20 SENSE

THE 20SENSE REPORT

Spotlight on the Canadian Specialty Pharmaceutical Market

April 2022
Issue 20

Specialty medicine and private payers

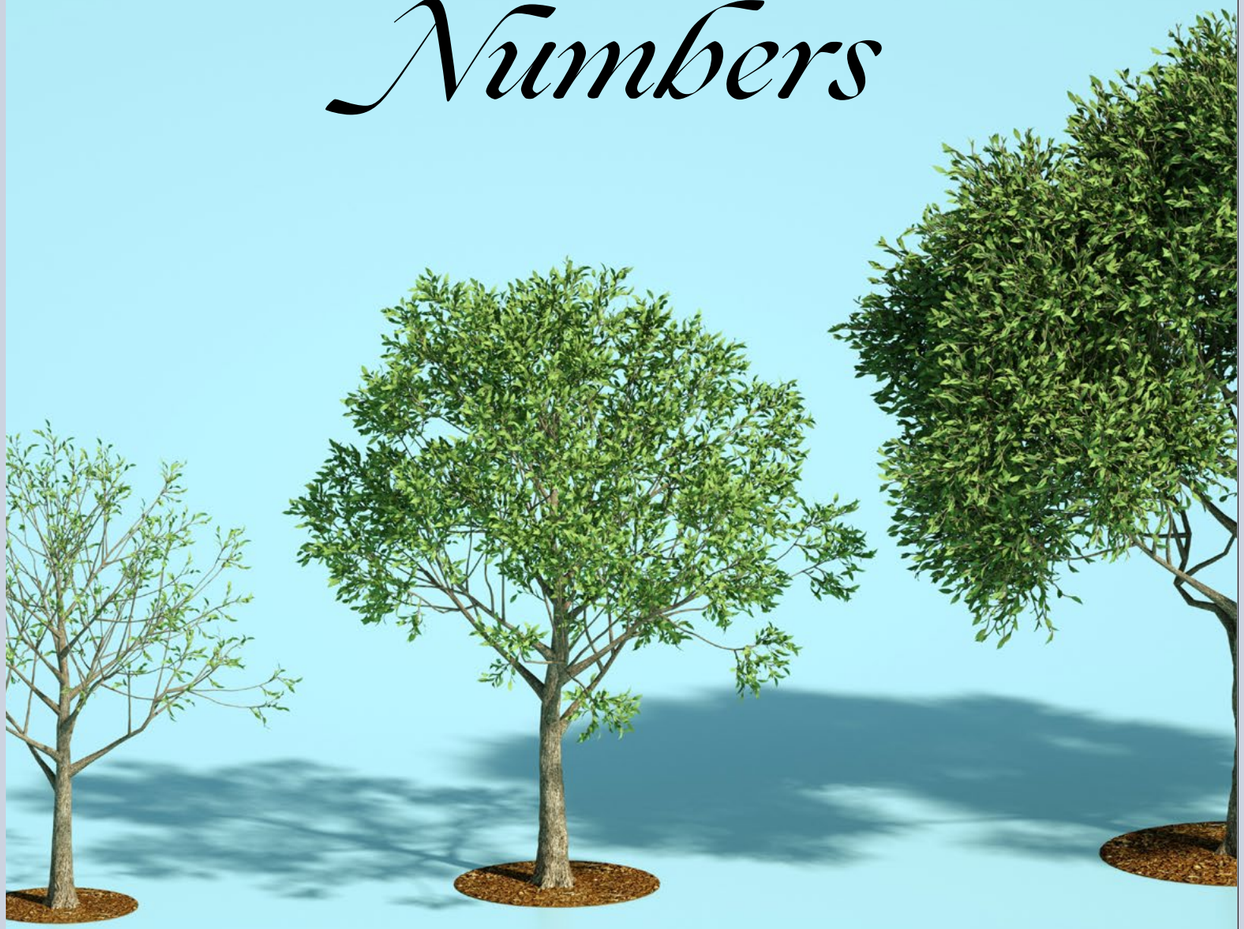
A key pillar of the specialty drug ecosystem, private insurers and the pharmacy benefit managers that support them are adapting to a rapidly shifting landscape.

The private payer landscape by the numbers

How private payers are meeting the needs of specialty medicine

TELUS Health's Daria O'Reilly on health and economics being allied forces

By the *Numbers*



The specialty pharmaceutical sector, which caters to patients with complex conditions requiring sophisticated and often costly treatments, depends on private payers to survive and thrive – and the private–payer commitment keeps growing.

PRIVATE PAYER LANDSCAPE IN CANADA

70%

Proportion of Canadians with private/supplementary health insurance – that's 26 million people.[1]

100K+

Number of private drug benefit plans, usually offered as employment benefits but also available for direct sale to individuals.[2]

36.9%

Share of total drug-spend carried by private payers, approaching the 43.6% funded by the public system.[3] In the US, private payers absorb a very similar proportion (42%) of drug costs, challenging the notion that Canada leans far more heavily on the public purse.[4]

$12.7B

Cumulative cost of prescription drugs covered by private plans in 2021.[1]

PRIVATE PAYERS AND SPECIALTY DRUGS

32%

Total private payer drug costs devoted to specialty drugs – approximately $4B as of early 2021.[5] These costs are associated with just 1.3% of patients.[6]

8.7%

Increase in specialty drug spend in the private payer space in 2020,[5] more than 6 times the increase (1.3%) in conventional drug expenditures.[6]

2.5%

Increase in the cost per private payer claim for a specialty drug in 2020. In contrast, the average cost of a traditional drug claim decreased by 0.8% during this period.[5]

SPECIALTY THERAPEUTIC AREAS COVERED BY PRIVATE PAYERS

44.4%

Proportion of costs devoted to rheumatoid arthritis, inflammatory bowel disease, and psoriasis among the top 1% of high-cost private payer claims in 2021.[6]

80%

Share of oncology drug costs allotted to oral medications within the private payer sphere – significantly higher than the overall figure of 50% in Canada.[7]

100% (DOUBLE)

Increase in the cost per oncology drug claim in private plans between 2010 and 2019, compared to just 5% for non-oncology drugs.[7]

> 50%

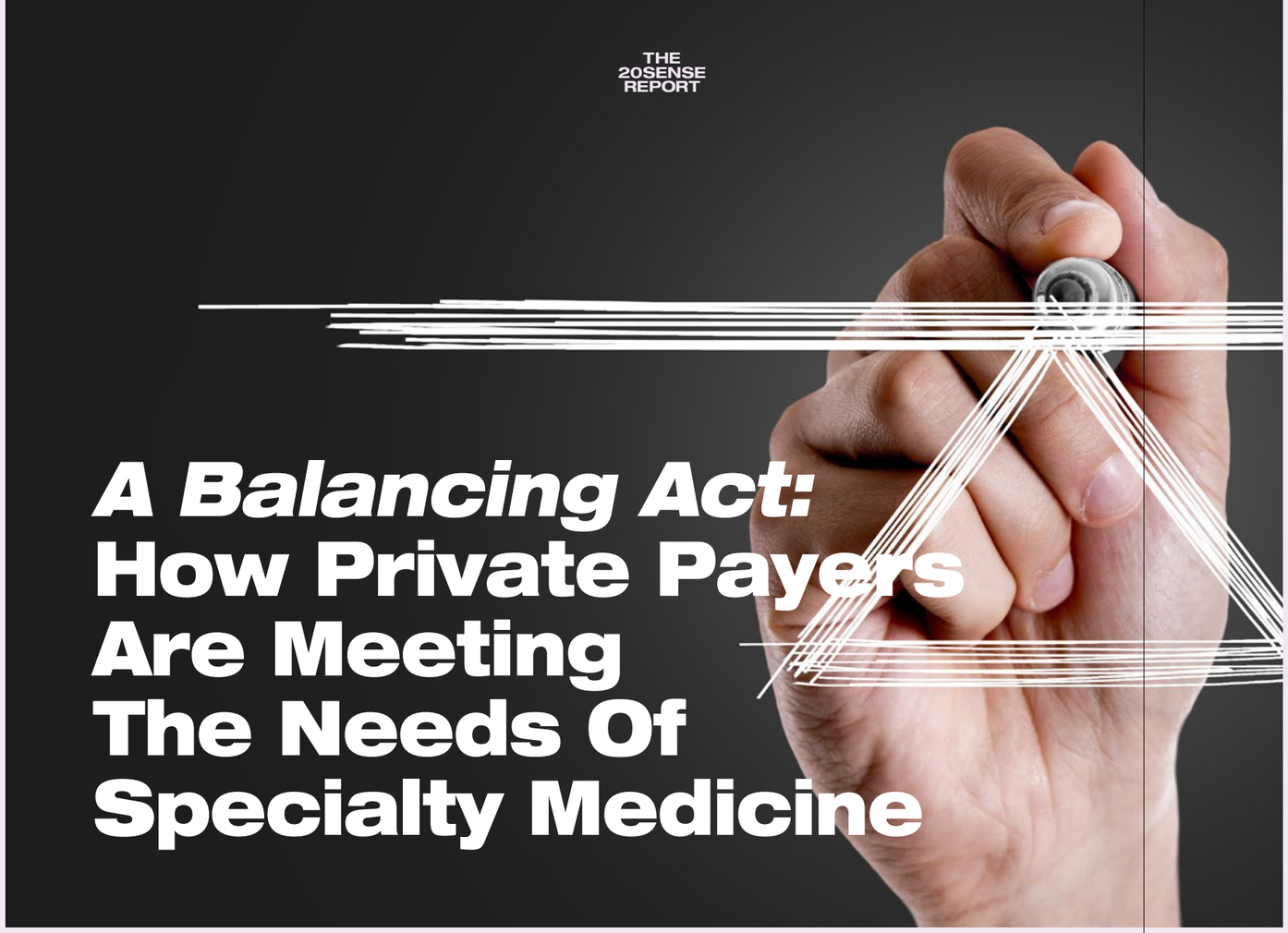
Proportion of oncology drugs in the pipeline designed for oral administration.[8]

> $650M

Amount paid out by insurers to cover rare disease drugs in 2020.[1]

32%

Growth in private payer expenditures for rare disease drugs in Canada between 2012 and 2019.[1]



A Balancing Act: How Private Payers Are Meeting The Needs Of Specialty Medicine

When we talk about the Canadian healthcare system, we often mean the public system. We take justifiable pride in a government-funded system that puts a premium on fairness and equity. That said, millions of Canadians depend on private coverage to pay for the medications that preserve their health and function. This dependence holds especially true for specialty medications, which provide enormous benefits to patients but cost a lot of money and must often be taken for a long time.

The fact is, private payers constitute a vital pillar of the Canadian healthcare system – but don't always get the recognition that befits their position, resulting in confusion about their processes and roles. Let's dig into the specifics to bring clarity to the topic.

Why private health insurance exists

Let's wind the clock back to the 1960s, when Canada first launched the universal healthcare program known as Medicare. At the time, prescription medicines consisted mainly of low-cost drugs for common conditions such as headaches and hypertension, so the architects of the program chose to focus on higher-ticket items such as hospital and physician services.[2] While they intended to add prescription medicines to the program at a later date, changing economic and political conditions sidelined this plan. In the absence of a national pharmacare program, provinces and territories developed drug plans for vulnerable groups, and employers began offering private health benefits (including drugs) to attract and retain talent.[2]

Today, the private payer landscape has ballooned into a rich ecosystem that collectively offers over 100,000 drug benefit plans.[2] While these plans usually exist as employee benefits, individuals can also purchase them directly. In Quebec, where medication insurance is mandated, residents who don't have access to private plans must enrol in the public plan (and pay a premium unless they belong to vulnerable groups such as low-income seniors).

BALANCING ACCESS AND SUSTAINABILITY

From a payer's point of view, specialty medications represent a class apart – and a growing share of drug costs. Throughout 2020, private payer costs for specialty drugs rose by 8.7%,[5] over 6 times the corresponding cost increase (1.3%) for non-specialty drugs.[6] By the time 2021 came into view, private payers were devoting close to a third (32%) of their drug-spend to specialty medications.[5] And while the average cost of a traditional drug claim decreased by 0.8% during 2020, the bill for a speciality drug claim went up by 2.5%.[5]

While specialty drugs span all disease states, a few therapeutic areas stand out in the private payer space. In 2021, just three conditions – rheumatoid arthritis, inflammatory bowel disease, and psoriasis – accounted for 44.4% of the expenditures for high-cost drugs.[30] Oncology has also emerged as a cost leader, with the average cost-per-claim doubling between 2010 and 2018.[7] (During the same period, the cost of non-oncology drug claims rose by a mere 5%.[7]) A notable trend within oncology is the shift to oral medications, which have not received consistent coverage from public payers and thus disproportionately strain the private payer system.[14] These medications, which continue to proliferate in the pipeline, currently account for 80% of the private-pay oncology drug cost pie.[7]

The scenario looks much the same for rare diseases. The explosive growth of new medications for rare diseases has escalated private payer expenditures to the point that, in 2020 alone, insurers paid out over $650 million to cover these products for over 13,000 patients.[1]

On the public side, concern about managing these rising costs has led the Government of Canada to develop a national strategy for rare disease medications. When consulted as a stakeholder in the strategy, the Canadian Life & Health Insurance Association (CLHIA) emphasized the importance of including private payers "to minimize the impact on patients and ensure the sustainability of the system."[15]

Like rare disease drugs, cell and gene therapies have the potential to treat the most challenging disorders. These sophisticated therapies aim to repair or reconstruct defective genetic material to produce a therapeutic effect, using technologies that require a substantial R&D investment.[16] Though many of them only need to be taken once, their sky-high price tags still strain budgets. "Most health insurance has co-pays, so members also bear some of the burden," notes Joan Weir, Vice President, Group Benefits at the CLHIA. "A $1 million treatment with a 20% copay leaves a bill of $200,000 to the patient, which would be obviously out of reach for most people."[16]

All told, the rise in specialty drug costs shows no signs of slowing down, bringing private payers face-to-face with the question: **how to contain costs while ensuring that patients have access to life-changing treatments?**

→ CONT.

WHO'S WHO IN PRIVATE HEALTH INSURANCE[9]

Plan member:

A plan member is an individual, often but not necessarily an employee, who belongs to a drug benefits plan.

Plan sponsors:

Many employers offer health insurance as part of their employee benefits. Such employers are called plan sponsors. The term "private payer" generally refers to the plan sponsor, who pays an insurer to reimburse plan members for drugs.

Insurers (or carriers):

Canada's 23 insurers, which include such giants as Sun Life, Manulife and Canada Life,[10] develop insurance plans that employers can purchase. (Note: the term "private payer," while technically reserved for plan sponsors, is sometimes used to describe insurers as well.) Private insurance plans offer a complex web of services, which typically include[11]:

- Maintaining and updating drug formularies
- Developing and maintaining a network of pharmacies
- Adjudicating and processing claims
- Coordinating services with provincial plans

Pharmacy benefit managers:

Insurers often subcontract the claims-processing component of their services to third-party providers called pharmacy benefit managers (PBMs). Acting as intermediaries between insurers and pharmacies to settle claims, PBMs may also provide extra services ranging from formulary maintenance and claims analysis to negotiating discounts with drug manufacturers.[11,12] Prominent PBMs in Canada include Express Scripts Canada and TELUS Health. Some insurers have created their own PBM capabilities, enabling them to act as both insurer and PBM for the group plans they administer.[11]

"A $1 million treatment with a 20% copay is obviously out of reach for most people."

Joan Weir
Vice President, Group Benefits at the CLHIA

TOP INSURERS[13]

RANK	INSURER	SHARE OF INSURED GROUP HEALTH PREMIUMS
1	Sun Life Financial	22%
2	Canada Life Assurance Co.	21%
3	Manulife Financial Corp.	18%
4	Desjardins Insurance	10%
5	SSQ Insurance*	7%
6	iA Financial Group	4%
7	Medavie Blue Cross	3%
8	La Capitale*	3%
9	Green Shield Canada	2%
10	Empire Life Insurance	2%
	Top 10 total insurers	**93% of industry total**

*SSQ Insurance and La Capitale merged to form Beneva in Dec. 2021. [29]

Updated toolbox

With this question top-of-mind, private payers have explored a variety of strategies to balance access and sustainability. One of the simplest is the coverage cap: a limit on either annual or lifetime claims for each individual. Between 2013 and 2017, the number of private plan members with such caps grew by about 40%, and over a quarter of plan members have capped coverage today.[2] Annual maximums typically fall in the $2,500-to-$5,000 range, while lifetime limits may range from $100,000 to $750,000.[2] Plan members who reach their limit must pay for additional costs out of pocket or, if eligible, can move to a public drug program. As specialty drug costs continue to climb, the capping trend will likely accelerate.

In tandem with price caps, insurers are limiting access to specific medications through a mechanism called tiered listing. This approach has become especially popular within the biologic drug space, echoing the trend among provincial/territorial governments to prioritize biosimilars over the more costly originators. Specific listing criteria vary widely among private coverage plans: some create lists of preferred biosimilars, others insist on exclusive use of biosimilars, and still others require patients on originators to switch to a biosimilar.[17] While tiered listing can bring down costs considerably, the added complexity of stocking multiple biosimilar products at pharmacies could create challenges in managing these drugs – a potential snag to watch for as tiered listing of biologics evolves throughout 2022.

For higher-cost drugs, private payers may also insert a step called prior authorization (PA) to ensure a good fit between product and patient. With criteria established by payers, the PA process requires patients or their physicians to submit medical evidence to justify the use of a drug.[18]

An insurer may also negotiate a pricing agreement with its preferred provider network (PPN) – a select group of pharmacies associated with that insurer. Participating pharmacies agree to lower the markup for a drug, receiving a predictable volume of business in return. Over the past decade, PPNs have emerged as an important tool for containing specialty drug costs. It should be noted that the patient support programs and service providers upholding many specialty medications have helped enable the successful management of both PAs and PPNs.

The same negotiation principle underlies the product listing agreement (PLA) – an agreement between a pharmaceutical manufacturer and payer to limit the budgetary impact of a high-cost drug.[19] In a typical PLA, the payer agrees to list a medication on its formulary in exchange for a (generally confidential) price rebate from the manufacturer. Canada's first-ever private-payer PLA took place in 2014, when Janssen Inc. negotiated a discounted price with SunLife for the biologic Remicade.[20] Since that time, PLAs have entrenched themselves in the private payer sphere.[21] These agreements can yield large savings on the payer side – tens of millions of dollars, according to one large insurer – while manufacturers enjoy a predictable volume of business.[21]

This shift reflects a general movement within the private system toward the health-economic, value-oriented focus observed in the public sphere. In recent years, insurers and PBMs have begun hiring their own professionals to evaluate the clinical and economic value of a drug and compare it to therapeutic alternatives. A 2020 study by TELUS Health, for example, explored how the perspective applied to a health-economic analysis can affect a drug's incremental cost-effectiveness ratio (ICER), a metric that often informs reimbursement decisions. Specifically, the study found that applying a private-payer vs. public-payer lens yielded different ICER figures.[22] Depending on the drugs considered in the analysis, these differences could be significant.

Coming soon

The relentless movement in the specialty drug world is prompting the private payer landscape to look at opportunities to innovate. Recognizing the need for greater efficiency and harmonization, stakeholders are considering ways to cut down on duplication of effort and bureaucratic complexity. A case in point: in an initiative called Simplify Prior Authorization, led by Connex Health Consulting, industry partners are exploring ways to increase transparency and standardization in the PA process, provide new online resources for stakeholders, including patients, to help them navigate PA, and are advocating for clearer reporting and metrics for payers.[18]

According to Denise Balch, president and principal consultant at Connex, the initiative plans to educate the private payer community about gaps in the PA process and the need for change. Through podcasts, webinars, blogs and articles, "we will continue to highlight the challenges that arise from inefficiencies in the process and focus on the need for improvements," she says.

High up on the priority list is digitization. In 2020, TELUS Health teamed up with Canada Life to develop the first electronic PA solution, which they tested in a pilot program.[23] The digitized system allowed staff in patient support programs to initiate the PA process via a web portal and deliver digital outputs directly to payers.[23] Exploring and fine-tuning such systems could lead to vast improvements over the antiquated but persistent paper-and-fax model – as long as the digital solutions remain simple and accessible. "High adoption of electronic PA will depend on having a common platform for the industry," says Karen Kesteris, Chief Product and Marketing Officer at Express Scripts Canada. She adds: "An ePA solution should be 'agnostic' to ensure it meets the needs of payers, pharmaceutical companies, patient support programs, prescribers, and of course patients."

Such initiatives pave the way for a broader use of the PA process, such as using PA data to support real-world evidence (RWE) initiatives. In line with this thinking, the 2022 RWE & OBA Working Group has been studying the feasibility of applying PA-generated RWD to outcomes-based agreements (OBAs) in Canada.[17] (Stay tuned for research findings in late 2022.) Also known as value-based agreements, OBAs help facilitate timely access to potentially life-changing therapies while mitigating the high clinical or economic uncertainties associated with many of these treatments.

A 2021 survey of both public and private Canadian payers found that 31% had successfully implemented at least one OBA.[24] Ned Pojskic, Leader for Pharmacy and Health Provider Relations at Green Shield Canada (GSC) and an adjunct lecturer at the University of Toronto, applauds this trend. "With OBAs, we can gain hard knowledge about how a drug performs in the real world, instead of speculating about its value," he says,[25] adding that "as stewards for plan sponsors' precious healthcare dollars, [insurers] have a responsibility to ensure that every dollar yields maximum value."[9]

As Canada marches toward an outcomes-based future, we can draw inspiration from the innovative OBAs in place in the US private payer sector, as exemplified by the Pfizer Pledge Warranty Program for the lung cancer drug Xalkori. As part of the agreement, Pfizer pledges to refund the entire cost of the medication (to the patient or health plan) if it fails to work within three months.[26] Amgen has upped the ante still further for Repatha, a medication that significantly lowers LDL cholesterol: the company will refund the full cost of the medication for patients who suffer a heart attack or stroke while on Repatha for at least 6 months.[27]

Such ambitious agreements depend on a strong data-collection infrastructure and on mutually accepted definitions of clinical benefit. Canadian stakeholders appear ready to tackle these challenges, and a major private payer has recently established an internal working group devoted to exploring innovative reimbursement models.[17]

Whether applied to an OBA or not, RWE can help shape the reimbursement destiny of a specialty medication. Tasked with balancing medical advances and market forces, insurers and PBMs have ample motive to accelerate RWE collection and bring forth reimbursement agreements that ensure timely access to life-changing medications.

Helen Stevenson, founder and CEO of the Reformulary Group – a third-party Canadian formulary developer advised by a committee of medical experts – sees "tremendous value in aggregating and analyzing real-world data on specialty drugs, including measurements of both productivity and quality of life. We need such metrics to holistically assess the benefits of these medications."

Shaping the future

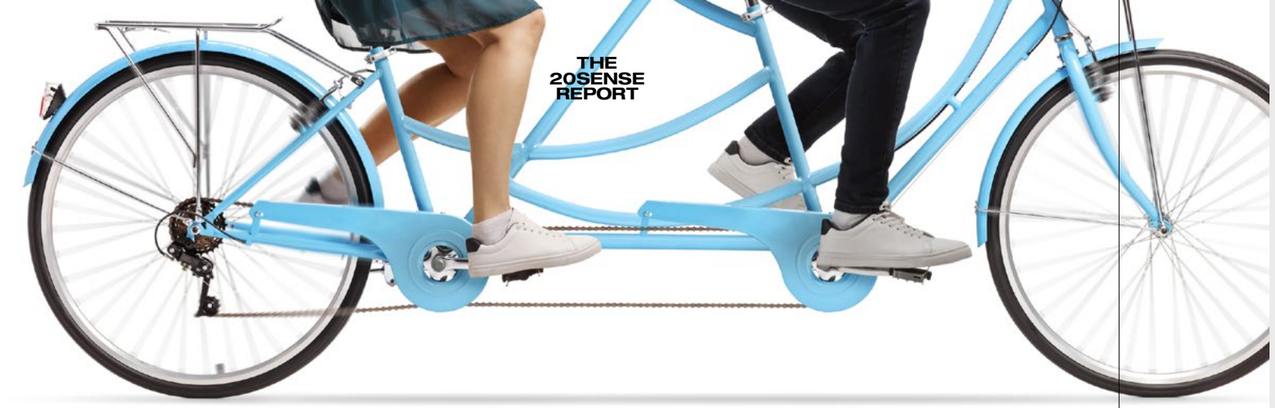
The private payer space has a tradition of agility, putting it in an ideal position to explore opportunities in RWE, OBAs, and other forward-thinking approaches. With specialty drug innovation showing no signs of slowing down, all signs point to disruptive changes within the space. As the need for health-economic approaches to drug reimbursement continues to grow, stakeholders are laying the groundwork for a value-based future.

At the same time, insurers and PBMs have been expanding their scope of expertise to deliver more comprehensive health services. As an example of this future-oriented thinking, GSC has recently acquired NKS Health, a specialty pharmacy focused on complex disease management, as well as digital pharmacy leader The Health Depot.[28] Zahid Salman, GSC's president and CEO, expects the acquisition to help position GSC as an "integrated health services organization and Canada's only payer-provider," with the ability to "deliver healthcare services while also administering all types of health benefits plans."

What happens next? Everyone with a stake in private drug reimbursement, including the 26 million Canadians who count on private payers to take care of their medical needs, will be watching with great interest.

"OBAs give us hard knowledge about how a drug performs, so we're not speculating about its value."

Ned Pojskic, Leader for Pharmacy and Health Provider Relations
Green Shield Canada



Better *Value*, Better *Health*

Daria O'Reilly sees health and economics as allied forces and is putting her forward-thinking ideas into action at TELUS Health

As TELUS Health's first full-time health economist (official title: Lead Health Economist, Pharmacy Consulting, Health Benefits Management), Daria O'Reilly uses both a clinical and an economic lens to help inform decisions around high-cost medications. With a PhD in epidemiology (specializing in pharmacoepidemiology), postdoctoral studies in pharmacoeconomics, and years of research and consulting experience in health technology assessment, Daria brings both academic depth and practical knowledge to her current role. Daria keeps it pragmatic and real in this chat about the management of high-cost drugs in the private payer space.

What prompted you to take on your new role?

It's not that new anymore – I've been here for four years! After spending all my life researching and assessing health technologies within a public payer framework, I thought it would be exciting to apply my learning to the private payer world. It hadn't been done before and it's an opportunity to blaze a new trail.

For context, what types of services does TELUS Health provide and where do you fit in?

TELUS Health is Canada's largest health IT company that offers broad and comprehensive healthcare services including electronic health records, benefits management, claims management, pharmacy management, and virtual care – which has come into its own since the pandemic.

I work in pharmacy benefits management (PBM), with a team of pharmacists and business analysts. Using both clinical and health-economic metrics, we work with our insurer clients to help them make evidence-based formulary decisions. We also have some formularies of our own. Our most comprehensive managed formulary is called Telus Complete. To get listed on this managed formulary, a medication needs to meet both clinical and cost-effective benchmarks.

I would also like to take this opportunity to make the distinction between a managed formulary – a formulary that we develop and that clients can select "off the shelf" – and formulary/plan management, which means applying tools to a formulary to support plan sustainability. Such tools may include prior authorization, generic substitution, and step therapy, and we can apply them to any formulary, whether managed, open, or provincial.

A few years ago, it would have been rare to find a health economist working for a PBM. What changed?

Drugs have become more complex and expensive, cell and gene therapies being notable examples. This means we need to consider the trade-offs between the cost of these medications and their value to patients and payers – and cost-effectiveness analysis is a way to quantify that. Cost-effectiveness involves more than determining cost: it also

assigns value to the outcome. So with the evolution of the medication landscape, we have seen a need for in-house health economics expertise within the private payer space. In fact, we're seeing more and more health economists enter the space, not just at TELUS Health.

Can you tell us about the evolution of health economics at TELUS?

TELUS first initiated the Enhanced Drug Review (EDR) process in 2017, based on requests from our insurer clients. They needed help interpreting evaluations from health technology assessors such as CADTH and applying them to the private payer landscape. So we developed a drug review process that considers both the clinical and economic impact of drugs being considered for formulary listing. What is unique about TELUS' EDR process is that we conduct the economic evaluation and budget impact analysis using a private payer lens. For example, we consider only private payer costs and also take elements such as productivity and absenteeism into account.

How has this initiative been received by your clients?

Carriers want to provide formularies that are attractive to employers, and our private payer lens helps them achieve this goal. Like all payers, our clients are looking to get value for their money and ensure plan sustainability.

Do you ever have to explain to payers how a high-cost medication can provide good value?

There may be instances when a costly medication may not seem affordable at first glance, but could provide great value in terms of increased survival, quality of life, or productivity. When talking to carriers and plan sponsors, my takeaway is always this: the goal is not to find the cheapest product, but the product with the greatest value.

How would you describe the main differences in perspective between the public and private payer worlds?

Cost-effectiveness is a well-established metric in the public sphere, but it's new to private payers. The same goes for budgets: unlike public payers, private payers don't use a budget as a starting point. Rather, they have tolerance limits for rising costs. On the flip side, concepts like pooling and risk management – standard considerations in the private insurance world – are foreign to public payers.

Do private payers consider different factors than public payers?

Yes. For one thing, private payers are dealing primarily with a working-age population, so they focus on goals such as keeping the workforce healthy, reducing absenteeism, and reducing disability claims. They also want to make sure their drug plans attract and retain quality employees. Public payers are primarily interested in society-level costs such as hospitalizations and physician visits. These differences in perspective can impact the cost-effectiveness of a drug.

How would you advise manufacturers when submitting drug dossiers to private insurers?

The submission process on the public side is rigorous and highly formalized, so manufacturers can use that as a starting point. They don't need to create a whole new process – just to tweak what they already have by removing irrelevant metrics and adding relevant ones. With a migraine medication, for example, productivity and absenteeism data is far more relevant than hospitalization data.

The past few years have seen product listing agreements (PLAs) become the norm in the private payer space. Where do you see this trend going?

PLAs are here to stay. We currently have negotiated PLAs and we have a PLA committee in place at TELUS. The next step would be to develop outcomes-based agreements (OBAs). Of course, OBAs come with their own challenges: Where do you find the data? Who collects the data? Who designs the studies? What outcomes are we interested in tracking? Even so, TELUS Health is very interested in getting into this area.

This raises the question of real-world data (RWD) and real-world evidence (RWE). How does TELUS Health generate or use RWE today?

We haven't used RWE to a great extent to date, but it's an area we plan to explore. With specialized treatments like gene therapies for rare diseases, it is sometimes impossible to generate the needed evidence through randomized clinical trials, so we need RWD to fill in the gaps. Potential sources of RWD include prior authorization forms, claims data, electronic medical records (EMRs), and patient support programs.

How do you see your own role at TELUS evolving in the future?

I'm interested in what happens not just in the lead-up to a formulary decision, but in the impact of the decision on the payer and patient. Did the medication deliver on its promises? Did the plan sponsor get the value they wanted? I hope to explore this area in greater detail.

> "Drugs have become more complex and expensive, and this is where a health-economic approach fits in. The goal is not to find the cheapest product, but the product with the greatest value."

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On the reading *list*

Private plan member use of specialty drugs on the rise with novel therapies

Private payer considerations: CADTH's pan-Canadian formulary discussion and the rare disease drug strategy

Pharmacoeconomic analysis and outcome-based agreements: What does it mean for private payers?

Processing delays for Quebec health coverage force patients to go private

Report on the 2020 Canadian private payer product listing agreement study

Public vs. private payer perspective: Implications on cost-effectiveness

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