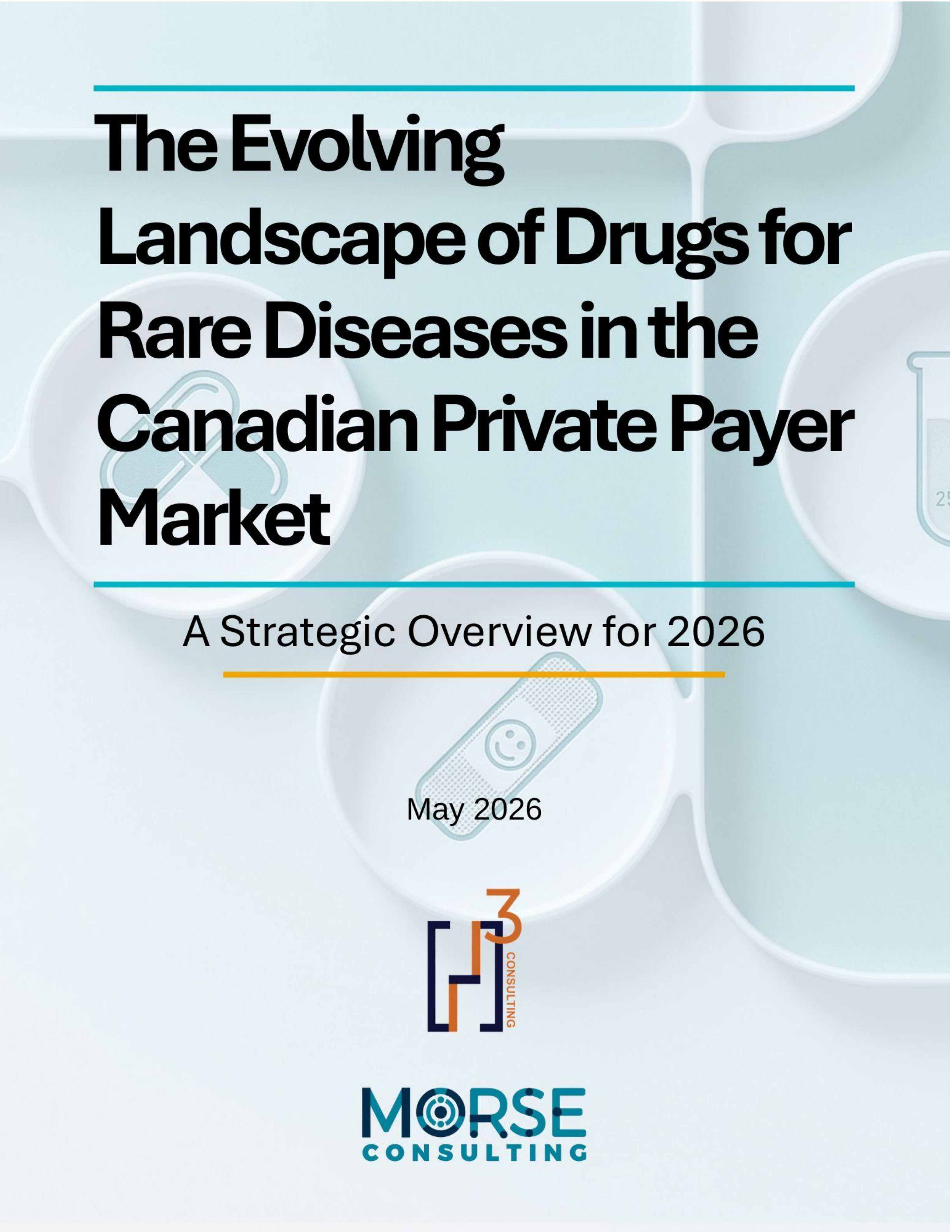

The Evolving Landscape of Drugs for Rare Diseases in the Canadian Private Payer Market

A Strategic Overview for 2026

May 2026

MORSE
CONSULTING

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At a Glance

1. DRD spending in Canada reached an estimated $6.1 billion in 2025, growing at 31% annually over the prior decade. DRDs still represent approximately 3% to 5% of total private plan drug costs.
2. The insurance industry's drug claim risk sharing mechanisms cover only a fraction of catastrophic drug claims, leaving most of the financial risk with insurers, employers, and plan members.
3. Based on 2019 data, private plans provided access to new drugs in one-third of the time relative to public drug plans. Public time-to-list has decreased since; updated timelines are not yet available for private plans.
4. The federal National Strategy for Drugs for Rare Diseases excludes private drug plans, leaving approximately 27 million Canadians outside its scope.
5. US "Most Favored Nation" pricing policies and a growing DRD pipeline are introducing new uncertainty into the Canadian market.

Executive Summary

Imagine someone's prescription costing three times Canada's median annual household income[1] — every year, for life. This is the reality facing Canadian employers as breakthrough therapies for rare diseases transform medicine. Most drugs for rare diseases (DRDs) offer genuine hope[2] to patients with previously untreatable conditions, but they also pose a growing challenge to the private health benefit plans that cover 27 million Canadians.

This desk research report is the first phase of a three-part inquiry into DRDs in the Canadian private payer market. It maps the current landscape through verified data and published sources. **Phase 2** will engage stakeholders across the ecosystem through expert interviews, and **Phase 3** will present a consolidated analysis with recommendations. Whether you work in the pharmaceutical ecosystem, insurance, benefits consulting, or patient advocacy, this work is designed to help all stakeholders understand the forces reshaping drug coverage in Canada.

What the data tell us

- **DRD spending has grown rapidly.** Total DRD spending in Canada reached $5.3 billion in 2022, and an estimated $6.1 billion in 2025. Between 2013 and 2022, DRDs had a compound annual growth rate of 31%, more than four times the rate for all prescription medicines (7%).[3] By the end of 2019, more than half (56%) of approved DRDs cost more than $200,000 per year,[4] and an average of 14 new DRDs were approved each year between 2019 and 2024.[5] By 2024, DRDs captured 28% of the Canadian branded pharmaceutical market.[6] Telus Health reported an average annual eligible DRD cost of $190,446 in 2025.[7] The drug innovation pipeline is increasingly a rare disease pipeline.

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[1] Statistics Canada reported that the median household after-tax income in Canada was $74,200 in 2023.

[2] PMPRB (2022) reported that about half (52%) of DRDs reviewed between 2020 and 2019 offered at least moderate improvement over available comparators.

[3] Patented Medicine Prices Review Board, 2024. *PMPRB Annual Report 2022*. The 2025 estimate uses the PMPRB percentage (13.4%) and 2025 forecast prescription drug spending ($45.2 billion) reported by the Canadian Institute of Health Information.

[4] Lungu, E, 2020. PMPRB Research Webinar, June 23.

[5] Ibid. Yang et al.

[6] Yang J, T Rahman, S Rizzardo, 2025. *Navigating the market landscape for rare disease drugs in Canada*. PMPRB poster at CAPT Conference, September.

[7] Telus Health, 2026. *Drug Data Trends & National Benchmarks*. p. 23.

- **Private payers play an important but bounded role.** In 2020, private insurers reported paying $650 million for DRDs[8] — roughly 21% of total DRD spending that year. Our estimates suggest private payers spent a comparable amount in 2025, which amounted to about 11% of total DRD spending.[9] DRDs accounted for roughly 3–5% of all private drug plan costs.[10] Public drug programs have absorbed most of the substantial cost growth, in part because many DRDs are intravenous oncology products administered in hospital or clinical settings which are generally excluded from private drug plans. An authoritative national source is needed to publicly report annual private DRD spending.
- **The safety net provides limited protection**. Canada's two insurance industry drug claim risk sharing mechanisms — CDIPC for most of Canada and QDIPC for Québec — provide limited protection. In 2023, only about 13% of catastrophic claims eligible for the national pool were actually covered;[11] the rest was absorbed by insurers and their plan sponsor clients. In Québec, the pool covered less than 5% of eligible claims.[12] Neither mechanism has been fundamentally updated to keep pace with the growth of DRDs.
- **Access varies widely**. Based on 2019 data, private plan members could typically access a new drug within 7 to 8 months of Health Canada approval, compared to approximately 25 months through public plans.[13] While timelines have likely improved for public plans,[14] updated data are not yet available for private plans. Where a patient lives, who their employer is, and whether public or private coverage applies first all shape access to treatment.
- **The National DRD Strategy excludes private plans**. The federal government's strategy is backed by $1.5 billion over three years, directed exclusively to provincial and territorial drug programs.[15] Employer-sponsored plans, which account for 40% of total prescription drug funding,[16] are outside its scope. Some employers are already excluding DRDs provided through their public plan,[17] which may sensitize them to the broader risk associated with covering DRDs.
- **External pressures are building**. US "Most Favored Nation" pricing policies[18] are introducing new uncertainty into drug manufacturer pricing and negotiation strategies worldwide, including in Canada. The full implications for DRD access, launch timing, and net pricing in Canada remain unclear and are evolving.

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[8] Canadian Life and Health Insurance Association, 2020. *Submission to the Government of Canada on its consultation on a National Strategy for High-Cost Drugs for Rare Disease*, March.

[9] Based on PMPRB's 2019 estimate that DRDs are 3.6% of private drug spending, and CIHI's 2025 forecasts for private drug insurance ($18.3 billion), private insurance accounts for 11% of total DRD spending: ($18.3 x 0.036 = $659 million, which is 11% of total DRD spending ($6.1 billion).

[10] Based on data from Telus Health (5.2% in 2025), Innovative Medicines Canada (2.9% in 2025), and the PMPRB (3.6% in 2019).

[11] Canadian Drug Insurance Pooling Corporation, 2025. *2023 CDIPC Pool Results At-A-Glance*; https://cdipc-scmam.ca/cdipc-information/

[12] Québec Drug Insurance Pooling Corporation (QDIPC), undated. *General Statistics (2018-2022)*. https://mutualisation.ca/wp-content/uploads/2024/04/Web_P2022_Summary-and-General-Statistics_EN.pdf

[13] Farago J, 2025. *Innovative Medicines Canada [IMC] Drug Policy Update, Cost Drivers and Preserving Value*. IMC presentation at Connex Breakfast Network, March 20, 2025.

[14] MORSE Consulting, 2025. Proprietary data in *CRaFT DRD Sub-Report 2025*.

[15] Government of Canada, undated. *The National Strategy for Drugs for Rare Diseases*. https://www.canada.ca/en/health-canada/services/health-services-benefits/strategy-drugs-rare-diseases.html

[16] Canadian Institute of Health Information, 2025. *National Health Expenditure Trends*, Table G.14.1a

[17] Personal communication (2026) conveyed by a senior insurance company private drug plan expert.

[18] United States White House, 2025. *Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation*. May 12.

1. The Critical Role of Private Payers in DRD Coverage

Private health plans are an important, highly valued part of an employee's total compensation. About 90% of private health insurance in Canada is provided through workplaces and tied to full-time employment.[19] While these plans offer a variety of benefits, prescription drug coverage represents the largest component.

1.1 How We Got Here: A Brief History

Employer-sponsored drug plans emerged in the 1970s as a direct consequence of government decisions to limit public drug coverage to seniors and those on social assistance. The growth of private plans was further encouraged by tax policy: employer contributions are tax-deductible, and benefits are non-taxable to employees in all provinces except Quebec.

This historical foundation created Canada's distinctive hybrid system—universal coverage for hospitals and physicians, but fragmented coverage for prescription drugs.

The system worked reasonably well when the most expensive drugs cost a few thousand dollars annually. It has struggled since the advent of DRDs.

1.2 Defining "Drugs for rare disease"

Unlike the United States or European Union, Canada has no formal regulatory definition of "orphan drug", also known as a DRD, in its drug legislation.

The Patented Medicine Prices Review Board (PMPRB) in Canada uses the term "Expensive Drugs for Rare Diseases" (EDRDs), defined below.

1. The drug must have an orphan designation from the US FDA or European EMA (confirming it treats a rare condition), and
2. It must exceed a cost threshold: $100,000 annually for non-cancer drugs, or approximately $97,500 annually for cancer drugs (~$7,500 per 28-day cycle).[20]

This definition deliberately excludes lower-cost orphan drugs. The PMPRB's focus for DRDs is on therapies that collectively pose sustainability concerns to payers—the intersection of rarity and extreme cost. Canadian governments and private sources use the same definition for DRDs. Orphan drugs costing less than $100,000 are excluded from consideration in this report.

Not only do DRDs have high unit costs at list price, aggregate spending on DRDs has grown substantially over the past 20 years. By the end of 2019, more than half (56%) of DRDs cost more than $200,000[21] per year, and up to $4.7 million[22] for *Hemgenix*®, a one-time gene therapy.[23] DRDs

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[19] Op cit. CLHIA, 2025.

[20] Op cit. PMPRB, 2024.

[21] Lungu, E, 2020. *PMPRB Research Webinar*, June 23.

[22] Canadian Agency for Drugs and Technologies in Health (CADTH), 2024. *CADTH Reimbursement Recommendation: Etranacogene Dezaparvovec (Hemgenix)*.

[23] These costs are manufacturers' list prices, but significant discounts are negotiated by public and most private insurance plans.

had a 31% compound annual growth rate (CAGR) between 2013 and 2022, more than four times the CAGR for all prescription medicines (7.0%). At 13.4% of the total prescription drug market,[24] Canada spent $5.3 billion on DRDs in 2022, and $6.1 billion in 2025.

On average between 2019 and 2024 (inclusive), 14 new DRDs were approved each year.[25] By December 31, 2024, 167 DRDs had been approved in Canada.[26]

1.3 The Rising Spending on DRDs and Private Payer Sustainability

Currently, 22 members of the Canadian Life and Health Insurance Association (CLHIA) manage more than 100,000 private health plans, covering about 27 million Canadians.[27] These plans provide vital access to DRDs—but precise, current cost data are difficult to obtain.

What we know about private plan DRD spending:

- In 2019, DRDs accounted for 3.6% of private drug plan claim costs.[28] Using $12.6 billion in total private drug insurance costs in 2019,[29] private plans paid approximately $454 million for DRDs that year.
- In 2020, the total DRD market was estimated at $3.1 billion.[30]
- However, CLHIA reported that its members paid $650 million for DRDs in 2020, providing access to 13,000 Canadians.[31] Private drug insurance expenditures were $12.8 billion in 2020,[32] meaning DRDs were 5% of total private paid claims, and roughly 21% of total DRD spending in Canada that year ($650M of $3.1B).
- More recently, Telus Health reported 5.2% of its 2025 eligible claims were for “ultra-high-cost drugs” ($100,000+) with nearly half (48%) of that spent on Trikafta.[33] Telus Health reported an average annual eligible DRD cost of $190,446 in 2025.[34] Another extensive data analysis reported 2.9% of private plan costs were for “high-cost drugs” costing more than $100,000.[35] There have been no industry-wide estimates since 2021.
- Using 2025 forecasted private insurer drug spending of $18.3 billion, and assuming DRDs remain at 3.6% of that amount, insurers likely paid $659 million for DRDs last year. This would be almost 11% of total estimated 2025 DRD spending.

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[24] Op cit. PMPRB, 2024.
[25] Op cit. Yang et al. 2025.
[26] PMPRB, 2025. *Meds Entry Watch 9th Edition*.
[27] Op cit. CLHIA 2025.
[28] Op cit. Lungu, 2020.
[29] Canadian Institute for Health Information, 2025. *National Health Expenditures*, Table G.14.1a
[30] PMPRB, 2022. *Expensive Drugs for Rare Diseases: Canadian Trends and International Comparisons, 2011–2020*.
[31] Op cit. CLHIA, 2021.
[32] Op cit. CIHI, 2025.
[33] TELUS Health, 2026. *Drug Data Trends & National Benchmarks*. p. 23.
[34] Ibid.
[35] Innovative Medicines Canada (IMC), 2025. *Cost Drivers Report*. p. 10.

Accurate accounting of DRD spending is essential, and yet there is no authoritative public source for either the total market or the private insurance segment. Values depend on the source and the quality of their estimates.

However, current cost estimates coupled with extremely high growth rates and an increasing DRD pipeline create a significant financing challenge for private drug plans. While this has not yet surfaced as a priority, that is likely to change in the near future.

1.4 Coverage Gaps and Limitations in Private Drug Plans

Not all workplaces offer health plans, and many cover only full-time, permanent employees and their families. Part-time and casual workers are rarely provided with coverage. In general, large and unionized workplaces have higher-quality health plans than small employers.

Small businesses (fewer than 100 employees) account for 98% of all private Canadian employers and 47% of private sector employment.[36] Yet only about half of them provide health benefit plans.[37] This represents a significant coverage gap affecting millions of working Canadians.

Plan design features can create significant financial risks for plan members:

- In 2024, one in five drug claims had plan designs with either annual (11%) or lifetime (9%) coverage limits, and seven in 10 claimants (71%) had some level of coinsurance applied to their drug claims. [38]
- Among "certificates" with coinsurance, about 65% paid 20% out-of-pocket, and 13% paid 25% or more in 2022.[39]
- While manufacturer Patient Support Programs (PSPs) often help cover out-of-pocket costs, coinsurance even at a typical 20% level (i.e., a minimum of $20,000 for DRDs) makes DRDs unaffordable for almost all Canadians without additional assistance.

2. The Current State: A Fragmented System

Treatment costs for rare diseases with available drug therapy are so high that patients must rely on private or public insurance for access. But coverage rules and regulations are not coordinated between these two payer groups in most provinces. There are no standards for plan design, drug eligibility, or cost-sharing. The result is a disjointed system that creates uncertainty for patients, providers, and payers alike.

2.1 The Public Payer Framework

Assessment of drugs for public drug coverage involves multiple organizations, typically operating in sequence. Following Health Canada approval, the Canadian Drug Agency (CDA-AMC) and INESSS (in Québec) conduct health technology assessments. The pan-Canadian Pharmaceutical Alliance

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[36] Innovation, Science and Economic Development Canada, 2026. *Key Small Business Statistics*.
[37] Manulife, 2013. *Small Business Research Report*.
[38] Express Scripts Canada, 2025. 2025 *Drug Trend Report*, p. 54.
[39] Telus Health, 2023. *2023 Drug Data Trends & National Benchmarks*. p. 42

(pCPA) then negotiates terms for reimbursement typically including confidential net pricing and potentially other risk mitigation elements. Combined, these steps took, on average, 25[40] to 30 months[41] between 2018 and 2023. Afterwards, each provincial government determines whether they will fund a drug based on the negotiated terms and jurisdictional priorities.

Although patient involvement in the HTA process and publicly available reports and formularies provide greater transparency, the market access process and jurisdictional differences lead to lengthy wait times and inequitable coverage for public plan beneficiaries. For non-oncology DRDs specifically, MORSE's CRaFT Report (2025) found it generally took 24.6 months for a new non-oncology DRD to become available to public plan beneficiaries after submission to CDA-AMC for review between 2021 and 2024, compared to approximately 20 months for non-oncology drugs overall.[42]

DRDs do receive some special consideration in the HTA process. CDA-AMC may accept less mature clinical data and place greater emphasis on real-world evidence when clinical trials are less feasible due to small patient populations.[43] INESSS states that rare-disease reviews involve "special attention to the promise and plausibility of treatments", in a context of high unmet need, limited evidence and other variables specific to DRDs.[44]

2.2 The Private Payer "Black Box"

Canada's private drug insurance market is competitive, highly fragmented, and opaque. There is no single private HTA agency, no standards for plan design or formulary outside Quebec, and no standard approach to prior authorization, a process that applies to virtually all DRDs.

The evaluation process, objectives, and decision criteria are not disclosed and vary by insurer and by product. There is no patient involvement in coverage decisions, unlike the public HTA process. On the positive side, manufacturers can sometimes expedite reviews through early consultations before Health Canada approval, and by providing timely, complete information customized to private payer priorities. As well, time to listing took one-third as long in the private market compared to provincial plans (226 vs. 772 days) in 2019.[45] Recognizing that timelines have changed and likely converged since then, updated data will be pursued in the next phase of this project.

Each insurer provides many formularies that address plan sponsor needs for coverage quality, access and cost control, i.e., affordability and sustainability. Many insurers negotiate confidential Product Listing Agreements (PLAs), either directly or through pharmacy benefit managers. Most PLAs involve relatively simple price discounts, per patient cost caps or progressive discounting based on volume. The form of cost reductions is evolving as PLAs become a market differentiator.

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[40] Conference Board of Canada, 2024. *Access and Time to Patient: Prescription drugs in Canada*

[41] Gaudette E, S Rizzardo KR Pothier, M Tadrous, 2025. *Factors delaying the public listing of drugs in Canada*. Presentation at ISPOR, May.

[42] MORSE Consulting, 2025. Proprietary data in *CRaFT DRD Sub-Report 2025*.

[43] Canada's Drug Agency, 2025. *Procedures for Reimbursement Reviews*. Table 24, pages 143-44.

[44] de Guise, M, 2023. Challenges of assessing the value of treatments for rare diseases: Insights from INESSS. Presentation at Canadian Organization for Rare Disorders, Fall Conference.

[45] Op cit. Farago, 2025.

While insurers and PBMs are providing increasingly sophisticated risk management, it's unclear whether they access the limited clinical and epidemiological expertise available on rare diseases in Canada to inform DRD listing decisions. A 2020 survey of drug manufacturers and private payers concluded: "[Private] Payers agree that DRDs are the most challenging reimbursement category."[46]

2.3 The First-Payer/Second-Payer Complexity

Patients with access to both private and public drug plans know that the two payer groups are far from synchronized in evaluation, eligibility, or coordination of benefits. Historically, a payer aims to shift costs to another, however, patients and plan sponsors benefit when insurers coordinate coverage with public plans. Insurers know or can often model their savings in provinces that are first payer. Still, patients must navigate different eligibility rules and documentation requirements, often during times of extraordinary stress.

- Private plans are typically first payer in Ontario, Quebec, and Atlantic Canada, but second payer in Western Canadian pharmacare provinces after provincial deductibles have been fulfilled. BC's Expensive Drugs for Rare Diseases program covers DRDs costing more than $100,000 on a last-resort basis. Alberta's Non-Group and Seniors plans will become payer of last resort later in 2026.
- Many oral cancer drugs require special authorization and exceptional access in Ontario and Atlantic Canada, shifting costs for those who don't fulfill the stringent public criteria to private plans or manufacturer Patient Support Programs (PSPs).
- Patients may need to document insurance denials or coverage limits to engage a second payer. Delays can mean patients must pay all costs; however, this is rare because manufacturer PSPs often cover costs during reimbursement navigation. After private or public insurance has been confirmed, PSPs also cover most copayments, saving patients thousands of dollars per month.
- Private insurers have often waited for public HTA outcomes before determining eligibility for coverage, which has slowed access for plan members. However, initiatives such as CDA's Time-Limited Recommendation and Target Zero initiatives can accelerate HTA, and minimize delays for private coverage because insurers will know CDA's coverage recommendation much more quickly.

Concerns exist that private plans might specifically reduce or eliminate DRD coverage, effectively transferring extremely high costs to public plans. Adding to this tension: private drug plans are excluded from the national rare disease drug strategy, which is discussed in section 7.

Adding to complexity, insurers are more frequently faced with "private only" reimbursement strategies when manufacturers decide not to pursue a public plan listing. When this occurs, private plans bear the full cost during patent protection and afterward due to the pCPA generic drug pricing framework. This approach is likely to delay private listing decisions.

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[46] Connex, PDCI Market Access, H3 Consulting, 2021. *Report on the 2020 Canadian private payer product listing agreement study*. p. 26.

3. The Safety Net: Claim Pooling and Insurer Risk-Sharing

If you manage the health benefits at a 50-person company and an employee is diagnosed with a rare condition requiring a $400,000 annual therapy, what happens to your insurance renewal? Without optional protection, you'll face a premium increase that might make continuing coverage impossible.

This is where claim pooling and risk-sharing come in. Although sometimes used interchangeably, they're not the same, but can be described as two sides of the same coin. Both are used to dampen large and unexpected swings in drug claim volatility.

Unfortunately, neither approach works perfectly in this age of rapid growth in DRD spending, and willingness to pay cannot be assumed. Improvements to these financial risk mitigation tools are essential for continued DRD coverage in the private payer market.

3.1 Plan Sponsor Claim Pooling

Pooling is an insurer mechanism to reduce the cost volatility of their plan sponsors' drug claims. Employers can choose to protect their plans from all member claims exceeding a certain threshold (e.g., $10,000 or $25,000) by paying a pooling charge. As a result, those employers are protected from excessive costs and can mitigate annual premium increases.

Insurers set pooling charges prospectively based on their historical costs, and in recent years both thresholds and charges have substantially increased. Many drugs impact pooling costs, not just DRDs. In fact, it is often patients with complex health needs taking multiple lower-cost drugs with or without a specialty drug, who most often trigger pooling. Employers have implemented a number of other controls to cap their liability (see Sec. 1.3), which affect access to DRDs. There is no information on how many plans limit out-of-pocket drug costs for members.

3.2 Insurer Risk Sharing

Risk-sharing is a complementary mechanism devised by CLHIA to distribute high-cost drug claims across insurer member companies based on market share. The Canadian Drug Insurance Pooling Corporation (CDIPC) was implemented in 2012 to spread risk across all insurers (N=22) providing drug insurance outside Québec.[47] Unlike claim pooling, this process does not directly affect plan sponsors.

Québec has had a separate—and arguably more effective—risk-sharing mechanism in place since 1997, when the province implemented its universal, social insurance drug plan. The Québec Drug Insurance Pooling Corporation (QDIPC), also controlled by the CLHIA, covers all drug plans provided by employers with up to 6,000 employees,[48] Claims not covered by QDIPC may be eligible for CDIPC protection.

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[47] Canadian Drug Insurance Pooling Corporation (CDIPC), 2025. Risk-sharing members are noted here: https://cdipc-scmam.ca/who-is-cdipc/

[48] Québec Drug Insurance Pooling Corporation (QDIPC): https://mutualisation.ca/en/

A) CDIPC: Canada, except Québec

Eligible drug claims must exceed the Initial Threshold of $65,000 annually for two consecutive years, and then must each year exceed the $32,500 Ongoing Threshold.[49]

In 2023, 734 plan members incurred claims of at least $100,000, double the number (364) in 2019. CDIPC supported over 16,000 employers and 36,000 members, and covered 81 new high-cost drugs.[50] However, its limitations are substantial:[51]

1. CDIPC only covers recurrent claims from fully-pooled plans, about 15% of the group market. Other plans are ineligible and must voluntarily buy drug claim pooling.
2. Only 12.6% ($52 million) of catastrophic drug claims exceeding $32,500 were subject to the industry pool. The residual risk ($360 million) was absorbed by insurers and recovered through their employer clients.[52]
3. CDIPC covers only up to $500,000 per claimant annually, so any excess costs revert back to the insurer and their clients.[53]

The CDIPC model provides protection only to the small businesses that buy fully pooled (insured) health plans. In addition to excluding all non-recurring (one-time) drug claims, such as gene therapies and many oncology drugs that confer only limited increases in survival, a large majority (by cost) of the private market is ineligible:

- Medium-sized companies, i.e., 25-100 employees, often use experience-rating for health benefits, where the sponsor is eventually responsible for all claim costs
- Larger companies, typically those with more than about 100 employees, carry the full risk of DRD claims, because the insurer provides administrative services only (ASO).

CDIPC has not been fundamentally updated since inception in 2012, despite the rapid ascent of DRDs.

B) QDIPC: The Québec Model

Drug insurance is mandatory in Québec, and a little over half (55%) of the population gets their drug insurance from private plans. QDIPC has existed since 1997, and differs from CDIPC in important ways, most notably that all drug plan funding models are included: pooled, experience-rated and ASO. Only plans covering more than 6,000 members are exempt because the largest companies tend to have more predictable claim costs.

QDIPC has its own challenges. The cost of eligible claims doubled between 2018 and 2022 to $184 million. The actual payout increased 26% during that time to $8.4 million, up 70% as a share of all

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[49] Thresholds may change. A glossary explains these: https://cdipc-scmam.ca/glossary/
[50] CDIPC, 2025b. News Release, April 28.
[51] CDIPC, 2025a. 2023 CDIPC Pool Results At-A-Glance; https://cdipc-scmam.ca/cdipc-information/
[52] Op cit. CDIPC, 2025a.
[53] Ibid. CDIPC, 2025a

eligible claims versus 2018.[54] Additionally the payout from the pool is just 4.4% of eligible claims, a much lower percentage than CDIPC (12.6%).

These low percentages, especially in Québec, indicate plan sponsors and members, as well as individual insurers, receive minimal protection from existing drug risk-sharing mechanisms. No changes have been announced to either model that would mitigate risk to employers or improve affordability for plan members.

3.3 Could Quebec's Model Work Nationally?

The core challenge for CLHIA members is whether they can expand, refine, and even consolidate their risk-sharing models and improve public reporting. Failure to properly, equitably and consistently protect plan sponsors, the largest of which operate across Canada, encourages employers to limit their own liabilities through unilateral plan design changes. Their changes will aim to reduce their financial risk from DRDs.

However, two significant barriers exist to adopting Québec's approach to the national market:

1. **The mandate problem.** QDIPC works because Québec requires drug coverage under the Prescription Drug Insurance Act, if the employer provides a health plan. Outside Quebec, health benefit design and cost-sharing are voluntary and determined by the employer or insurer, unless they are collectively bargained. Mandatory pooling fees might push some employers to drop health coverage entirely.
2. **Performance comparison**: QDIPC and CDIPC do not report annual results in the same way, so anticipating results under a new consolidated national model is very difficult.

That said, Québec has successfully operated its regulated and more comprehensive system since 1997. CDIPC was voluntarily established by the CLHIA in 2012, and its 22 member insurers would have to agree on a significant expansion of coverage, and their own liability. At time of writing, there is no public indication they are considering expanded protection for plan sponsors.

4. Patient Support Programs: Critical Infrastructure with Limitations

Manufacturer-funded Patient Support Programs (PSPs) provide critical services for patients with rare diseases, including administrative and financial support, reimbursement navigation assistance, training in drug administration and temporary access to free doses during coverage gaps. For many patients, PSPs are the only way to afford and access medications.

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[54] QDIPC, undated. General Statistics (2018-2022). https://mutualisation.ca/wp-content/uploads/2024/04/Web_P2022_Summary-and-General-Statistics_EN.pdf

A 2019 survey indicated PSPs retain over 75% of patients for two years or longer—evidence of their importance in the patient journey.[55] When structure and contracts permit, PSPs can also provide vital real-world evidence on treatment outcomes to drug manufacturers.

However, PSPs also have limitations. Program designs and services vary—even within a single manufacturer—and collected data are proprietary and usually unavailable to inform other stakeholders. This creates information silos that limit system-wide learning.

DRDs are primarily dispensed and administered through hospitals, selected clinics and specialty pharmacies, rather than retail pharmacies. Note that medicines administered in hospitals, or “hospital-like” settings, are almost always ineligible under private drug plans.

Major PSP vendors include Shoppers Drug Mart, Sentrex, McKesson, Bayshore, Cencora, and BioScript. Some of these companies provide similar services (‘specialty drug access programs’) to large insurers. The combination of limited suppliers and significantly overlapping services between drug manufacturers and insurers raises questions about transparency, coordination and competition among the vendors.

5. Managed Entry and Outcomes-Based Agreements

Plan member access to DRDs may be protected through managed entry agreements (MEAs) and outcomes-based agreements (OBAs). In addition to a price reduction, these arrangements can link reimbursement to demonstrated patient outcomes, sharing risk between manufacturers and payers when clinical evidence is uncertain.

In a 2021 survey, 89% of stakeholders saw a need for OBAs in Canada, and 31% of surveyed payers reported having successfully implemented one or more.[56] The number of approved DRDs increased by one-third between 2021 (125) and 2024 (167). However, not all insurers have the specialized expertise and sophisticated systems needed - or the will - to negotiate contract terms and report real-world data and outcomes, although systems have been improving. OBAs may require manufacturers to pay when contracted outcomes don't materialize as expected. The next phase of this project will investigate private payer MEAs and OBAs.

Given very limited patient populations and clinical expertise, and their ultra-high cost, it is likely that a single, consolidated public-private market will be needed to properly evaluate DRD performance and value.

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[55] 20Sense, 2023. Real-world data from patient support programs in Canada: Where we are today, and what’s next. *The 20Sense Report*, Issue 24. https://static1.squarespace.com/static/61d708f9587415184afa9452/t/6446bd3aad7ed1687f11b76a/1682357567257/Issue24.pdf

[56] Op cit. Connex-PDCI-H3, 2021.

6. US Market Considerations: The MFN Policy Impact

The recent American "Most Favored Nation" (MFN) policy,[57] may significantly influence drug manufacturer pricing in many countries, and subsequent negotiations with Canadian payers for drugs including DRDs.

6.1 The US Executive Order

In May 2025, the US president ordered drug manufacturers to lower drug prices in Medicare and Medicaid to the lowest selling price in certain other nations.[58] The president also threatened tariffs in September 2025 on pharmaceutical ingredients and finished products. By January 2026, 16 drug manufacturers had reached deals to accommodate the executive order.[59]

The policy is being implemented through several mechanisms at varying stages of development: (i) A voluntary Medicaid pilot (GENEROUS) referencing prices in eight countries including Canada,[60] and (ii) Two proposed mandatory Medicare models (GLOBE for Part B,[61] GUARD for Part D[62]) referencing prices in up to 19 countries, also including Canada.

US patented drug prices are by far the highest among OECD nations.[63] Price negotiation and HTA processes are not universally applied in the US as they are in most other countries.[64]

6.2 Implications for Canadian DRD Access[65]

1. **The list and net price distinction**: In Canada, list prices are regulated by the PMPRB and are publicly visible. However, net (discounted) prices are negotiated and confidential, meaning

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[57] United States White House, 2025. *Delivering Most-Favored-Nation prescription drug pricing to American patients*. May 12. https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/

[58] United States White House, 2025. *Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation*. May 12.

[59] Allan AK, 2026. AbbVie inks MFN drug pricing deal, pledges $100bn to US R&D. *Pharmaceutical Technology*, January 13. https://www.pharmaceutical-technology.com/news/abbvie-mfn-us-drug-pricing-deal-trump-randd-commitment/?cf-view&cf-closed

[60] Centers for Medicare & Medicaid Services, 2026. GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model. March 2. https://www.cms.gov/priorities/innovation/innovation-models/generous

[61] Centers for Medicare & Medicaid Services, 2025. *GLOBE (Global Benchmark for Efficient Drug Pricing) Model*. December 29. https://www.cms.gov/priorities/innovation/innovation-models/globe

[62] Centers for Medicare & Medicaid Services, 2025. *GUARD (Guarding U.S. Medicare Against Rising Drug Costs) Model*. December 29. https://www.cms.gov/priorities/innovation/innovation-models/guard

[63] Mulcahy AW, CM Whaley, M Gizaw, et al., 2021. U.S. Prescription Drug Prices Are 2.5 Times Those in Other OECD Countries. *Rand Corporation*. April 20.

[64] Mulligan K, D Lakdawalla, PJ Neumann, et al., 2020. Health technology assessment for the U.S. healthcare system. *A White Paper from the USC Schaeffer Center-Aspen Institute Advisory Panel on Health Technology Assessment in the U.S.*

[65] Many of these points are drawn from: MORSE Consulting, et al., 2026. *US MFN and Its Implications for Pharmaceutical Access: From a Multinational Expert Network*. March. Available from MORSE Consulting.

prices here are less exposed to US reference pricing than countries where final negotiated prices are more transparent, such as Germany or Japan.

2. **Potential "chilling effect" on access:** Despite contractual protection, drug manufacturers are concerned that confidential net prices in Canada and elsewhere could eventually be exposed or inferred, triggering significant price cuts in the much larger US market. Drug manufacturers could become less willing to negotiate aggressively on net Canadian pricing and potentially delay market entry.[66]
3. **DRD price increases:** Rather than simply reduce US prices, the Executive Order appears more likely to result in increased prices in other countries. At least one manufacturer has stated intentions to increase prices for one product in Canada and the United Kingdom.[67] However, Eli Lilly then reduced the Canadian price of Mounjaro and Zepbound by 20% just four months later in the face of regulatory and competitive pressures.[68]
4. **DRD-specific considerations**: The MFN policy's impact varies by therapeutic area, payer mix, and the gap between list and net prices, all of which tend to be pronounced for ultra-high-cost DRDs.
5. **Indication strategy**: DRDs often launch with a single narrow indication and later expand it. If indication expansions trigger price renegotiations in reference countries, manufacturers may become more cautious about pursuing label expansions, potentially limiting access to new DRD indications in Canada.
6. **Global precedents:** Some countries like France and Switzerland have had scheduled price reduction assessments on all patented drugs for some years, creating additional MFN-related pricing uncertainty in global and perhaps Canadian markets.

Certainly, pricing negotiations here do not occur in isolation. The full impact of MFN policies on Canadian DRD access remains uncertain and will evolve during implementation.

7. The National DRD Strategy and Private Drug Plans

In March 2023, the federal government launched Canada's first National Strategy for Drugs for Rare Diseases, backed by up to $1.5 billion over three years (2024-2027) to help provinces and territories improve access to new and existing drugs, early diagnosis, and screening for rare diseases.[69] It has since extended annual funding at the same $500 million level, or at about 8% of estimated 2025

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[66] In December 2025, negotiations were concluded by the pCPA when Amgen was "not prepared to enter negotiations." It is unclear to what extent US-MFN motivated Amgen's response. https://www.pcpacanada.ca/negotiation/22488.

[67] Hannay C, 2025. *Eli Lilly hikes price of Mounjaro weight-loss drug in Canada, Britain after pressure from Trump*. Globe and Mail, August 14.

[68] Hannay C, 2025. *Elli Lilly & Co. cuts price of popular diabetes and weight-loss drugs in Canada*. Globe and Mail, December 17.

[69] Health Canada, 2023. News release: Government of Canada improves access to affordable and effective drugs for rare diseases. March 22.

spending (13.4% of $45.2 billion). The Strategy initially appeared to be a landmark moment for the rare disease community.

By March 2025, all provinces had signed bilateral deals with the federal government. Six provinces have listed all nine drugs identified, but there is no indication yet that limited funding and provincial caution have significantly expanded DRD access.[70]

The strategy channels federal funding through provinces to help their drug programs cover a limited number of new and emerging therapies for rare diseases. The strategy aims to eventually standardize access and reduce interprovincial variation in public DRD coverage.

However, employer-sponsored plans are ineligible for federal rare disease drug funding, so approximately 27 million Canadians are outside the strategy's scope if they are not covered by a public drug plan. Consequently, employers are already excluding DRDs covered by their province,[71] and this may sensitize them to the risk of covering *any* DRDs.

Small volumes, ultra-high cost, uncertain evidence and very high business risk exacerbated by inadequate insurer claim pooling and risk-sharing, indicate the need for a coordinated approach between public and private plans to help ensure appropriate DRD coverage.

8. Different Lenses: Stakeholder Perspectives

Drug manufacturers and insurers often have points of tension and misaligned interests. In most cases, both are interested in timely and appropriate patient access while managing prices and costs—but they weigh and track these goals differently. Contracts to control drug prices or pharmacy services are neither standardized nor transparent to other stakeholders, such as employers and plan members who ultimately pay.

For patients, it can be overwhelming to navigate a "labyrinth" of forms, phone calls, waiting periods, and language and literacy barriers across public and private systems without help from PSPs and patient groups.

When it comes to coverage decisions, differing perspectives and recommendations on how to interpret clinical and economic evidence, including real-world patient outcomes, can create extremely difficult and controversial decisions on sustaining or discontinuing DRD coverage.[72] This dynamic situation challenges all payers, especially those in the private payer community.

Patient groups play an important role in advocating for coverage, although they have formal input only in the public reimbursement pathway. Private payers will want to ensure advocacy groups operate independently of their funding sources, which typically include drug manufacturers.

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[70] Health Canada, 2026. *Drugs for rare diseases bilateral agreements*.

[71] Personal communication, conveyed by a senior insurance company private drug plan expert.

[72] Deppner W, 2025. *B.C. Health Ministry restores drug funding for girl with rare disease*. National Post, July 18. https://nationalpost.com/news/canada/b-c-health-ministry-restores-drug-funding-for-girl-with-rare-disease

In later phases, this project will explore DRD-related positions and perspectives of key stakeholders, including drug manufacturers, private insurers, public drug plans and patients.

9. Key Findings Summary

1. DRDs had a 31% compound annual growth rate (CAGR) between 2013 and 2022, more than four times the CAGR for all prescription medicines (7.0%). Canada spent about $6 billion on DRDs in 2025, of which private insurers covered about 11%. DRDs capture 28% of branded medicine sales while representing 13.4% of total market spending. The innovation pipeline is increasingly a rare disease pipeline.
2. The CLHIA reported that its members paid an estimated $650 million for DRDs in 2020, about 20% of total DRD spending that year. No updated national figures have been published, although our estimates indicate about the same cost ($659 million) in 2025, equivalent to 11% of total DRD spending.
3. Only about 13% of claims exceeding thresholds were covered by the insurance industry's Canadian pool (CDIPC). This means 87% was absorbed by an insurer and its plan sponsors.
4. Québec's mandatory, tiered pooling model offers a more comprehensive alternative, though structural barriers complicate national adoption. QDIPC covered just 4.4% of eligible pooled drug claims.
5. Based on 2019 data, access timelines diverge dramatically: 7 to 8 months for private coverage versus 25 to 30 months for public drug plans. By 2026, we expect this gap has converged, but how much is unknown.
6. US MFN pricing policies introduce new uncertainties into market dynamics and may impact launch timelines and net pricing expectations in the Canadian market.
7. The National DRD Strategy excludes private payers, exposing employer-sponsored drug plans to significant sustainability risks.

10. Looking Forward: What we will explore in Phase 2

This report reveals a system under strain and in transition. Through their formularies, private drug plans usually provide access to more drugs than public plans, and often faster. But they face significant threats: affordability pressures for both sponsors and members, plan sustainability concerns, and difficulty keeping pace with the evolving market for new drugs, especially DRDs.

Phase 2 will engage stakeholders across the ecosystem. Cost- and efficacy-related concerns create the potential for delayed, reduced or no access to both existing and new DRDs. Any coverage reduction or elimination of a private drug plan is likely to shift costs to public programs or become a personal, impossible out-of-pocket burden.

Among the questions we'll explore:

1. What structural changes would make private DRD coverage more sustainable for private payers and affordable for patients?

2. How does readiness to adapt to DRDs differ by stakeholder group? How should payers and drug manufacturers consider DRD value?
3. Should private payers have a role in ongoing federal DRD strategy and policy?
4. How can private payers interact with public payers and their agencies to better understand and address cost and access challenges related to DRDs?
5. What data infrastructure, including generation and access to real-world data and evidence, would enable meaningful outcomes-based agreements for DRDs in the private market?
6. Can CLHIA members expand and consolidate risk-sharing models to better protect plan sponsors across Canada? How should drug manufacturers address willingness to pay?
7. How will international pricing pressures, including MFN policies, affect Canadian DRD access and negotiations?

Private health plans are voluntarily provided except when collectively bargained. This distinguishes them fundamentally from public programs—employers can change or eliminate coverage in ways governments cannot. The sustainability of private DRD coverage therefore depends on maintaining employer confidence that their plan and the system at large can manage costs without catastrophic premium volatility and reputational risk.

It is clear that treating private plans as a passive funding mechanism is not tenable in the long-term, especially for DRDs. The private market has now adopted many cost control and public plan risk management tactics. The question is what comes next—and that's a conversation our continuing research is designed to inform.

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H3 Consulting
Health Research & Strategy / *Communicated*

H3 Consulting offers its clients insightful, actionable health research and strategic advice, focusing on complex challenges that often benefit from collaborative solutions. For more than 25 years, H3 has specialized in investigating, positioning and communicating private payer issues crucial to employers, insurers, drug manufacturers, health professions, patient groups, governments, industry associations and others to ensure the quality and sustainability of our health plans.

H3 provides a unique combination of deep knowledge of the private payer community, health benefit plans and prescription drug policy with advanced research skills and strong communication abilities in three key areas:

- Prescription drug policy for private and public payers
- Workplace health strategy and chronic disease management
- Private health insurance market access

MORSE Consulting

MORSE Consulting Inc. is Canada's leading market access strategy consultancy, focused on developing comprehensive reimbursement strategies that address our clients' needs. MORSE is known for its credibility and unique insights and expertise with a team of reputable experts in health technology assessment (HTA), health economics, the pan-Canadian Pharmaceutical Alliance (pCPA), and numerous ex-public and ex-private payers. Our team of experts use their unique combination of real-world experience, technical skill, and nuanced understanding of the Canadian reimbursement and payer context to provide honest and practical guidance to our clients on navigating the market's complexities.

Our consultants have 10-20+ years each in public jurisdictions and consulting agencies; our team has had direct involvement as payers and consultants in over 400 pCPA negotiations and over 800 files that have gone through the public reimbursement pathway.

Our consultants have clinical, policy, and methodological backgrounds and have been directly involved with HTA assessments and negotiations for drugs in almost every therapeutic space including but not limited to ALS therapies, oncology, immunology, drugs for rare diseases (DRDs), neurology, respiratory, dermatology, etc.

MORSE experts are well-equipped with industry and government insights to unearth hidden gaps, barriers, and opportunities in assessment, access and pricing.

We have conducted numerous thorough negotiation strategy & support projects in complex therapeutic spaces to guide our clients' reimbursement strategies and decisions including DRDs.

We explain complex and challenging issues to clients in an authentic, unbiased, and highly credible manner, with a goal of providing realistic and actionable insights to guide Client's decision making and optimize their product's market access success.

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