

CANADIAN
LEADERSHIP COUNCIL
DRUG EVALUATION


SUMMARY OF PROCEEDINGS FOR COUNCIL MEMBERS

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PROOF OF VALUE

As drugs steadily claim higher healthcare costs, a growing number of plan sponsors feel they cannot continue to cover all drugs. In fact, the incidence of chronic disease and the availability of higher-cost specialty drugs are causing many to consider the move to managed formularies.

While the logic may be sound, significant questions emerge: How do we choose which drugs to cover? Can we use public formularies as a guide? Do we have the tools and systems in place to know we are making the right decisions?

"Plan sponsors want to move to a model where their drug plans pay for only effective and affordable drugs," says Suzanne Lepage, private health plan strategist and moderator of the 2012 Canadian Leadership Council on Drug Evaluation. "What we often hear is, 'If two drugs are equally effective, then why not pick the cheapest one?' The challenge is that 'effective' and 'cheapest' do not always mean the most cost-effective."

Cost-effectiveness is a reflection of value, and "that is more difficult to assess," continues Lepage. "For example, if drug X will get your employees back to work faster compared to drug Y, we have to assess the value of work time saved versus the relative value of the medication."

A SHIFT IN MINDSET

"HR has to start talking about the value of drug benefits, not the costs," urges Thomas Parry, president and CEO of the Integrated Benefits Institute, a U.S. not-for-profit dedicated to demonstrating the business value of a healthy workforce. In his presentation, Parry shared research showing that pharmacy benefits costs are relatively low compared to the financial burden of absenteeism, wage replacement and lost performance productivity (see sidebar, "Beyond drug benefits").

A better understanding of the disease behind the drug also adds value to the equation. "Average employers today are never going to see a submission for drug coverage, nor should they," says Martin Chung, council member and assistant vice-president, strategic health management, Equitable Life of Canada. "Yet employers need to understand that we're not just talking about 'this drug.' We're talking about its impact on the disease. We need higher-level, relevant, practical Canadian facts about the disease. It could be a one-page fact sheet attached to the submission."

Where does one begin to build value assessments into drug evaluations? Multi-stakeholder collaboration is essential, says Ben Harrison, council member and manager, group strategic relationships, Great-West Life. "The more we integrate with pharmacy, with pharmaceutical manufacturers, with advisors and others, the more we are aligned and the better the solutions we can ultimately bring to plan sponsors. We do not want to wait for them to come to us with a problem, because often their answer is, 'We'll just cut it.'"

THE RIGHT INFORMATION

The pharmaceutical manufacturers at the table appear ready to do their part. "We want to move into that space of showing the real-world value of our products in the workplace. But we can't do it alone," says Priscilla Nykoliation, council member and external affairs manager, private payers, AstraZeneca Canada. "Right now we can't just phone an employer and ask if we can track productivity data for employees on drug X. We need to build new partnerships to figure this piece out. We may have a variety of goals as stakeholders but at the end of the day we want to get to the same place, which is optimal health and productivity outcomes."

If we picture the many partnerships between stakeholders as the spokes of a wheel, then information-sharing is its hub.

Take, for example, the ability to prove the value of a drug in terms of its impact on the disease. Currently, drug claims are not linked to the conditions treated, which is especially important for drugs with multiple indications. "I see reports all the time that misclassify drugs or the classifications are too simplistic," says Mike Sullivan, council member and president, Cubic Health Inc. "You can't do anything with that from an integrative perspective. In fact, you can make some profoundly big mistakes."

NEW COLLABORATIONS

The council explored deepening partnerships with pharmacy providers as a way to bridge some of these gaps. For example, the current pharmacy standard for submitting drug claims already includes an optional field for entering the condition treated—could that become a mandatory part of adjudication? What barriers need to be overcome?

"If we don't take meaningful steps to start changing some of this data and people's understanding of it, my fear is that this level of very informed discussion isn't going to be applied practically," says Sullivan.

As well, community pharmacies can serve as a link to patients in the collection of real-world data, also referred to as comparative effectiveness research. "Pharmacists can have a tremendous impact on adherence," says Parry. "If the pharmacist could collect additional information from the patient, asking simple

questions around performance and work time missed, that information could demonstrate the value of the medication as well as the pharmacist's role."

Pharmaceutical manufacturers' patient assistance programs represent another "good opportunity to collect vital post-market data," suggests Godfrey Mau, council member and pharmacist consultant, Medavie Blue Cross. "They are able to collect more information than just claims patterns or prescription fills; for example, assessing medication adherence and tracking health outcomes for those patients who have enrolled in the assistance program. Even if it is patient-reported, there is some value to that."

"At the end of the day, employers are not looking for academic excellence in the data; what we need is functional, directional data so we understand where the opportunities are," adds Chung. "It comes down to systems and people: Do we have systems in place to pull, interpret and convert the data? Do we have sufficient people to be able to speak to it? We have to expand the knowledge base. To do that, we can't make it so complicated that the average advisor can't speak about it."

ROAD TO INTEGRATION

To that end, the insurers and PBMs on the council are stepping up to do more with existing systems and data. "As an industry we've been guilty of looking at drug costs in silos," says Connie Wong, council member and director, pharmacy benefits, Manulife Financial. "We have addressed this so we can now measure the total cost-per-disease state, including drug costs, disability, absenteeism and paramedical costs, based on group-specific data. However, it's resource-intensive and, hence, an expensive process. We'd love to be able to push this data out more broadly but, right now, cost is a barrier for some groups."

Insurers and pharmacy benefits managers (PBMs) also recognize the need for collaboration amongst themselves, since many employers spread their benefits across multiple providers. "We can address that, but it takes a lot of time and extra cost," says Wong. "Mechanisms have been put in place to facilitate such non-competitive collaboration. The use of multiple providers is no longer a barrier."

"Integrated data is not easy or inexpensive," agrees Parry. "This is one reason why we build models as a starting point." Ideally, however, carriers and adjudicators will partner with a plan sponsor in order to work with real data.

Seek out the early adopters to create a path and build momentum, suggests Chris Bonnett, council member and president, H3 Consulting. "It's within our ability to screen organizations for their readiness to act based on issues related to culture and leadership. We need to start with the leaders because those workplaces provide the environment that allows health promotion, pharmacy management and overall performance to flourish."

Acquiring the right information is a long-term commitment to partner on many levels, concludes the council. The results, however, are worth the effort. "When you assess aggregate data that include disability, absenteeism and productivity, sometimes you get a very different perspective on what conditions are impacting your bottom line," says Lepage. "For example, based on drug plan data alone you might focus on rheumatoid arthritis; however, when you look at the aggregate analysis you realize you have a much bigger problem with diabetes."

Expert view: beyond drug benefits

Thomas Parry, president and CEO, Integrated Benefits Institute

Since business has its eye firmly on the bottom line, it's understandable to focus on cost when assessing drugs. However it's also important to put drug costs in their proper context to avoid coverage decisions that do more harm than good, advises Thomas Parry, president and CEO, Integrated Benefits Institute in San Francisco.

"Employers, by and large, have focused on costs, which are a *lagging* indicator of health. You're never going to get on top of the spending curve if you manage costs. Employers need to think about the leading indicators of health, things like biometric screenings and the prevalence of chronic conditions," says Parry.

The institute accesses large-plan member databases to build business impact models that break down cost silos and "help employers understand what's really at risk," says Parry. A recent model for automakers, for example, found that the pharmacy benefit accounted for just 15% of costs, versus a staggering 46% linked to lost performance productivity (also referred to as presenteeism). Wage replacement (26%) and absenteeism (13%) made up the remaining costs (note that medical costs have been removed from this breakdown, since they are not applicable for Canadian employers).

"The fact of the matter is that the incidence of chronic conditions is much higher than employers typically believe," says Parry. "These conditions go beyond those defined by diagnosis, such as diabetes. They include conditions that are more symptomatic, such as fatigue and back pain, that affect an employee's ability to work effectively."

Another study on drug-plan design found that adherence to medications for rheumatoid arthritis dropped as copays increased, leading to a "significant negative impact on disability costs," says Parry. As well, the overall adherence level was well below the "75% that is considered as critical to drive improvements in disability and productivity."

Industry stakeholders in Canada are at somewhat of an advantage, since the discussion is still in early days, notes Parry. However, the time to act is now. "The people in this room have a unique opportunity to help employers understand the broader issues, and how the pharmacy benefit plays into these issues. Regardless of how healthcare is financed in your country, the health of the workforce is a critical business strategy."

THE PUBLIC CONNECTION . . . OR NOT

While drug evaluations for public drug plans can save private payers considerable resources regarding clinical information and, to some extent, cost considerations, they cannot be relied upon for decisions on coverage, observes the leadership council.

"Public agencies talk about the number of lives saved. Private payers talk about the number of people who will be frustrated because you don't cover a drug," says Johanne Brosseau, council member and senior associate, Aon Hewitt. "Historically it's taken for granted that if you have a private plan, any new drug will be covered. We don't talk about drug insurance, we talk about benefits. We tell people, 'It's part of your salary, it's part of how we attract and retain your services.' And now on the other end, we want to introduce a controlled formulary. How do we transition to that? That's a big question, and as long as private payers continue to talk about it in terms of benefits rather than insurance, there will be a huge discrepancy between decisions made on the public and the private sides."

MATTER OF PERSPECTIVE

Public plans primarily cover the lives of seniors and low-income individuals, and use a health-system perspective to assess the value of drugs; for example, the drug's potential impact on physician visits or surgical procedures, explains Lepage. Private plans, on the other hand, typically serve an active, working population and need to consider a drug's value from the perspective of productivity and profitability; for example, its impact on absenteeism.

Even when public and private evaluations assess similar factors, such as disability, one needs to tread carefully, says Chung. "Submissions will reference various disability statistics, very often based on studies from Health Canada. But Health Canada's societal view of the impact of disability is completely different than the view of private payers. We need to determine the right baseline for the submitter to know what reference points, or even educational facts, to provide to the payer."

The emergence of provincial product listing agreements (PLAs) has further widened the gap between public and private plans. PLAs have "basically changed the whole analysis on cost-effectiveness," says Priscilla Po, council member and manager, clinical services, Express Scripts. "When plan sponsors say, 'Oh, we can

follow the provincial formulary,' we reply that the landscape has changed. We need to look at different aspects and arrive at our own decisions."

"PLAs create an 'illusion of value' with prescribers," adds Mark Jackson, pharmacy services consultant, Green Shield Canada. A provincial plan can make a coverage decision based on a PLA's lower confidential price, but this price does not extend to private plans. "The provincial PLA can drive utilization on our book of business, at a higher price tag, and as a result it's conceivable that those PLAs may present a barrier to private-sector coverage at some point."

TOOL FOR DECISION-MAKING

The Canadian Agency for Drugs and Technologies in Health (CADTH) reviews and public formulary coverage recommendations are "a tool, or a guide," continues Jackson. "If they make a listing decision that's geared for a population that's not necessarily representative of our book of business, you always have to keep that in mind."

"We like the CADTH reviews for their clinical information," says Kathy Ho, council member and pharmacist, pharmacy services, TELUS Health Solutions. "As well, CADTH publishes reviews or critiques of clinical guidelines at times, which can be very useful." As for the pharmacoeconomic analysis, "that's a bit challenging," continues Ho. "They are costly to produce so you can't expect that all pharmaceutical manufacturers will have the resources to do it from the perspective of the private payer. Perhaps a place to start is to let us know which costs are not that relevant to the private payers. That would be useful if submissions could be upfront about that."

Bring subjectivity into the balance

> *"I believe that managed formularies will be part of the solution for private drug plans because you're looking at some fairly difficult expenditures to manage. Therefore, drug evaluation will be a necessity. But it's really important that you don't let 'the perfect' be the enemy of 'the good.' In other words, don't linger on the fact that we don't have the right objective measures for the various populations we're trying to treat. Instead, recognize that we can do a pretty good job and can go a long way with the measures we have—and then we need to let subjective judgment come into play to enrich the decision making."*
>
> — MATTHEW BROUGHAM, VICE-PRESIDENT, PRODUCTS AND SERVICES, CANADIAN AGENCY FOR DRUGS AND TECHNOLOGIES IN HEALTH

SUBMISSION IN PROGRESS

In light of public-sector reforms and the unique measures for the value of drugs in private plans, the industry needs to consider how pharmaceutical manufacturers can put together formulary submissions tailored to the needs of private payers, suggests the council.

"Drug submissions today are very rigorous and technical. We forget the 'HR factor' that needs to take into account workplace-related healthcare costs," says Bessie Wang, council member and director, professional services, TELUS Health Solutions. "It's difficult for pharma companies because they don't know enough about that environment. Now that there is more attention to drug coverage in the private sector, it would be worthwhile for manufacturers, perhaps through Rx&D [Canada's Research-Based Pharmaceutical Companies], their advocacy body, to get together with pharmacy benefit managers to standardize submissions for the private sector. For example, to determine criteria to measure the impact on disability."

"It would be great to have something for the private sector that indicates, 'Every dossier should include this type of data,'" agrees Mau.

THE AMCP MODEL

Adaptation of the Academy of Managed Care Pharmacy's (AMCP) *Format for Formulary Submissions* could be a starting point (see sidebar, "Raising standards"). The *Format* "has improved the content and flow of information and evidence between the pharmaceutical industry and payers," says Peter Penna, a founder of the Academy of Managed Care Pharmacy and chair of the AMCP Format Executive Committee, who was a guest speaker at the Leadership Council meeting. "In the early years there was some pushback, but it's widely adopted and accepted now."

While there would be differences in terms of the type of data that could be presented (since U.S. pharmacoeconomic modelling looks at overall healthcare costs, which would not apply in Canada), the *Format*'s framework and objectives are generally transferable. "If you decide to go down this path, to develop a Canadian dossier, I encourage you to approach the AMCP to establish a Canadian working group. That is a definite possibility," says Marissa Schlaifer, council member and AMCP's director, pharmacy affairs.

Manufacturers with U.S. parents or affiliates may already be able to use the dossier as a guide. "If a drug is launched in the U.S. prior to Canada, one of the first things I recommend to Canadian manufacturers is that they get their hands on their U.S. office's AMCP dossier, which can be very helpful in creating the Canadian private payer dossier," says Lepage.

FOUND IN TRANSLATION

In addition to standardization, perhaps more can be done with existing data, suggests the leadership council. "On the one hand, the private payer does not really want to see a cut-and-paste of the public submission. Looking at hospital admissions and reduced lab costs is really hard for me to explain to a plan sponsor in terms of justifying why these medications are covered," says Tara Besant, council member and director, pharmacy benefits, Great-West Life. "On the other hand, if we can relate it back to absenteeism then we've established a link. For example, the drug reduces the number of lab tests required, which also means less work time missed to go for tests. Or the new drug is oral, so employees don't have to take three work hours off every two weeks to get the original infused drug. It's a matter of transforming data to a private payer's point of view."

Taking that one step further, "it could be feasible to take certain clinical findings and model them through to an impact on productivity or absenteeism," suggests Richard York, council member and private payer manager, Merck Canada Inc.

For example, a symptom may consistently result in lost work time, and there is a new drug that treats that symptom, explains Lepage. "That drug doesn't have outcomes that say you get someone back to work sooner, but you can make the correlation."

"As long as the correlation is transparent, then yes we would look at that," agrees Jackson. However, it's important to link such modelling to comparative effectiveness or comparative safety. "It has to be about how your product impacts productivity or absenteeism compared to what's already on the market. And how it compares to existing products as opposed to no treatment."

WHAT'S MISSING

Off-label use is also "something that we always talk about but that's never in the submission," says Leanne MacFarlane, council member and senior director, business development, Managed Health Care Services Inc. "How is this drug going to be prescribed in the real world?"

"Currently, off-label use is a risk," says Jackson. "Even legitimate on-label advertisements in other jurisdictions easily cross the border and can be off-label in Canada. The bottom line is that it has the potential to undermine any pharmacoeconomic or budget impact analysis that we get in our submissions."

Canadian law (under the *Food and Drugs Act*) dictates that pharmaceutical manufacturers can address only the indications approved by Health Canada and contained within the product monograph, says Mark Ferdinand, council member and senior director, health and economic policy, Rx&D. In the U.S., the Food and Drug Administration permits manufacturers to share off-label uses only when specifically asked. "Hence the AMCP *Format* asks for a thorough discussion about off-label indications. It also asks pharmaceutical manufacturers if they are actively researching other potential indications," says Penna.

IN SUMMARY

Several insurers and PBMs on the leadership council singled out the addition of an executive summary to submissions, written with the plan sponsor and business advisor in mind.

"Let's say we recommend a favourable formulary decision for a drug that is efficacious but does not appear to be as cost-effective on the surface compared to other common therapeutic alternatives, although the data around productivity or absenteeism indicate otherwise," says Ho. "The actual economic evaluation is often pretty complicated. It's worth it for pharmaceutical manufacturers to invest in an easy-to-understand executive summary that PBM managers and insurers can adapt and share with their clients, including plan sponsors, where appropriate. It will also be worthwhile if pharmaceutical companies can provide a good economic analysis from the perspective of the private payers, with relevant costs and benefits listed clearly, for some of their important drugs."

The *Format*'s executive summary could be used as a template for a plan sponsor–friendly summary. "It's key to a good dossier," says Penna. "It relates the drug to the disease and summarizes epidemiology, severity and burden, as well as the evidence for safety, efficacy and effectiveness. It states the drug's economic value to the payer. It's meant to be a quick, easy-to-read overview."

A tailored, standardized submission format or dossier for private drug-plan evaluations is worth exploring as an industry, concludes the leadership council. The overriding objective is to close the gap between the academic, clinical content and "how things are going to work in the real world," says Tim Clarke, council member and senior vice-president, Aon Hewitt. "There are a number of different aspects of that, from adherence to physician behaviour to off-label use and future indications. It's a big challenge, and there is no easy solution, but we need to begin."

Expert view: raising standards

Peter Penna, co-founder, Academy of Managed Care Pharmacy (AMCP); chair, AMCP Format *Executive Committee; and president, Formulary Resources*

Marissa Schlaifer, director, pharmacy affairs, AMCP

The Academy of Managed Care Pharmacy (AMCP) *Format for Formulary Submissions* for private-sector drug plan evaluations has streamlined the submission process and enabled more accurate value assessments for pharmaceutical manufacturers and evaluators in the U.S. (www.amcp.org/AMCPFormatforFormularySubmissions). A version of it, or selected components, could be used to guide the creation of a standard format in Canada.

"We are not the American Academy of Managed Care Pharmacy; we are the Academy of Managed Care Pharmacy, and we're excited to be here in Canada to share our learnings," says Marissa Schlaifer, AMCP's director, pharmacy affairs. "While there are some differences in structure between our healthcare systems, the challenges are the same."

Development of the ACMP *Format* more than a decade ago was based on the premise that, for private payers, "there are many things that could influence a formulary decision beyond the primary considerations of safety, efficacy and effectiveness," says Peter Penna, one of the founders of AMCP and president, Formulary Resources. Consumer expectations, physician support and supportive disease management programs are just three examples.

Seven components comprise the *Format* and related dossiers. The latest modifications underway for version 3.0 will "expand the dialogue around comparative effectiveness research, companion diagnostics and specialty pharmaceuticals," says Penna.

1. EXECUTIVE SUMMARY
A two- to four-page summary stating the case for covering the drug, including a description of the disease and its economic burden.

2. PRODUCT INFORMATION
Information on approved uses, off-label uses, other potential indications and comparison data (how the drug compares to other products used for the same indication).

3. DISEASE BACKGROUND/PLACE IN THERAPY
The epidemiology and burden of the disease, including clinical guidelines.

4. SUPPORTING CLINICAL INFORMATION
Key clinical study results for approved and unapproved indications.

5. ECONOMIC VALUE
Modelling reports to predict system-wide consequences of changes to the formulary.

6. OTHER SUPPORTING EVIDENCE
Any other related studies.

7. SUPPORTING MATERIALS
References and hard copies of key documents (e.g., patient information).

THANK YOU TO THE LEADERSHIP COUNCIL PARTICIPANTS

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