Point of Care Tests: The Long and Winding Road to Reimbursement in the US and Canada

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BACKGROUND
- Market access for innovative new technologies can be challenging and time-consuming.
- Demonstrated healthcare decision-making also can be a significant hurdle.

OBJECTIVE
- To characterize the process and identify challenges for health technology assessment (HTA), pricing, and reimbursement for point-of-care (POC) tests in the United States (US) and Canada.

METHODS
- Desktop research of published literature, HTA reports, and third-party websites was conducted to identify the critical steps and the most valuable data for healthcare decision-making.
- Qualitative one-on-one interviews were conducted with payer decision makers in the US (14 payers) and Canada (7 payer advisor and 2 laboratory directors).

RESULTS AND DISCUSSION

United States
The US Department of Veterans Affairs and the Radiologic and Medical Drug Administration (FDA) in the regulatory agency that approves POC tests, typically through the CMS process.

Reimbursement decisions in the US are made at the individual health plan level.

Evidence
- A POC test must demonstrate clinical utility, defined by payers as follows:
  - Test is actionable (i.e., changes patient management) if 43% (paid)
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Coding and Claim Review (Figure 1)
  - A CPT code is linked to a CMS code, and the price is intact for the Center for Medicare & Medicaid Services (CMS) fee schedule.
- CPT Code: CMS
  - CMS has not established a fee schedule for CPT Category III codes.
  - If a fee schedule has been established for a CPT Category III code, it is the price paid for that test.

Local Level
- Manual review is burdensome to the health plan and can go up. Unregulated
- Fees and/or fees paid to the physician.

Provincial and territorial HTA agencies may have different procedures for evaluating POC technologies. If recommended and required.

Figure 1. Claim Payment Pathway

Local HTA
- Local HTA agencies can influence the decision process, but the Ministry of Health is responsible for funding.
- It varies by province, but manufacturers should engage with the Ministry of Health to set the reimbursement process (procedures for Ministry of Health set for fee schedule).
- Manufacturers should determine which province is most likely to reimburse based on provincial HTA processes.

Regional Level
- An existing reimbursement listing with adequate payment or a new reimbursement listing must be established by the provincial Ministry of Health for broader adoption and use in privately owned, office-based clinics and hospital outpatient clinics.
- It varies by province, but manufacturers should engage with provincial Ministries of Health as well as HTA committees and/or HTA agencies for evaluating POC tests.
- Evaluate local and national and economic value and are provided to the provincial Ministries of Health to set the guidelines for HTA.

Specific provincial priorities
- Support POC technology (including physicians to drive the process)
- No funding for POC technology
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- At the payer level, HTA agencies and/or ad hoc committees to review new medical technologies and make recommendations based on clinical and economic value.

Medical Devices Bureau of Health Canada is the regulatory agency that issues licenses for devices and diagnostics.

RHT(h)(3)
- RHT(h)(3) is a voluntary board that issues licenses for devices and diagnostics.
- The board will review applications, and if approved, a reimbursement code will be established.
- Manufacturers should engage with the Medical Devices Bureau of Health Canada, as the process begins with a clinician and/or manufacturer engaging with provincial Ministries of Health as well as ad hoc committees.
- The process begins with a clinician and/or manufacturer engaging with provincial Ministries of Health as well as ad hoc committees.

REFERENCES
- Funding for medical tests.
- Market access in Canada begins at the national level for reimbursement under global hospital budgets. Market uptake will be driven by clinician demand and reimbursement at the provincial level.

CONCLUSIONS
- There are multiple access pathways for various theatres of care (e.g., diagnostic, treatment, diagnostic, emergency), with varying requirements and value drivers.
- Market access may differ and be driven by the manufacturer’s ability to obtain a CPT code and demonstrate evidence of value for the POC test in clinical and payer settings.
- Market access in Canada begins at the national level for reimbursement under global hospital budgets. Market uptake will be driven by clinician demand and reimbursement at the provincial level.

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Figure 2. Percentage of Health Plans that Pay for All POC Markers and Laboratory Tests (a) and (b)