regard to cost, quality, and timeliness as well as is equivalent or more appropriate than the one requested.

CROSS REFERENCE: Policy 3.1 – Requirement for Informed Consent

Part 3 - Required Patient Information

POLICY 3.1 – Requirement for Informed Consent

PURPOSE

To articulate the patient informed consent requirements and expectations.

POLICY
The OOP/OOC program requires informed consent to ensure that patients are aware that their personal information will be shared by the ordering physician with the OOP/OOC program, for the purposes of administering the OOP/OOC program, tracking outcomes and results, and to improve the functioning of the OOP/OOC program.

The ordering physician must submit the OOP/OOC program consent form signed by the patient or the patient's legal guardian and the following information is required:

a) Patient full name
b) Patient date of birth
c) Patient personal health number (PHN)

In addition, the ordering physician and/or the ordering physician's health authority is responsible for obtaining additional informed consent from the patient that at a minimum will explain;

1. The purpose of the test.
2. That, by signing the form, the patient consents to the release of the sample and related personal information (if any) to the performing laboratory for the sole purpose of execution of the requested test.
3. Any risks associated with performing the test.
4. Any risks associated with performing genetic testing (if applicable) to patients and family members (if applicable).
5. That the patient's personal information and samples may be stored outside of Canada (if applicable) by commercial entities, and the associated risks.

The ordering physician and/or the ordering physicians' health authority have a responsibility to ensure the additional informed consent they obtain from patients meet patient privacy and privacy standards in alignment with provincial and national privacy legislation, including the *Personal Information Protection Act,* the *Freedom of Information and Protection of Privacy Act,* the *E-Health (Personal Health Information Access and Protection of Privacy) Act,* and/or other relevant policies, legislation, frameworks, or guidelines.

GUIDELINE

Some OOC performing laboratories may also request additional informed patient consent documents that capture patient identifying details. Ordering physicians and patients are advised that patients should opt-out of any non-medically necessary terms and conditions or 'options' (such as requests for

long term sample storage, or research), as these may have unintended and unforeseen long term negative impacts for patients and their family members, especially with regards to genetic testing.

LIMITATIONS/EXCEPTIONS

Due to the nature of the OOP/OOC program, patients should be informed by ordering physicians that their samples will be sent OOP and/or OOC. Under foreign disclosure laws, personal information held by laboratories located outside of Canada are potentially subject to disclosure demands under the local legal requirements of the country in which the performing laboratory resides.

CROSS REFERENCE: Policy 2.5 – Required Information

POLICY 3.2 – Use of Personal Information

PURPOSE
To articulate how the OOP/OOC program uses patient personal information.

POLICY

OOP/OOC Program Responsibility - Personal Information

The OOP/OOC program requires patient personal information and sufficient clinical information to justify the need for testing not available from BC laboratories. The OOP/OOC program uses this information for the purpose of substantiating the rationale for public funding and to assess, evaluate and improve program services.

Personal information is required to:

a) assess the merits of the funding request,
b) enable the performing laboratory to perform the test,
c) inform the ordering physician of the funding decision,
d) support result distribution to the ordering physician and OOP/OOC program,
e) manage invoicing and payment of services.

OOP/OOC Program Responsibility - Test Results

The OOP/OOC program receives a copy of the patient test results to inform strategic direction for future delivery of laboratory services in BC, and for quality assurance and evaluation of the OOP/OOC program.

The OOP/OOC program securely stores documents containing personal information in compliance with the *Freedom of Information and Protection of Privacy Act,* the *E-Health (Personal Health Information Access and Protection of Privacy) Act,* guidance from the Information and Privacy Commissioner for BC, and PHSA privacy and data security standards and policies.

Ordering Physician Responsibility

The ordering physician is responsible for protecting the privacy of the patient's information and results, in accordance with the *Personal Information Protection Act,* the *Freedom of Information and Protection of Privacy Act,* the *E-Health (Personal Health Information Access and Protection of Privacy) Act,* and/or other relevant policies, legislation, frameworks, or guidelines.

Part 4 - Application Assessment

POLICY 4.1 – General Approach

PURPOSE

To articulate the approach that the OOP/OOC program takes when reviewing a request for OOP/OOC funding.

POLICY

When assessing an application for OOP/OOC funding, the OOP/OOC program bases its decision on the information provided by the ordering physician in the application and medical consultation note. The assessment and/or adjudication processes may vary by the test ordered.

Funding approvals do not establish precedence for future decisions. Where utility is not proven over time, the OOP/OOC program may discontinue funding for specific tests in consultation with the appropriate medical advisors and the Ministry of Health.

When assessing applications, the assessor will:

a) apply mandatory criteria and the policies outlined herein,
b) document considerations and reasons for judgement, and
c) exercise best judgement based on latest data.

GUIDELINE

Additional Expertise

To ensure applications are thoroughly, fairly, and efficiently assessed, the OOP/OOC program may refer an application to a third-party subject matter expert or group of experts for additional diagnostic clarification to inform the decision. Identifying patient information will not be shared with third party experts.

POLICY 4.2 – Application Assessment

PURPOSE

To articulate the steps undertaken when assessing an application for OOP/OOC funding.

POLICY

The assessment undertaken by the OOP/OOC program personnel includes all the following elements:

a) validation that the patient has an active PHN and is eligible for MSP benefits (i.e., PHN eligibility check),
b) confirmation that all mandatory sections in the application are complete and accompanied by the signed OOP/OOC program patient consent form and medical consultation note,
c) confirmation that the information provided is adequate to identify the test that is needed and to select the appropriate performing laboratory (alternatively, assess the appropriateness of the suggested laboratory),
d) evaluation of whether the test is requested by the appropriate specialist for the disease/disorder presenting in the affected beneficiary, and
e) application review to ensure there is known clinical utility/relevance of the requested test and, application review to ensure test results will change/impact the medical treatment or management of the patient's condition.

GUIDELINE

The assessor may:

a) make an assessment as to whether the ordering physician has provided sufficient information to support funding the request,
b) consult with BC medical/technical subject matter experts as needed to seek further clinical opinion or to confirm the testing is in line with generally accepted clinical utility,
c) consult with the performing laboratory personnel regarding clinical utility, technical, logistical, or pricing as needed, or
d) examine literature or supplemental information to inform a decision.

POLICY 4.3 – Criteria for Genetic Testing Funding Requests

PURPOSE

To articulate the criteria to approve OOP/OOC funding of genetic testing.

POLICY

The OOP/OOC program uses additional criteria to review requests for genetic testing and approves funding decisions for these patients based on the merit of the information provided by the ordering physician. All the following criteria are considered:

a) known existence of genetic cause for the condition being tested,
b) submission by the physician specialist with the appropriate expertise to adequately obtain informed consent and scope of practice to interpret and follow up on the results of testing,
c) involvement of a genetic counselor or medical geneticist,
d) clear benefit for the patient (e.g., alters treatment), and
e) completion of the appropriate consultations and initial in-province tests.

LIMITATIONS/EXCEPTIONS

Genetic testing sought for any of the following purposes are ineligible for OOP/OOC funding:

a) the test result will not immediately influence patient care or management. (e.g., for experimental or developmental/research purposes which includes establishing phenotype-genotype correlations or informing future care should treatment options become available),
b) genetic testing that is merely predictive (e.g., simply to provide information about a beneficiary or a fetus' biological circumstances) and is not necessary to determine or change the way the individual is or may be medically treated,
c) a non-genetic cause is highly suspected and likely to explain the patient's symptoms, such as a teratogen, environmental exposure, injury, or infection,
d) pre-implantation genetic diagnosis/screening of an embryo,
e) tests that are currently covered and available in province through other program areas (e.g., B.C.'s Hereditary Cancer Program),
f) a clinical diagnosis has been made based on assessment/other investigations, and a genetic confirmation will not alter treatment or management, or,
g) a genetic diagnosis has already been established that explains the clinical presentation.

GUIDELINE

Due to the complex and dynamic nature of genetic and genomic testing, the OOP/OOC program may develop and implement additional criteria and guidelines in consultation with genomic clinical specialists and the Ministry of Health.

POLICY 4.4 – Application Decision and Appeals Process

PURPOSE

To describe the application decision process for the OOP/OOC program and to articulate when an ordering physician may appeal the decision to deny OOP/OOC funding.

POLICY

Once an application for funding is approved or denied, the OOP/OOC program will:

a) notify the ordering physician in writing of the decision.
b) provide opportunity to appeal decision if denied.

An ordering physician may appeal the OOP/OOC program's funding decision within three months of issuance of the decision letter and requires the ordering physician to initiate a formal appeal with additional evidence to address the reason why the initial application was denied.

An appeal may be made under both of the following conditions:

a) the patient's care and treatment plan is contingent upon the test results, and
b) additional information is available that was not previously included and may have further informed the review and outcome.

LIMITATIONS/EXCEPTIONS

Approvals are valid for three months following issuance of the decision letter from the OOP/OOC program.

GUIDELINE

For genetic testing, if the OOP/OOC program's clinical reviewers believe that the additional information provided during the appeals process still does not warrant approval, the case may be referred to an adjudication committee comprising medical and genetic subject matter experts. These experts are selected at the discretion of the PHSA.

POLICY 4.5 – Extensions of Application Funding Requests

PURPOSE

To articulate the OOP/OOC program policy for application extensions.

POLICY

The OOP/OOC program does not grant extensions.

GUIDELINE

Ordering physicians are responsible for ensuring that patients approved for OOP/OOC funding visit a local health authority (public) referring laboratory to have the sample collected and sent out within the three-month timeframe. If the approval letter expires and the patient did not have the sample collected and forwarded to the approved performing laboratory, the ordering physician must submit a new application.

Conclusion

These policies and guidelines have been developed in consultation with and approved by the BC Ministry of Health and the PHSA. New policies or revisions to existing policies will be reviewed and approved by both the BC Ministry of Health and the PHSA.