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10.58931/cdt.2026.7s04173

Expanding Patient Access to Innovative Drugs in Canada

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Canadian patients must consistently wait an average of two years for public reimbursement of new medicines following their approval by Health Canada.[1,2] While Canadian regulatory approval rates for new medications are comparable to those in other markets, Canada ranks among the slowest of Organization for Economic Co-operation and Development (OECD20) countries in providing publicly funded reimbursement for these treatments.[2] Access barriers and inequities also apply to public reimbursement of innovative therapies in Canadian dermatology.[3-5]

Canada's reimbursement landscape is complex and multi-layered, comprising both public and private elements. While private insurance plans may choose to cover new treatments immediately following approval by Health Canada, the same treatments must undergo a lengthy series of additional reviews by federal, provincial, and territorial agencies before becoming eligible for inclusion on public formularies.[1] As a result, patients who depend on publicly reimbursed medications including seniors and lower income families, face significant disadvantages in accessing new therapies.[6]

Canada has an opportunity to learn from best practices in other jurisdictions to streamline reimbursement pathways and provide earlier, equitable access to new therapies for a greater number of patients.[2,7] This article examines barriers to drug reimbursement in Canada, including specific access challenges associated with new dermatological treatments. It also reviews Canada's current efforts to improve treatment access and describes strategies used in other jurisdictions that could be leveraged to facilitate more equitable patient access to innovative treatments for Canadian patients.

Canada Compares Unfavourably to Other OECD20 Countries

Time to Reimbursement

Canada is among the slowest of OECD20 countries to bring new drugs from global regulatory approval to initial public reimbursement listing **(Figure 1)**. While Canada's timelines to new drug approval and launch (time from country approval until market availability) were similar to other countries between 2012 and 2018, Canada's time from first global approval to public reimbursement was the third slowest out of 20 countries during the same period, with a delay of 926 days. Furthermore, the time from market launch to public reimbursement was 559 days, exceeded only by Portugal among OECD countries.[2]

Reimbursement Rate

Between 2011 and 2018, 124 new medicines were launched in Canada; however, only 53% achieved public reimbursement (country-wide) during the same period.[2] In comparison, the OECD median was 96%.

Barriers to Reimbursement in the Canadian System

Complex Structural Barriers

Among OECD countries, Canada is somewhat unique in that prescription medicines are not universally covered by public health insurance.[8] Canada has consequently developed a complex network of public and private prescription drug insurance plans. The publicly financed health insurance system in Canada is further complicated

by a highly decentralized structure involving federal, provincial, and territorial plans. Delays are structurally inherent to Canada's sequential and fragmented reimbursement system.[2] Before reaching patients, a drug must move through a series of gatekeepers performing clinical and economic health technology assessments (HTA) and pricing negotiations **(Figure 2)**.[8,9] The system is further disconnected by the existence of two separate HTA agencies, the Institut national d'excellence en santé (INESSS) for Quebec and Canada's Drug Agency/ L'Agence des medicaments du Canada (CDA-AMC) for the rest of Canada. Differences in their reimbursement recommendations can contribute to inequitable access between Quebec and other provinces. Even after receiving a positive HTA recommendation and successfully completing price negotiations, a therapy is not guaranteed public reimbursement. Final decisions on whether to include a drug on formulary are then made independently by federal drug programs (e.g., Correctional Services Canada, Non-Insured Health Benefits [NIHB]), provinces, and territories).[10]

Systemic Inequities

Public versus private reimbursement. A drug is eligible for listing by private insurance plans immediately after receiving a Health Canada Notice of Compliance (NOC). As a result, patients with private insurance plans can gain access to new medications sooner than those relying on public plans. On average, patients with private plans can expect access to a new drug less than a year after NOC (226 days), whereas patients covered by public plans wait more than two years (736 days) for the same drug to be listed on public formularies.[9]

Approximately two-thirds of Canadians are covered by private insurance plans in which costs are typically shared among individuals, employers,

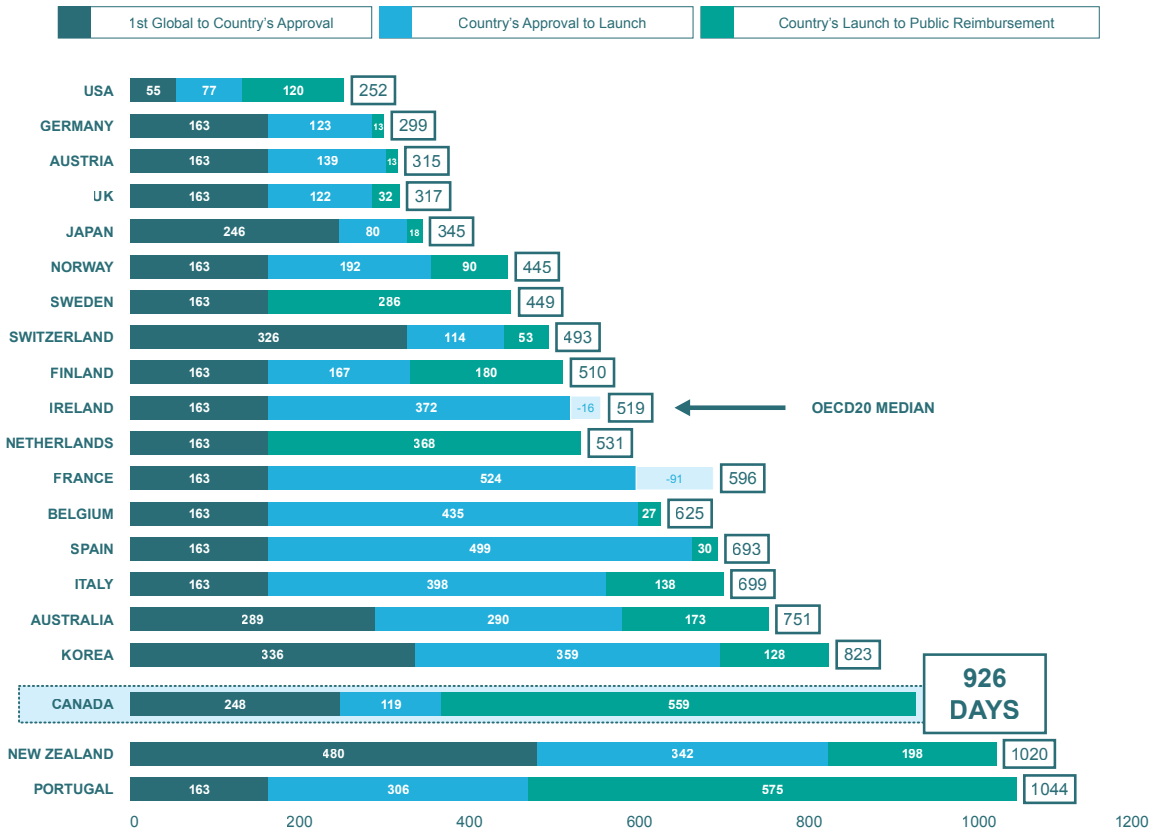


Figure 1. Total Time from First Global Approval to Local OECD20 Country Reimbursement, 2012–2018.[2]

Abbreviations: OECD: Organization for Economic Co-operation and Development; reproduced with permission from Innovative Medicines Canada.

or unions. Private plans generally provide access to a broader range of drugs than public formularies. While public plans are limited by cost concerns, private plans, intended to incentivize employment, are more generous.[10] By 2023, 84% of new treatments approved between 2017 and 2022 were covered by private plans, whereas only 55% were covered by at least one provincial drug plan.[11] In addition, many private plans maintain open access (without prior authorization requirements) to newly launched and innovative treatments.

Geographic disparities.

Significant interprovincial variation exists in both time to access and the number of drugs listed following pricing negotiation by the pan-Canadian Pharmaceutical alliance (pCPA). In 2022, the average time between completion of pCPA negotiations to public coverage ranged from 44 days in Quebec to 662 days in Prince Edward Island.[1] Overall trends indicate that time to reimbursement is shorter in Quebec and longer in the Atlantic provinces.[1,10] Differences in the number of drugs listed are also evident across jurisdictions. Between January 2012 and March 2023, the number of drugs listed varied from 35 in Newfoundland and Labrador to 54 in Alberta.[1]

Reasons for Public Listing Exclusion[8]

- Economic concerns that medications exceed public budgets
- Resourcing issues resulting in administrative backlog
- Time-consuming and burdensome effects of sequential review processes
- Lack of performance targets to ensure timely reviews and agency accountability
- Lack of coordination across different review processes
- Lack of expertise in review bodies

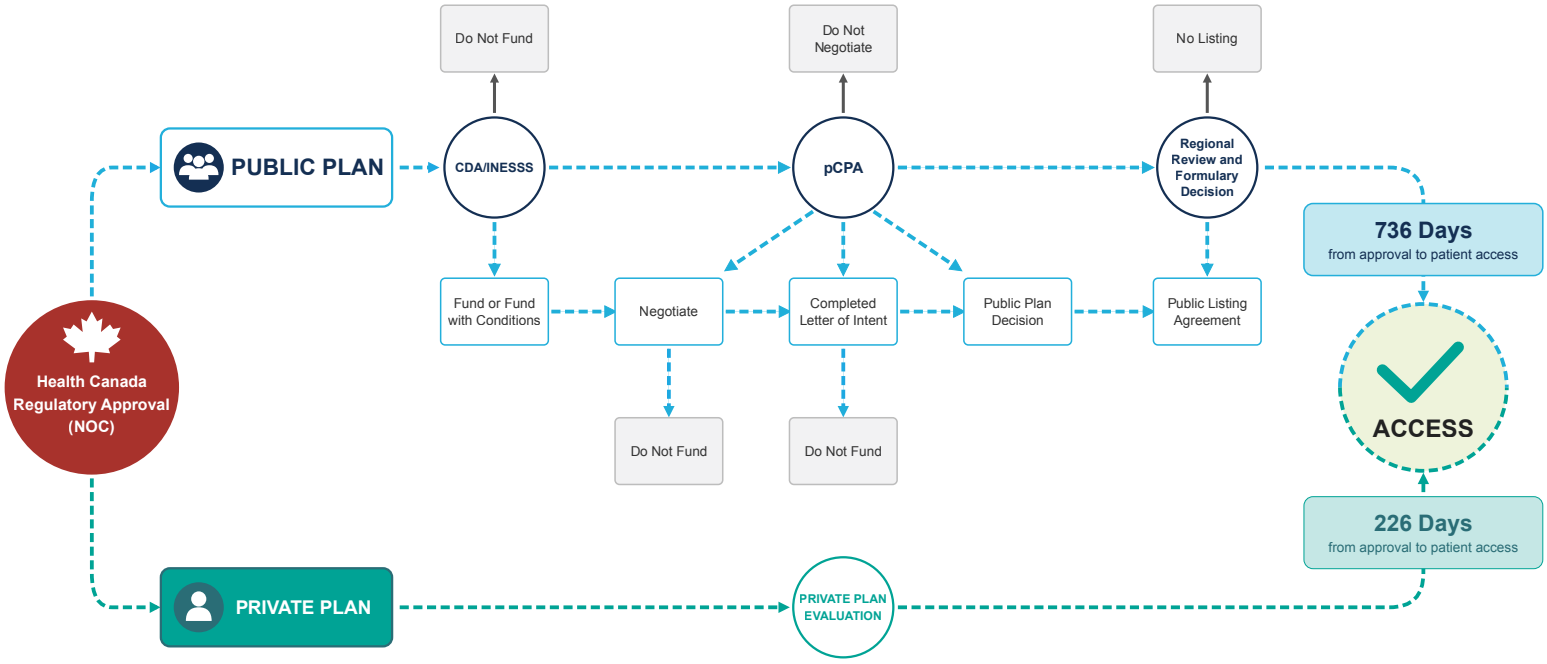


Figure 2. Drug Access Pathway in Canada[1,8]

Abbreviations: CDA: Canada's Drug Agency; **INESSS:** Institute national d'excellence en santé et services sociaux; **NOC:** notice of compliance; **pCPA:** pan-Canadian pharmaceutical alliance.

Negative Impact on Patients

Delays in the public listing of new medications are understandably frustrating for physicians and patients with high unmet needs who remain unable to access the drug they need despite approval by Health Canada.[7] Patients may be living with uncontrolled symptoms that negatively impact their quality of life. For patients with progressive conditions, such as cancer or multiple sclerosis, these delays may result in irreversible deterioration that can become life-threatening without treatment. Lifileucel, a tumour infiltrating lymphocyte therapy for metastatic melanoma, illustrates this challenge. Although Health Canada issued an NOC in August 2025, the therapy remained in the early stages of the public reimbursement process one year later, limiting access for patients with advanced melanoma who have limited time to wait for treatment.[12]

Access Barriers and Dermatological Drugs

Complex Access Pathway

Contrary to the pCPA's stated objective to improve consistency in funding decisions through collective bargaining access, disparities between provinces have nonetheless been recorded for dermatological drugs following successful pCPA pricing negotiations **(Figure 3)**.[4,13] While several provinces demonstrated consistently high listing rates, others were characterized by delayed or limited adoption of newly negotiated therapies.[4] In an analysis of eight innovative dermatology products that successfully completed pCPA negotiations between 2016 and 2021, British Columbia approved only 25% (2/8) of products, Prince Edward Island approved 75% (6/8), Alberta approved 88% (7/8) while all remaining provinces approved all products.[4] Similar findings were observed in a separate analysis identifying 16 products with successful pCPA agreements between 2016 and 2025, in which British Columbia again had the lowest listing rate, approving only 44% (7/16) products.[5]

Access to optimal dermatological treatment may be impacted by these complex reimbursement processes. Recent evidence suggests that provincial formularies continue to reimburse older, less effective treatments for the treatment of plaque psoriasis.[14] Despite robust head-to-head clinical evidence demonstrating the superiority of new generation biologic therapies (targeting interleukin [IL]-17 and IL-23 cytokines), many provinces are continuing to reimburse older biologic therapies (anti-tumour necrosis factor-alpha and IL-12/23). In addition to offering lower clinical efficacy, these earlier generation biologics are often more costly, having entered the market before the establishment of pCPA price negotiations. Furthermore, although many older generation biologics have lost market exclusivity, uptake of biosimilar versions has been delayed or limited by public formularies. Together, these findings highlight both a clinical and economic imperative for policy makers to consider more rational use of biologics for patients with plaque psoriasis. However, the implementation of a universal mandate for more appropriate use of biologics for psoriasis is unlikely to occur under the current decentralized system.

HTA Challenges

Unequal access to dermatological drugs is also seen at the HTA level, as illustrated by treatment pathways for atopic dermatitis (AD).

As with all medications, patients with private insurance have earlier access to innovative treatments for AD while those with public coverage must wait for HTA review, pCPA negotiations, and individual provincial formulary decisions before reimbursement is available.[1]

Public formularies provide access to fewer innovative treatments for AD compared with private insurance plans. Although there is an unmet need for more efficacious topical treatments for AD that can be safely used on a long-term basis, many newer treatments with novel mechanisms of action, including Janus kinase-inhibitors (ruxolitinib) and phosphodiesterase-4 inhibitors (crisaborole and roflumilast) have received an initial negative reimbursement recommendation from

CDA-AMC.[15-17] The lack of publicly funded access to these therapies leaves patients whose AD is not controlled with topical corticosteroids, topical calcineurin inhibitors, or phototherapy with treatment alternatives. For many patients, older systemic immunomodulators such as methotrexate often provide an inadequate response or are poorly tolerated while advanced systemic options such as dupilumab impose substantially greater costs on the healthcare system than the newer topical therapies.[15-18]

Publicly listed dermatology therapies are often subject to restrictive prior authorization requirements, while private plans often provide more open access to covered treatments.[11] To qualify for advanced treatments for AD, such as dupilumab, upadacitinib, and abrocitinib, patients must have documented proof of a suboptimal response to a sequence of prior treatments for at least three months, creating substantial delays before effective treatment is obtained.[18-20] Although these prerequisite treatments may appear less costly, their use often requires increased healthcare utilization, including additional physician visits, laboratory monitoring, and management of complications, which increase the collective costs on the Canadian Health Care system. In some cases, these complications may require hospitalization of the patient, further increasing the overall cost burden to the healthcare system.

Conditional reimbursement recommendations for systemic AD treatments, such as lebrikizumab, are often contingent on price reductions that cannot exceed the least expensive advanced systemic AD treatment option.[21] This pricing requirement may not be acceptable to manufacturers.

Negative HTA recommendations are often given to treatments for dermatologic conditions such as vitiligo that are trivialized as 'appearance related' or 'cosmetic' rather than medical conditions warranting reimbursement.[3] This perception fails to consider the substantial psychosocial harms and burden of disease associated with visible skin abnormalities. Additional equity concerns arise when access to treatment is restricted for conditions such as vitiligo and melasma, which disproportionately affect patients with skin of colour.

Impact on Canadian Dermatology

Overall, restricted public coverage limits Canadian dermatologists' ability to prescribe treatments deemed medically appropriate for individual patient needs, which results in poorer outcomes.[3] In addition, limited access to innovative therapies may reduce opportunities for Canadian dermatologists to gain experience with innovative products that have become standard of care in other jurisdictions, potentially constraining participation in and contributions to global dermatology research.

Addressing Access Barriers

Current Drug Access Initiatives in Canada

Health Canada's review timelines for new drug approval is comparable to those of other OECD countries, with a median approval time of 248 days versus an OECD median of 240 days.[2] This performance may be attributed to several mechanisms, such as Priority Review and Conditional NOC for drugs in areas of high unmet need. These programs have shortened target review timelines and facilitated early NOC based on promising phase II clinical evidence and the manufacturer's commitment to conduct confirmatory trials.[2,22] There are also emerging mechanisms intended to compress timelines between approval and public listing at the HTA review, pCPA, and provincial formulary negotiation stages. However, these programs, while promising, apply almost exclusively to a limited number of oncology products and their impact, while tangible, has yet to be realized across a broader range of therapeutic areas.

Suggested Strategies from Other Jurisdictions

Accelerated access programs.

Several European countries have established formal early-access programs that enable patients to receive therapies before market authorization is

granted.[1,8] Canada should consider alignment with international regulatory decisions from the U.S. Food and Drug Administration and the European Medicines Agency (EMA), to facilitate earlier access to drugs approved by these agencies. Under this approach, medicines approved by these agencies could be considered for expedited review in Canada, reflecting the robust evidence standards used to demonstrate that they are sufficiently safe and beneficial for Canadian patients.[10]

Real-world evidence-based conditional listing agreements.

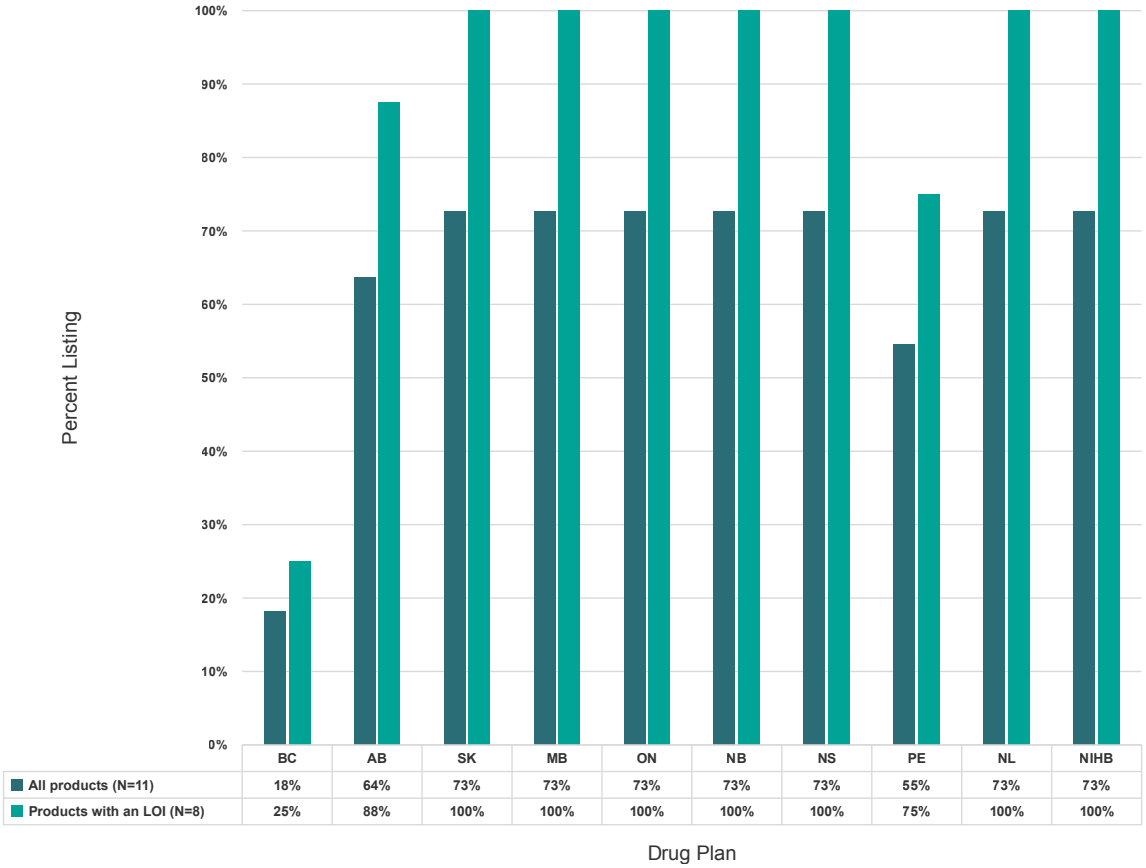
In return for earlier listing privileges, manufacturers agree to pricing discounts and a commitment to monitoring and real-world evidence generation to support future HTA re-assessment.[23] This model has been successfully used to reduce the time to access in the United Kingdom (UK) and in many European Union (EU) countries.

Target timelines.

EU members are mandated to make listing decisions within 3–6 months of EMA marketing authorization.[8] Similar performance benchmarks could be considered for the CDA and the pCPA to achieve performance targets in 90% of reviews with transparent reporting of delays.[10]

Standardized national formulary.[8]

The UK operates a national formulary model in which regional committees are mandated to



	BC	AB	SK	MB	ON	NB	NS	PE	NL	NIHB
All products (N=11)	18%	64%	73%	73%	73%	73%	73%	55%	73%	73%
Products with an LOI (N=8)	25%	88%	100%	100%	100%	100%	100%	75%	100%	100%

Figure 3: Percentage Dermatology Listings Per Province Following pCPA Completed Letter of Intent[4]; reproduced with permission from the authors.

Abbreviations: AB: Alberta; **BC:** British Columbia; **LOI**: letter of intent; **MB:** Manitoba; **NIHB:** non-insured health benefits; **ON:** Ontario; **NB:** New Brunswick; **NL:** Newfoundland and Labrador; **NS:** Nova Scotia; **pCPA:** pan-Canadian Pharmaceutical Alliance; **SK:** Saskatchewan.

list medications with a positive recommendation from the National Institute for Health and Care Excellence (NICE) within 90 days. This coordinated system has resulted in timely reimbursement and consistency throughout the country.

Summary and Conclusion

Patients in Canada must wait on average two years from market authorization to public insurance listings, resulting in substantially longer wait times for access to innovative medicines than those observed for peers in OECD20 countries. This review highlights access inequities between patients with public and private insurance and between provinces. While Health Canada's review timelines are comparable to those of other countries, the sequential and fragmented nature of downstream stages of the approval process present opportunities for intervention and improvement. Key leaders at the HTA, pCPA, and provincial drug plan levels are encouraged to streamline their respective processes, building on current initiatives and adopting best practices proven successful in other jurisdictions.

Interventions such as accelerated access pathways, parallel review processes, a standardized national formulary, and conditional listing agreements have the potential to facilitate faster and more equitable access to new medications.

In conclusion, patients, caregivers, and healthcare providers, including those in dermatology, have an important role in advocating for policy reforms that promote timely access to innovative therapies for all Canadians.

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Financial Disclosures

Medical writing support was provided towards the development of this manuscript and funded by Incyte Biosciences Canada Corporation.

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