PGt

in Canada
prepares for lift-off

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Insurers' pilot projects and publicly funded initiatives are testing the feasibility of pharmacogenetic (PGt) testing to guide prescribing decisions.

A number of insurers in Canada today are exploring the logistics and business model for pharmacogenetic (PGt) testing, and if all goes well the service will be a standard offering for these carriers' eligible plan members on disability leave come 2019. Some plan sponsors may also be able to opt into coverage as part of extended health benefit plans. However, legislation, logistics and public funding are among the barriers to widespread uptake.

> "The intent is to match the ideal therapy to the right person, and no one can argue against that," says Martin Chung, assistant vice-president, strategic health development at Equitable Life. "But ultimately it's about economics and scalability. Certain tests are easy to do; some are not. Some are quite expensive; some are not. Canada also has a new law in place that may limit what we as insurers can do. We're exploring all of that now, knowing that there is a lot of opportunity, for sure."

Four of the five insurers contacted by TELUS Health are piloting PGt in the disability space to begin, to assess its impact on health outcomes and the duration of leaves; two of them are also considering its potential as an extended health benefit. All of them are also testing PGt for drugs used to treat depression and anxiety, with one insurer also testing the approach for treatment of pain.

Insurers' pilot projects in flight

Sun Life Financial was the first insurer to launch a pilot, in August 2017. They joined a large clinical trial (the IMPACT study) that has been underway at Toronto's Centre for Addiction and Mental Health (CAMH) since 2011.[1] The PGt vendor is Assurex Health and the pilot was scheduled to run for a year, or until enough tests have been completed for the purpose of analysis.

Sun Life's disability case managers explain the program to eligible plan members and if they consent to the testing as well as participating in the trial, CAMH researchers work with them and their physicians directly. The kit to collect the saliva sample (obtained by swabbing the inside of the cheek) is sent to the patient's home or doctor's office, and the sample is couriered to CAMH. Researchers email the test results directly to the physician within two business days, and follow up with the patient four weeks and eight weeks after the test to assess health outcomes.

Great-West Life launched a pilot late last year, with GeneYouln as its PGt provider. After Great-West Life's case managers capture consent from plan members, GeneYouln works directly with them to coordinate the test and deliver the results. The results are delivered in two parts: a full report to plan members, which only they receive, along with a "pharmacist's letter" that summarizes recommended changes, if any, to prescriptions. This letter is also sent to Great-West Life's case managers. The case managers, in turn, ensure that members' physicians receive the pharmacist's letter for their review.

At Manulife, its pilot project offers PGt testing for drugs commonly prescribed for pain, as well as for depression and anxiety drugs. In addition to piloting in the disability space, Manulife is exploring PGt as an extended health benefit. "We're excited to offer PGt to members at work suffering from depression and anxiety so they have a better chance of getting on the right drugs faster and getting the relief they need. For these plan members, we will be partnering with the sponsor to help create awareness of these tests," says Nathalie Khalaf, director, pharmacy benefits, at Manulife.

As with the other carriers, Manulife's PGt vendor will offer to contact plan members' physicians on their behalf. "Although it's entirely up to the plan members, the case manager or the PGt test provider will encourage them to share what they're doing with their physician, and the PGt test provider will also offer to contact the physician to share and discuss the results," says Khalaf.

Meanwhile, at Desjardins, a pilot for PGt testing for drugs to treat depression and anxiety in the disability space will be underway some time in 2018. The carrier also plans to go ahead with coverage under extended health benefit plans. "We will probably implement base coverage in 2018, for certain conditions and with a coverage maximum," says Alain Dagneault, director, research and development, group insurance, at Desjardins.

Patient consent: obstacle or opportunity?

While the potential for PGt testing is promising, Canada's new Genetic Non-Discrimination Act, which became law in May 2017, complicates matters because it requires consent for each and every test.

> "The focus of the bill was generally on insurance underwriting and the approval process for life insurance," explains Brent Mizzen, assistant vice-president, underwriting and policy, at Canadian Life and Health Insurance Association (CLHIA). "One area that didn't receive a lot of attention, if any at all, was pharmacogenetics [in the context of testing to optimize medication selection]. The result is that the legislation was drafted in a very broad manner, which has raised some questions when it comes to pharmacogenetic testing."

With that in mind, the current law states that it is prohibited for any person (for example, an insurer) to require an individual to take a genetic test or disclose the results of a genetic test as a condition of providing goods or services to that individual. As a result, despite the fact that PGt is an opportunity to benefit both patients and the healthcare system by providing a more efficient approach to treatment, it can't be an automatic part of the prescribing process. The consent of the patient is required.

Mizzen notes that other countries have frameworks that address genetic testing differently. In the U.K., for example, the government and the insurance industry have agreed to a policy framework that distinguishes between predictive genetic tests, which indicate a person's risk for certain diseases, and diagnostic genetic tests used to confirm diagnoses or help determine treatments. Their agreement states that "genetic test results can confirm diagnoses of ill health and inform treatments and insurers can ask for this information."

Canada's Genetic Non-Discrimination Act, however, may not yet be set in stone. The Government of Quebec has referred the legislation to the Quebec Court of Appeal, questioning whether it is unconstitutional because insurance is regulated at the provincial, not federal, level. As one of a number of recognized "intervenors" in this process, CLHIA is supporting Quebec's position that the legislation is unconstitutional.

The Quebec court is expected to rule on the appeal by the end of this year or early next year. Says Jean-Michel Lavoie, assistant vice-president, product development, at Sun Life Financial Group Benefits: "Any scalable solution for PGt on the insurer's part is very much dependent on what happens with that challenge."

Physicians' acceptance remains essential

Physician acceptance is key to scalability, and insurers will closely study prescribers' actions during the pilot projects. "Some physicians might be unfamiliar with PGt testing and that's why the PGt test provider will support them to understand and interpret the results. If we find that physicians are not really willing to look at the results or change prescriptions, then it may be too soon to offer this type of program," notes Khalaf.

Dr. James Kennedy, lead researcher of the IMPACT study in Ontario and head of the Tanenbaum Centre for Pharmacogenetics at CAMH, is confident that physicians, including family physicians, will steadily come on board.

> We are up to 10,000 patients in our study, who have been referred by more than 3,000 doctors—and half of our referrals are now from family doctors. That's a good starting cohort of doctors who are comfortable with this science.

Perhaps more importantly, most physicians do not need much convincing. "When we first approach them to refer their patient, nine out of 10 agree. The overwhelming majority think this testing is valuable," says Dr. Kennedy.

The fact that their patients with depression and anxiety are part of a large clinical trial likely helps pave the way for physicians' acceptance. "What we're learning in working with CAMH is how to bring PGt testing to physicians' attention in a way that doesn't seem like it's the big insurance company pushing it," notes Lavoie. "The focus really has to be on education and the science, and preparing materials that plan members can bring to their physicians."

TELUS Health to be a key player to remove logistical barriers

A large, multi-sectoral pilot project in B.C., funded in part by the federal government, will see TELUS Health serve as the technology enabler to seamlessly connect pharmacogenetic (PGt) testing results with physicians, pharmacists and patients. Aggregate data analysis of the economic and health-system benefits should also help make the case for funding by public and private payers, particularly by provincial governments, so that "every citizen in Canada will eventually be able to access pharmacogenetic testing," says Dr. Michel Hébert, medical director, provider solutions, at TELUS Health.

Affordability will be a key part of the funding equation. "As testings scale up, part of our analysis for sure will be to assess pricing, and to crunch the numbers so that PGt testing can be affordable for everyone," notes Hébert.

The pilot project is part of the newly minted Digital Technology Supercluster, one of five "superclusters" that will receive a total $950 million in federal funds over the next five years. Members of the Technology Supercluster, representing private businesses, post-secondary educators and research institutes, have also committed more than $500 million in funding. The Technology Supercluster will focus on maximizing the use of technologies to drive data visualization, collection and analysis in three main areas: natural resources, industry and, last but not least, precision health (including PGt testing).

The PGt pilot in B.C. is scheduled for 2019. Similar to what TELUS Health already does for electronic drug plan claims and laboratory test results, the telecommunications provider will create a single, secure interface so that physicians' electronic medical records (EMRs) and pharmacies' management systems can easily access PGt test results as part of their existing workflows. Those results will be presented as easy-to-interpret reports that use colour coding to indicate when changes to medications may be required.

The patient's pharmacogenetic profile then remains available for ongoing care. "As patients' medication needs change, doctors and pharmacists will be able to simply press a button to get another analysis of the testing results. Patients will not have to be retested," says Hébert.

The pilot's results will be used to help guide funding decisions by public and private payers. "We expect that 2020 will be a pivotal year [for pharmacogenetics] in Canada," predicts Hébert.

Pharmacogenetics or pharmacogenomics?

Pharmacogenetics refers to how a single gene can influence a person's response to a drug. Pharmacogenomics is broader, referring to the study of how all of the genes (the genome) can influence responses to drugs. The words are becoming increasingly interchangeable, whether rightly or wrongly so; as with many new areas of discovery, it can take time for terminology to become fixed.

Plan members open to pharmacogenomics testing

Two out of three plan members would be interested in pharmacogenomic testing for certain drugs, increasing to 76% among those taking three or more medications on a regular basis, according to the 2017 Sanofi Canada Healthcare Survey, an annual survey of Canadians with private health benefit plans. The survey specified that the DNA sample would be collected by swabbing the inside of the cheek.

Pharmacies may be an additional avenue

PGt vendors are also partnering with retail pharmacies, which offer another venue for plan members to claim coverage under extended health benefit plans or health spending accounts. GeneYouln's Pillcheck test (www.pillcheck.ca), for example, includes pharmacists' recommendations to help guide physicians' prescribing decisions, and the company is partnering with pharmacies—such as Whole Health Pharmacies, with 28 locations in Ontario—to offer the service to patients.

As well, a joint venture between the B.C. Pharmacy Association and myDNA Life Australia enables consumers to purchase a test from more than 120 participating pharmacies across Canada, where pharmacists have been trained to interpret results and recommend next steps to patients and physicians. The retail price for the myDNA test is $199 for a report on four conditions (mental health disorders, pain, cardiovascular disease and gastrointestinal reflux disease) or $149 for a report on one of these conditions. The cost includes a consulting fee for the pharmacist. Consumers can locate a participating pharmacy at www.mydna.life/en-ca.

What about the public purse?

In a perfect world, PGt testing would become part of the prescribing process, in which case public health budgets would pick up the costs. This may one day prove to be the case, but as with private payers, the business case must be made.

Enter the IMPACT study, the first major clinical trial for PGt testing in Canada, funded in part by the Ontario Ministry of Research and Innovation and Genome Canada. The study's protocol states an expectation that "IMPACT will continue to demonstrate the feasibility of pharmacogenetic testing and facilitate its introduction and implementation in routine healthcare practice."

To that end, the researchers assess the impact of PGt testing on hospitalizations, physician and emergency department visits based on an analysis of Ontario's healthcare billings data. Final results from the eight-year study should be available by mid 2019. While Dr. Kennedy recognizes reimbursement through the public system will take time, he expects the study's results will spell out a return on investment that cannot be ignored.

Meanwhile, he is happy to incorporate the Sun Life pilot project into the IMPACT study and "glad to hear this is gaining traction with other insurers as well." And he envisions the day when PGt testing will be commonplace for a wide range of conditions. "It will be a revolution in how prescriptions will be written. Well-informed patients should be able to ask their doctor for a genetic test before they start any new medication," says Dr. Kennedy.

Drugs for mental health - a good place to start

More than 30 drugs are available to treat depression and anxiety, and non-adherence to therapy is extremely high—clinical studies show that less than half of patients with depression respond to their first prescribed treatment, and more than 70% fail to achieve remission after trying one or more treatments.[2] The potential for a positive impact from PGt testing, therefore, is high, and early research results indicate significant reductions in hospital and physician visits, in absenteeism and in disability claims when physicians prescribe based on test results. One study also resulted in savings of just over US$1,000 in medication costs per participant in one year.[3]

1 Herbert D, et al. Genetic testing as a supporting tool in prescribing psychiatric medication: Design and protocol of the IMPACT study. J Psych Res 2017. 96(2018):265-272.

2 Trivedi MH, et al. Evaluation of outcomes with citalopram for depression using measurement-based care in STAR*D: implications for clinical practice. Am J Psych 2006. 163(1):28-40.

3 Winner JG, et al. Combinatorial pharmacogenomic guidance for psychiatric medications reduces overall pharmacy costs in a 1 year prospective evaluation. Curr Med Res Opin 2015. 31(9):1633-1643.