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OPTIMIZING PATIENT ACCESS TO PRECISION THERAPIES: PREPARING FOR THE EMERGING ERA OF ADVANCED TESTING

POLICY POSITION

Patients around the globe are benefiting from a revolution in pharmaceutical and diagnostics innovation. The traditional medicines paradigm of "one-pill-for-all" is rapidly shifting towards a much more tailored approach to "precision medicines" where therapies are targeted to those patients who will specifically benefit from them. This has been made possible through scientific advances in pharmacogenomics,[i] high-throughput testing services, and next-generation genome sequencing technologies. Increased adoption of advanced diagnostic testing enhances the treatment selection process for individual patients, potentially bringing the benefits of precision medicines seen in clinical trials to the real-world setting.[ii] These more efficient and effective treatment approaches can improve patient health outcomes and enhance disease management.[iii] However, governments will need to build robust public testing infrastructure if patients are to fully realize these benefits. This will require policy agility and the adoption of a multi-stakeholder, holistic system approach to the Canadian testing infrastructure.

The COVID-19 pandemic has highlighted the critical importance of testing infrastructure to the health of Canadians. Testing is also a broader issue that impacts an entire range of technologies where the current pace of pharmaceutical innovation is rapidly outstripping Canada's current testing capacity. However, Canada can become an international leader in this space if federal and provincial governments, health technology assessment (HTA) bodies, industry and other stakeholders work together to ensure that the policy framework evolves with the pace of science.

This policy note proposes some core principles to address implementation considerations for further collaborative discussion.[iv] Its purpose is to characterize the current situation in Canada and factors that are hindering current and future patient access to the best available outcomes from treatment. Within Canada's decentralized healthcare systems, funding decisions for diagnostic tests are often made in isolation of decisions regarding provincial funding for associated medicines. As a result, implementation and access to provincially reimbursed diagnostic testing lacks consistency across the country. This inconsistency leads not only to unequal access to diagnostic testing, but also the associated innovative medicines which can only be prescribed upon receipt of an individual's diagnostic test results. For example, oncology medicines that require or recommend on their prescribing labels pharmacogenomic testing prior to use increased from 19 medicines in 2009 to 70 in 2019.[v] Without improvements in access and funding for testing in Canada, many patients may not benefit from innovative cancer medicines, regardless of their health system value, demonstrated cost-effectiveness, or governments' willingness to invest.

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The approach to the laboratory service function in Canada today has not kept pace with technologic advances It is still largely based on a model of delivering either traditional low-cost clinical biochemical tests at high volume or one-off more expensive genetic tests for limited numbers of patients. This situation is similar to the provision of pharmaceuticals in the early 1980s, before the advent of more advanced biologics which created the need for effective tools to assess value (i.e., formulary management and HTA) as the rate of technological advancement exceeded the system's ability keep pace. We are currently in the middle of a new wave of technological innovation that could have even more profound impacts on the delivery of care. Canada still has time to respond and prepare for these changes, but this will require both concerted effort and timely action.

There are clear opportunities to enhance system-wide preparedness for innovative diagnostic testing to improve health, build healthcare infrastructure including reliable domestic supply, and position Canada to benefit from future research and development investments. As a starting point, the innovative industry would recommend multi-stakeholder dialogue on the following core principles to promote effective change:

1. **Enhanced Publicly Funded Testing to Support all Canadians –** Testing is a critical component of health care that transcends drug reimbursement and should be available to all Canadians.[vi] IMC and BIOTECanada support ongoing discussions with health care jurisdictions to enhance testing and diagnostic infrastructure for all Canadians.

2. **Coordination and Anticipation of Future Needs** – To address patient needs, funders need a holistic system view to health technology management with a focus on coordinating disconnected service pathways. Enhanced multi-stakeholder coordination of the processes around horizon scanning, pre-submission (drug) meetings, diagnostic test assessment, medicine assessment, dedicated test funding and medicine funding is needed to deliver cohesive and timely patient access to both diagnostic testing and treatments.[vii] In particular, given the time to develop and validate tests is often longer than the time required to assess treatments, there is a need to start planning and coordination work on diagnostic testing earlier, possibly through provincial early engagement processes.

3. **Transparency and Accountability –** Provincial Ministries of Health can create more transparent, connected, and accountable systems, transforming the testing adoption pathway to one that is transparent regarding access and funding of diagnostics and accelerates access to targeted therapies. Within each province, a single accountable point of contact and a published protocol for diagnostic decision making with meaningful stakeholder input and engagement would be a positive first step.

4. **Context-Specific HTA** – While HTA plays an important role, given the diversity of funding mechanisms and local health system considerations, this should continue to be addressed at the provincial level. Establishing HTA processes for diagnostic testing requires the consideration of numerous technical, logistical, and biologic factors that are highly context specific. As such, useful evaluation will require HTA processes that are closely linked to communities of practice and consider local care pathways, data availability and other factors. CADTH could play a role to help convene interprovincial dialogue and coordination, for example, through a diagnostic testing policy advisory committee of provincial funders and laboratory leaders (see terms of reference for the similar Drug Policy Advisory Committee). This can help to address the interprovincial variability that currently exists in funding and operational process affecting adoption and patient access to diagnostics, while maintaining provincial leadership in this area. The Québec synchronized evaluation process for companion diagnostic tests initiated by INESSS is

an exemplary practice since it allows a test to be added to the list of covered medical acts at the same time as the medicine's indication becomes listed on the provincial list of medications.

5. **Priority Setting Driven by Patient and Health System Needs** - Decisions to introduce new diagnostic technologies still typically follow fiscal and technology management policies of hospital- and clinical program-based care, guided by expenditures rather than capturing health system value in a vertically integrated manner. Indeed, the need to move beyond traditional budget silos to align resources is apparent within provincial health ministries (e.g., between drug plans & diagnostic funding). Decision makers can move away from these *ad hoc* "one test, one biomarker" approaches driven by the current finance model and toward a more strategic "one test, many biomarkers" solution. For example, multi-target assays are tests that simultaneously provide multiple relevant patient insights, and hold the potential to deliver efficiencies, reduce the cost of testing and permit more patients to be tested and at earlier stages for preventative and treatment purposes. [viii]

6. **Appropriate Role for Industry and other Stakeholders in Diagnostic Testing** – The funding of medically necessary public diagnostic services should be driven by public health objectives and not be left primarily to medicine manufacturers, who do not typically supply testing technology directly. While treatment manufacturers are often willing to assist with testing considerations, provinces should develop sustainable funding mechanisms for independent testing capacity that can be more resilient over the long run than one-off approaches.[ix] Adopting a more coordinated public approach with the goal of simultaneous public funding of diagnostic tests and precision medicines, along with clarity on the integrated and supportive role that medicine manufacturers could play in the process, is required.

[i] Pharmacogenomics is the study of how a person's unique genetic makeup (genome) influences his or her response to medications. https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/personalized-medicine/art-20044300

[ii] Targeted treatment through advanced diagnostic testing (including molecular, cytogenetic, and immunohistochemical tests) hold promise for meaningful improvements in patient outcomes from new medicines, including improved response rates, reduced toxicity, and improved survival.

[iii] Leifer BP. Early Diagnosis of Alzheimer's Disease: Clinical and Economic Benefits. J Am Geriatr Soc 51:S281–S288, 2003. Brooks BR. Earlier is better: the benefits of early diagnosis. Neurology. 1999 ;53(8 Suppl 5):S53-4; discussion S55-7. PMID: 10560640.Beyond improved health outcomes, patients and their caregivers value timely and accurate diagnoses because such knowledge provides the opportunity to learn about the disease, enable future planning for financial and legal needs, and can enhance management of chronic conditions.

[iv] While this policy note was based on experience and learnings from precision oncology, the concepts and commentary apply more generally to precision medicines and testing.

[v] IQVIA Institute, 2020. Based on those products launched in the U.S.

[vi] Public plans do not always have the same priorities as private insurers. In particular, private drug insurers and their beneficiaries tend to place a higher importance on patient choice and rapid access compared to public drug plans. In scenarios where private coverage is broader than public coverage for precision medicines, there will be a gap in access to diagnostic testing that only the private insurer can fill. In addition, there will frequently be a time-limited gap in private access to precision medicine and public access to diagnostic testing which the private insurer can fill.

[vii] Stakeholders include but are not limited to provincial governments, public drug plans, patients, laboratory networks, and manufacturers.

[viii] Considering a host of biomarkers at once instead of assessing, reviewing, and implementing them one-by-one introduces a number of efficiencies, including: the administrative burden of scoping, assessing and implementing; the workflow at the point of care; and the delay in patient access to novel precision medicines, diagnostic technologies or both.

[ix] Medicine manufacturers often step in to support development and validation of new tests to help ensure their adoption is timed with treatment availability. However, relying on drug manufacturers to finance tests may create risk to the stability and sustainability of domestic supply chains for diagnostic services—testing technologies are developed and sold by diagnostic test developers, not by the developers of the medicines. In some cases, solutions are sought using out-of-country providers. And while some pharmaceutical developers may be willing to fund the public operation of diagnostic services, it is not a guarantee that all will. For those that do fund, there is no obligation they continue funding public services indefinitely. The result is that arrangements by private entities could lead to suboptimal test delivery, and ultimately could be unsustainable as circumstances – unstable market conditions, competition, regulations, and other factors– may quickly disrupt the ability of a pharmaceutical developer to finance the public delivery of diagnostic services.