Mood Disorders Society of Canada
Société pour **les troubles de l'humeur** du Canada

SYSTEM BROKEN

How Public Drug Coverage is Failing Canadians with Mental Illness

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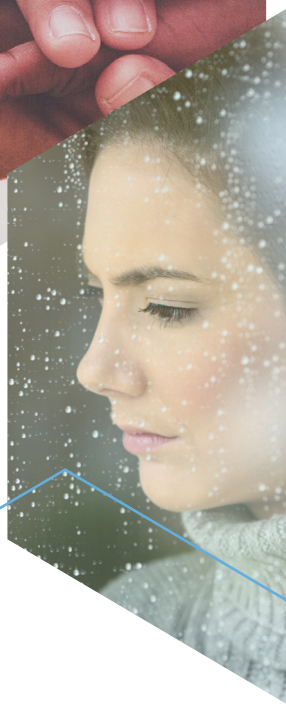
Note: Words and terms underlined throughout the report will appear in the glossary



Executive Summary

In the aftermath of the global pandemic, Canada is grappling with an escalating mental health crisis. Access to medication is a crucial element of recovery for individuals with mental illness, complementing peer support, psychotherapy, lifestyle interventions, and alternative therapies. However, access is challenging in Canada due to the health system and gaps within it.

Canada's intricate healthcare system is decentralized among its 10 provinces and three territories, with varying responsibilities, including public drug access. Some Canadians also possess private or workplace insurance plans that may cover some or all of the cost of medications. Recent research highlights a growing dependence on public drug plans for accessing necessary medications for mental illness. [1]

Against the backdrop of this crisis and our complex mental health system, Canadians facing mental illnesses deserve better access to modern medications, known for their effectiveness, enhanced tolerability, minimized side effects, and other distinct advantages. Unfortunately, substantial access barriers hinder the availability of these medications through public plans.

A better understanding of the **barriers** that exist within Canadian drug reimbursement processes for medications for mental illness is needed to identify why Canadians requiring these medications are falling through the cracks.

To identify those barriers, Mood Disorders Society of Canada (MDSC) commissioned **a new report, *System Broken: How Public Drug Coverage is Failing Canadians with Mental Illness,*** which reveals the stark reality that public access to the newest medications for mental illness is hampered by a complex system that takes **too long** and results in **inequitable access** – or in many cases, no access at all.

1. Time:

The reimbursement process in Canada takes too long, causing substantial delays in access to newer medications for mental illness. The report demonstrates that, at best, it takes 2.5 years, and **at worst, up to 6 years for these drugs to become publicly accessible. Comparatively, the average time-to-patient for all publicly reimbursed medications is two years in Canada.** [2]

2. Inequity of Access:

Negative Health Technology Assessment (HTA) recommendations result in some drugs not receiving public reimbursement, making them accessible only through private means. The report found that medications for mental illness have a higher rate of negative HTA assessments compared to medications for other medical disorders **(54% negative assessments from the HTA agency that reviews medications for most of Canada, compared to only 17% negative for other non-oncology disorders from the same agency)**. This results in a lack of public coverage, creating inequities between individuals with private coverage and those without. Because of Canada's decentralized system, even when there are positive HTA outcomes, the drugs are often reimbursed differently across regions, further exacerbating regional disparities in access.

Collaborating with all stakeholders, including government, to investigate the underlying causes of these barriers will help to create strategies to improve Canadians' access to these medications.

We urge all stakeholders within the mental healthcare system, including government officials and decision makers, to work with us to conduct comprehensive research, delve into root causes, and discuss and prioritize viable solutions that can be effectively implemented. Together, we can dismantle these barriers, ensuring equitable access to these essential medications for all Canadians.

1 Learn more: mdsc.ca/research/2022-mental-health-care-system-study-report/

2 Source: IMC calls on Canada's premiers to improve patient access to medicines https://www.newswire.ca/news-releases/imc-calls-on-canada-s-premiers-to-improve-patient-access-to-medicines-890331363.html#:~:text=Canadians%20wait%20two%20years%2C%20on,amongst%2020%20peer%20OECD%20countries

Introduction

Chelsea Meldrum was 12 years old and feeling suicidal.

Overwhelmed by fear, crying uncontrollably, feeling lonely but unable to socialize, and experiencing emotional highs and lows and auditory hallucinations, Chelsea self-harmed frequently and repeatedly missed school. She wanted and needed help to lead a 'normal' life. It took a number of years, and multiple visits to family physicians, psychiatrists, and different specialists to confirm Chelsea's diagnosis. "When I was 13, my psychiatrists gave me the diagnosis of depression and anxiety. At 14, I was diagnosed with schizophrenia; then at age 20, I also received the diagnosis of borderline personality disorder," said Chelsea. As a teen, once connected with the right psychiatrist, she spent six weeks in the psychiatric ward of the local children's hospital. Following this, Chelsea entered a specialized learning program to receive ongoing treatment in parallel with her high school education. She has continued with her treatment plan through to her adult years.

Today, at age 28, Chelsea considers herself fortunate to have a supportive family and access to care, notably her family's private healthcare coverage, which includes a comprehensive drug plan that provides access to the newest drugs to treat her mental illnesses. Managing her array of symptoms is still a constant battle and requires a combination of exercise, sleep, medication and talk therapy. With all this support, Chelsea is living life on her own terms: she is in her third year of university, and in her spare time enjoys painting and caring for her cat and two dogs. She openly shares her personal experience with mental illness to help reduce stigma and help others in need. As she puts it, ***"…having mental health issues is not a flaw in personality, but a flaw in chemistry."*** [3]

Chelsea's situation is not unique. In fact, it is all too common - in any given year, one in five Canadians experiences a mental illness [4] and by the time they reach 40 years of age, 1 in 2 Canadians have – or have had – a mental illness. [5] While mental illness encompasses a range of disorders with differing but overlapping symptoms and degrees of severity, the common link is a change in how someone thinks, feels or behaves, which is usually associated with significant distress or impaired functioning in social, workplace or other activities.

Chelsea credits medication for playing a significant role in her recovery journey. Without those medications, she says, she would be very unstable and much worse off. She's thankful that she found the medications that work for her (through trial and error), but, if she was diagnosed today, she would want access to the latest advancements. Unfortunately, there are barriers in Canadians' access to medications for the treatment of mental illnesses via public

Mental illness treatment is not prioritized within the Canadian healthcare system and there are complex barriers to access that people must navigate to get the supports they need. There is a critical need for meaningful reforms so that Canadians living with mental illness can gain vital access to the mental illness supports necessary to continue to live a healthy life and contribute to society.

Cynthia Black, Caregiver, Mental Health Advocate and President of the Board, Mood Disorders Society of Canada

3 Source: https://federatedhealth.ca/2021/04/02/federated-health-campaign-support-mental-health-in-challenging-times/

4 Source: Smetanin et al. (2011). The life and economic impact of major mental illnesses in Canada: 2011-2041. Prepared for the Mental Health Commission of Canada. Toronto: RiskAnalytica. https://www.mentalhealthcommission.ca/wp-content/uploads/drupal/MHCC_Report_Base_Case_FINAL_ENG_0_0.pdf

5 Source: https://www.camh.ca/en/driving-change/the-crisis-is-real/mental-health-statistics#:~:text=Prevalence,Canadians%20experiences%20a%20mental%20illness.&text=By%20the%20time%20Canadians%20reach,have%20had%20%E2%80%93%20a%20mental%20illness.

drug plans – the process to access the latest medications takes too long and there are inequities in that access across the country. Chelsea knows she's been able to focus on her personal goals and future studies because she has access, through her parent's private drug plan, to medications that helped to get her well and have kept her well. If she were to leave home and live independently, she would lose access to that private drug plan, and it's unlikely she would be able to afford her current medications on her own.

Recent research by the Mood Disorders Society of Canada (MDSC) shows that Canadians affected by mental illness are becoming more reliant on public drug plans [6] to access their medication. This high reliance may be due in part to the reality that many people with severe mental illness face significant rates of unemployment – up to 90% of Canadians with serious mental illness are unemployed. [7] As such, these individuals may not have access to private or workplace insurance plans that provide better (but not always full) coverage for, and access to, the latest medications they may need to manage their symptoms.

Furthermore, the shift to a reliance on public drug plans is of great concern because the current processes to determine if a medication should be publicly funded are very complex and lengthy, and result in inequities to coverage depending on where people live or whether they are employed (i.e., with access to a workplace drug plan).

In short, the healthcare system, with its public drug plans, is broken for those Canadians with mental illness who need access to medications to get them well and keep them well.

Canadians who require access to medications for mental illness are falling through the cracks within our public drug plan healthcare system. To fully understand and address those gaps, we must first understand the barriers. To uncover the barriers, MDSC* undertook the development of this report.

*MDSC undertook the development of this report recognizing that MDSC has explored other aspects of mental health supports and treatments in other research. https://mdsc.ca/research/

Going public

Canadians are increasingly relying on public drug plans vs. private/employer plans, according to a recent Mood Disorders Society of Canada (MDSC) survey. [8]

Compared to 2015, when MDSC conducted a similar survey, access is worsening for those affected by mental illness:

46%

had access to both public and private drug plans (down from 50% in 2015).

42%

had access to only a public drug plan (up from 39% in 2015).

63%

of those with private coverage said it was inadequate for the mental health care they need (up from 54% in 2015).

6 Source: https://mdsc.ca/research/2022-mental-health-care-system-study-report/
7 Source: https://www.mentalhealthcommission.ca/wp-content/uploads/drupal/2016-06/Workplace_MHCC_Aspiring_Workforce_Report_ENG_0.pdf
8 Source: https://mdsc.ca/wp-content/uploads/2022/10/MDSC-2022-Mental-Health-Care-Study-Report_Oct-12.pdf

A Devastating Illness

Our collective and individual mental health status has reached crisis proportions. [9] This has been a growing area of concern in recent years, due to its exacerbation resulting from the global COVID-19 pandemic. Fear of a virus that was not well understood, combined with significant changes to how we interacted with one another to mitigate its spread, took a toll. COVID-19 resulted in an estimated additional 53.2 million cases of major depressive disorder (MDD) globally in 2020. [10] By the end of 2020, 84% of Canadians polled said their mental health had worsened since the start of COVID-19, and 41% of youth reported symptoms of anxiety and high stress levels. [11] A different poll also found that between 2022-23 more than one in 10 Canadians said they thought about suicide. [12]

There is a difference, however, between mental health and mental illness. It's common to experience physical and mental health ups and downs - we all have bad days when our mental health isn't at its best. However, not everyone experiences a mental illness. **The World Health Organization defines mental health as, "A state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community."** [13]

Like most aspects of life, our mental health exists on a spectrum:

- Sometimes we feel mentally healthy, especially when we have access to a solid support system. At those times, we feel in control of our thoughts, feelings and behaviours, and we're able to function optimally in our usual roles. At times of high stress, we might be more irritable and anxious, but we're still able to function adequately in our usual roles.
- A further decline along the spectrum of mental health leads to function impairment, where we are unable to functional adequately in our usual roles, whether at home, at work or at school. Here we feel less in control and might turn to self-medication to help manage anxiety, poor sleep and other challenges.
- If there is no intervention, at or before the functional impairment stage, we can move to the crisis end of the mental health spectrum, which is when a diagnosis of a mental illness is established.

Mental illnesses are medical conditions that impact emotions, thinking and behavior. A mental illness is diagnosed when there is a constellation of symptoms (e.g., depressed mood, insomnia, high anxiety) that persist for at least several weeks (each diagnosis has a specified time period, ranging from weeks to months) and causes marked emotional distress and impaired functioning.

> **Mental illness can happen slowly and because it can be an invisible disease; people could be suffering severely, and no one would know. For me, it wasn't until something alerted me that I had changed that I realized the person who I was had left. I was no longer me and I had been replaced by someone I didn't want to be.**
>
> Michael Landsberg, Founder, Sick Not Weak,
> Person With Lived/Living Experience

The severity of mental illness can vary from mild to extremely severe and include emotional, physical and cognitive symptoms – some observable and others invisible. Even someone experiencing mental illness may not fully realize the extent to which their symptoms have progressed. Emotional symptoms include feeling sad or down, hopeless, worthless or useless. Additionally, anxiety symptoms – such as feeling tense, keyed-up, restless, on edge, or irritable – are common emotional symptoms. Auditory hallucinations and delusions (holding false beliefs) – most often associated with schizophrenia – and mania associated with bipolar I disorder, are highly impairing symptoms that are not always recognized as illness-related by the person who is experiencing them. Mental illnesses can also manifest through physical symptoms such as loss of appetite; pain, such as chronic head, body or backache; loss of energy and fatigue; and chronic gastrointestinal issues. Cognitive symptoms include an inability to concentrate, poor short-term memory and disorganization.*

9 Source: https://www.camh.ca/en/driving-change/the-crisis-is-real
10 COVID-19 Mental Disorders Collaborators. Lancet 2021; 398: 1700–12
11 Source: https://www.gov.nl.ca/cssd/files/2.-Conference-Board-of-Canada.pdf
12 Mental Health Research Canada. https://www.mhrc.ca/findings-of-poll-16, May 2023
13 World Health Organization. Promoting mental health: concepts, emerging evidence, practice (Summary Report) Geneva: World Health Organization; 2004

Mental illnesses can lead to suicidal thoughts and feelings that life is not worth living, which can persist, intensify, and overwhelm everyday thinking – worse yet, suicidal thoughts can turn into suicidal action. In Canada, we lose approximately 4,500 people a year to suicide. [14]

Unmanaged mental illness can have a significant and devastating impact not only on the person experiencing the symptoms, but also their friends, family, colleagues, neighbours, loved ones and communities. This impact is even further exacerbated when mental illness leads to loss of life.

* The degree and severity of mental illnesses are generally assessed by using clinical rating scales. These scales can also track change over time, for instance, assessing whether symptoms are improving in response to a treatment. Clinician-rated scales are completed by a healthcare provider, while self-rated scales are completed by the individual seeking the assessment (see Appendix III for a list of some of the commonly used rating scales).

Our mental health care system is broken. There is a lack of access to high-quality, timely care and a lack of compassion for those who seek care. This results in even more suffering and greater loss of life. Many people can't access mental healthcare unless they're in crisis. Then, they're forced to go to an emergency department, where they might wait for 12 or 15 hours just to be assessed. Access to both psychological counseling and tolerable medication is just abysmal. No part of our system is working, and our leaders are not taking the right steps to fill the gaps.

Dr. Diane McIntosh, BSc Pharmacy, MD, FRCPC; Community Psychiatrist, and Clinical Assistant Professor at The University of British Columbia; Founder of SwitchRX.com, PsychedupCME.com and RAPIDS, an innovative technology to support clinicians to provide evidence-based, personalized psychiatric care.

The Recovery Journey

Regardless of the severity of symptoms, getting the right diagnosis and having access to appropriate treatment are essential to help people manage their symptoms, overcome challenges, and lead happy and productive lives. [15] Working with a qualified healthcare professional is key to developing a holistic treatment plan, with options that may include peer support, medication, psychotherapy, lifestyle interventions, including eating a healthy diet, good sleep habits, and regular physical activity, as well as evidence-based alternative therapies.

Medications are not always required to treat a mental illness. However, if the symptoms are severe, highly distressing and functionally impairing, medications may be helpful, and sometimes, they're absolutely essential. It is vital that those who require medication to treat a mental illness have access to the treatment that works for them and their unique needs – in particular the newest medications as they are effective, better tolerated, cause fewer side effects, and have unique benefits.

It is estimated that in Canada, mental illnesses have an economic cost of at least $50 billion per year, a figure that is projected to cumulatively exceed $2.5 trillion in the next 20 years. [16] Some of these costs are associated with workplace productivity, including absenteeism, presenteeism, and employee turnover, but the majority are related to use of social services, income support, and healthcare. For example, since 2006/07, there has been a 75 percent increase in the number of mental health-related emergency department visits by children and youth aged five to 24. [17]

14 Statistics Canada. Canadian Vital Statistics – Death Database (CVDS). https://www23.statcan.gc.ca/imdb/p2SV.pl?Function=getSurvey&SDDS=3233
15 Source: https://mdsc.ca/docs/MDSC_Quick_Facts_4th_Edition_EN.pdf
16 Source: https://www.mentalhealthcommission.ca/wp-content/uploads/drupal/2016-06/Investing_in_Mental_Health_FINAL_Version_ENG.pdf
17 Source: https://journals.sagepub.com/eprint/I35PD64UCK9G75TVB3IB/full

While Chelsea Meldrum was fortunate to have the supports she needed to successfully navigate the healthcare system and access the medications she needed, as an advocate for others living with mental illness, she is all too aware of the system gaps that result in people slipping through the cracks. She cites a lack of family physicians, psychiatrists, and other supports, along with long waitlists, as myriad factors that can stand in the way of recovering and returning to full functioning.

These same challenges have been identified by MDSC and are among the most significant barriers affecting access to high-quality, timely mental health care, along with the ongoing stigmatization of mental illness, as well as the lack of compassion and frank racism that permeates some care settings. While these barriers are very real and significant, the primary purpose of this specific report is to highlight the untimely and inequitable access to medications for mental illness. [18]

Doctors are often not able to use their first choice of medication for patients because those medications are not accessible. In situations where patients are non-responsive to a variety of medications, we have to go to some of the newer medications. But because they are not covered by government plans, patients cannot access them, and we have to go into different supplemental strategies that aren't the preferred treatment strategy.

Dr. Pierre Blier, MD, PhD; Professor, Departments of Psychiatry and Cellular & Molecular Medicine, Distinguished Research Chair, University of Ottawa; Fellow of The Royal Society of Canada

Access to Medications

Mental illnesses are complex medical disorders. In the case of major depressive disorder (MDD), for example, a diagnosis requires having five of nine symptoms, which means there are 227 possible ways to meet the diagnostic criteria. [19] As such, depression can be experienced differently by each person and treatment must also be individualized. For example, one individual with MDD could experience severe insomnia and benefit from a sleep-promoting medication, while another might experience excessive sleep (hypersomnia) as part of their depression, which would be worsened by a more sedating medication. Likewise, a medication might be effective in managing someone's depression symptoms but it might not be well tolerated (meaning it has side effects that make it difficult to take). What works for one person with MDD may not work for another with the same diagnosis, and medications can affect or impact one person differently than another.

Personalizing treatment means providing the right treatment to the right person at the right time. Unlike other medical specialties, psychiatry currently lacks the use of objective measures, such as lab tests, x-rays or brain scans, to help determine the best treatment. This means that medication trial and error is commonly part of the treatment process, which is particularly difficult to endure because it can take several weeks, and sometimes months or even years, to find an effective and tolerable treatment. All the while, the person is suffering, sometimes unable to work, attend school, care for their children, or function effectively in day-to-day life.

Yet, clinical experts describe the challenges they face when trying to access medication choices that are better aligned with their patient's needs, whether due to efficacy, tolerability, or both. Clinicians know that personalizing treatment choices can make a meaningful difference in their patient's recovery journey. The lack of access to Health Canada approved options is the result of a number of barriers within the public drug access system.

For those who have gone through the medication "trial and error" process and exhausted available options, clinicians then struggle to provide patients with newer treatments, whether due to delayed access, sometimes years after Health Canada approval, or no access at all. **"Medications that are both effective and well tolerated are scarce, despite misconceptions of an abundance of choice," notes Dr. McIntosh. "Newer psychiatric medications are often better tolerated, particularly reducing some of the most bothersome side effects, like sexual dysfunction and weight gain, and they can also offer unique benefits. Patients are more willing to take a treatment and stay on it longer when it's tolerable and effective, and timely treatment is critical. For instance, symptoms of MDD are most likely to fully remit if treated within six months of onset. Treatment delay increases the risk of treatment resistant depression (30% cases), which is linked to more severe impairment, higher suicide risk, and greater healthcare costs."**

18 Source: https://mdsc.ca/people-with-mental-illness-continue-to-face-barriers-to-accessing-care-and-treatment/
19 Source: https://pubmed.ncbi.nlm.nih.gov/25266848/

Dr. Diane McIntosh believes the barriers to timely and equitable drug access for mental illnesses in Canada are:

"The Canadian reimbursement process has too many sequential steps that slow down the whole system.

The oversight organizations appear to lack an understanding of meaningful clinical trial endpoints for medications used to treat mental illness.

Psychiatrists are clinical experts on the pharmacological management of psychiatric disorders. The decision-making group lacks adequate input or doesn't appear to listen to or truly consider feedback from clinical experts who treat patients.

People who have a mental illness, and their supporters, aren't well-represented in the decision-making process.

Decision makers don't fully understand how prescribed medications work in real-world settings and how new treatments could provide critical benefits. Improving tolerability, for example, by reducing the risk of metabolic syndrome or sexual dysfunction, can markedly increase medication adherence.

There is a general lack of consideration for the economic value associated with providing medications that are both effective and well tolerated, supporting patients to recover and stay well because they are adherent to treatment.

There is a general a lack of recognition of the stigma that continues to surround mental illness diagnoses and treatments, which exists in the community and in the medical field, that may be creating unconscious bias in reimbursement decision-makers."

Mental Illness by the Numbers

In any given year, **1 in 5** Canadians experiences a mental illness. [20]

1 in 3 Canadians will experience a mental illness in their lifetime. [21]

Nearly **50%** of caregivers to loved ones living with mental health problems and illnesses report their role has a negative impact on their own mental health. [22]

An estimated **3 million** Canadians have a mood (such as depression) and/or anxiety disorder, making these disorders among the most common in the country. [23]

5% of Canadians report having received a post-traumatic stress disorder (PTSD) diagnosis. [24]

2.2% of Canadians will experience bipolar disorder at some point in their lifetime. [25]

More than **360,000** Canadians have some form of schizophrenia and 3% of the population will experience psychosis at some time in their lives. [26]

Up to **80%** of people with mental illnesses are affected by poor sleep, including falling asleep, staying asleep, or waking up earlier than intended. [27]

20 Smetanin et al. (2011). The life and economic impact of major mental illnesses in Canada: 2011-2041. Prepared for the Mental Health Commission of Canada. Toronto: RiskAnalytica.

21 Source: https://www.canada.ca/en/public-health/services/about-mental-illness.html

22 Source: https://mentalhealthcommission.ca/what-we-do/caregiving

23 Source: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/mood-anxiety-disorders-canada.html

24 Source: https://www150.statcan.gc.ca/n1/daily-quotidien/220520/dq220520b-eng.htm

25 Source: https://cpa.ca/psychology-works-fact-sheet-bipolar-disorder/

26 Schizophrenia Society of Canada 2020/2021 annual report https://schizophrenia.ca/wp-content/uploads/2022/03/SSC-annual-report-2021-v03-3-compressed.pdf

27 Source: https://www.camh.ca/en/camh-news-and-stories/mental-illness-associated-with-poor-sleep-quality

Canadian Reimbursement System

Before revealing how Canada performs, in terms of providing timely and equitable access to medications for mental illness, it's important to understand how the drug reimbursement system works in Canada.

Canada's complex healthcare system is characterized by its public funding and decentralized nature. The responsibility for healthcare delivery predominantly lies with the 10 provinces and three territories. Complementing this, many Canadians have access to private or workplace insurance plans through their employers, which can include some degree of medication coverage.

Many hospitals in Canada have their own drug formulary, a list of medications stocked by the hospital's pharmacy, which is usually approved by their own internal formulary committee and are provided to hospitalized patients free of charge. A hospital's formulary may or may not align with their respective provincial formulary. In order for an out-patient (someone receiving healthcare outside of an in-patient hospital setting) to access a prescribed medication, it must be listed on their respective province or territory's public drug formulary or be covered by their private health/employer insurance plans.

When I first went to a psychiatrist, I was like the walking dead, and I knew I needed something to help me. I was placed on medication for the first time and just days after starting, I remember this unbelievably emotional moment where I realized I felt better. It was the first little, tiny break in the deep dark clouds that I could see.

Michael Landsberg, Founder, Sick Not Weak, Person With Lived/Living Experience

The journey to medication access in Canada is visualized in the diagram on the next page. It starts with approval from Health Canada, the regulatory body that evaluates the safety and efficacy of all medications made available to Canadians. Subsequently, access to prescription medications follows two distinct paths: public or private. In order to assess a medication's clinical and cost-effectiveness for public coverage, most provinces rely on a Health Technology Assessment (HTA), which is conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH). One exception is Quebec, which relies on an evaluation from the *Institut national d'excellence en santé et en services sociaux (INESSS)*. It's not uncommon for the recommendations of CADTH and INESSS to differ, and provinces are not required to follow HTA recommendations, which complicates the process and causes inequities for medication coverage across Canada.

A HTA recommendation is generally needed to proceed to the next step in the provincial reimbursement process. The HTA process can be the longest step in the medication access journey - it can extend over many years, especially if a medication requires multiple reconsiderations and resubmissions - but there have been some steps taken to align regulatory and HTA reviews. Particularly relevant to treatments for mental illness, there are no clinical experts (practicing psychiatrists) on the CADTH deliberations committee. Another complication, caused by Canada's complicated reimbursement process, is that some drug manufacturers chose to opt out of the HTA process. As a result, their medication may only be accessible through private drug plans, exacerbating existing disparities.

Following the HTA review, public drug plans collaborate through a relatively new process (since 2010), via the pan-Canadian Pharmaceutical Alliance (pCPA), to negotiate pricing and reimbursement criteria with the drug's manufacturer. The pCPA is generally reluctant to negotiate in the absence of a positive HTA. [28] Successful negotiations between the pCPA and the drug company result in a Letter of Intent (LOI), establishing payment terms for the reviewed medication. This process alone can extend the access journey by more than six months; there are no clear timelines or transparency into the decision-making process. After the LOI is completed, medication coverage is still contingent on the completion of a Product Listing Agreement (PLA) between the drug company and each province or territory. There is also no set timeline or consistency for PLAs, adding more time to the process and resulting in uneven drug coverage across Canada. Overall, the Canadian system can be described as a slow-moving race, where, most often, each runner can only proceed after receiving a baton from the previous one, causing delays as decisions from earlier stages determine the pace of progress.

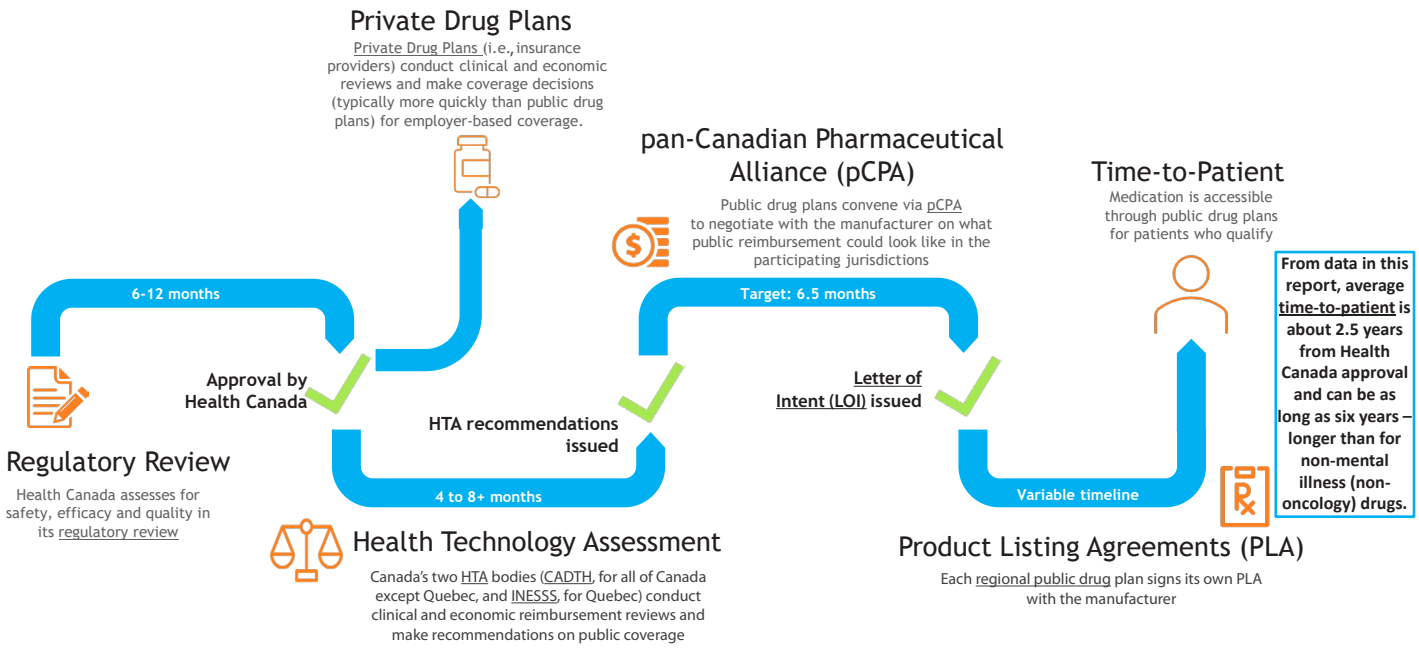
Private drug plans follow different processes than outlined above, though they typically have their own approaches to cost-benefit analysis, some subsequent to the public HTA's (again causing time delays). However, private plans generally cover more medications and do so more quickly than public plans. [29, 30]

28 Source: https://www.valueinhealthjournal.com/article/S1098-3015(23)00062-1/pdf#:~:text=%E2%80%A1Not%20all%20drugs%20reviewed,initiate%20a%20negotiation%20or%20not.

29 Source: https://innovativemedicines.ca/browse-by/private-drug-coverage/

30 Of the 182 new medicines authorized for marketing by Health Canada from 2016 to 2020, public drug plans covered only 43 (24 per cent) by the end of 2021, compared to 116 (64 per cent) in private drug plans. On average, the wait to access new medicines under a public drug plan was 724 days compared to 227 days under private sector drug plans: https://www.thestar.com/opinion/contributors/canada-has-in-fact-achieved-universal-drug-insurance-coverage/article_65bc7a1e-8fb2-56d5-abb8-1b5890909597.amp.html

Canada's Regulatory and Reimbursement Pathway (for Non-oncology Drugs)



Research Approach

To develop this report, MDSC worked with a national, independent healthcare consulting firm to gather and assess relevant publicly accessible data with respect to Canada's performance in providing equitable and timely access to mental illness medications.

While there are many medications used to treat mental illnesses, this report focused on medications that:

- ✓ Are indicated for the treatment of one or more of the following **mental illnesses**:
  - o **Anxiety Disorders,** including general anxiety disorder, panic disorder, and social anxiety disorder (social phobias),
  - o **Bipolar Disorder,**
  - o **Depression,** including major depressive disorder and treatment-resistant-depression,
  - o **Insomnia,**
  - o **Schizophrenia.**
- ✓ **Are innovative:** original brand-name medications rather than generic versions of innovative therapies.
- ✓ Underwent an initial or subsequent **health technology assessment (HTA) between 2012 and 2022 in Canada by CADTH and/or INESSS.**
  - o In instances where a medication was indicated for more than one mental illness and underwent an HTA review for each indication, each HTA review was evaluated separately.
- ✓ Did not undergo a Canadian HTA within the 2012 and 2022 timeframe but **received Health Canada approval** within the same 10-year period.

Specifically, this report evaluated reimbursement status and timelines for patient access to medications for mental illness that met the above parameters in four Canadian jurisdictions: **British Columbia**, **Alberta**, **Ontario**, and **Quebec**. These four provinces account for more than 85 percent of the country's population and enable general conclusions to be drawn about the timeliness and variability of public reimbursement for much of the Canadian population.

The following were also reviewed and assessed, for comparative purposes, to shed light on potential systemic inequities both within Canada and abroad:

- ✓ Health Canada-**approved therapies in other disease areas** (excluding oncology) that underwent an HTA review (specifically by CADTH) between 2012 and 2022
- ✓ Status and timelines to patient access, from approval to **public reimbursement, in Australia, the United Kingdom (UK), and Scotland (jurisdictions with HTA processes similar to Canada's**) for innovative medications that:
  - o Were approved and indicated for one or more of the five indications stated above.
  - o Went through HTA review during the same time period (2012-2022), including those that did not undergo HTA review in Canada during that period.

Canadian Context

Based on the above-mentioned criteria, 12 medications, and 13 CADTH or 13 INESSS reviews were assessed for this report per Table 1 (some medications had multiple indications, but there wasn't a public record of HTA for every indication).

Notes: At the time of this report's publication, one medication was still in active pCPA negotiation, so reimbursement outcomes are not yet known. In some other cases, the reimbursement status was either not publicly available or the specific listing date was not published.

The data in Table 1 is constrained by what is available from publicly accessible sources (links provided), except for two specific instances noted.

Canadian HTA Recommendations for Mental Illness Medications Compared to Other Medications

As a comparator, CADTH's reimbursement recommendations for non-mental health drugs (excluding oncology drugs) were reviewed over the same time period, as reflected in Table 2.

Table 1. Reimbursement status and total 'time-to-patient' for mental illness medications undergoing HTA review between 2012 and 2022 for selected indications, in Canada's four most populous provinces.

Brand name of medication (Chemical name of medication)	Indication	Health Canada approval	HTA recommendations [c]		pCPA Letter of Intent (LOI) signed	Provincial reimbursement [b] Total approximate "time-to-patient," from Health Canada approval to public reimbursement			
			CADTH	INESSS		BC	AB	ON	QC
Trintellix (vortioxetine hydrobromide)	Major Depressive Disorder (Adults)	22-Oct-14	12-Feb-20 [a]	6-Nov-19 [a]	3-Dec-20	6-Jul-21 2,449 days (6.7 years)	1-Mar-21 2,322 days (6.4 years)	29-Jan-21 2,291 days (6.3 years)	3-Feb-21 2,296 days (6.3 years)
Rexulti (brexpiprazole)	Schizophrenia	16-Feb-17	22-Nov-17	5-Aug-20	14-Dec-18	16-Dec-19 1,033 days (2.8 years)	1-Apr-19 774 days (2.1 years)	30-Apr-19 803 days (2.2 years)	No listing information available
	Major Depressive Disorder	22-Feb-19	No public record of HTA review specifically for MDD [c]	No public record of HTA review specifically for MDD [c]	No public record of negotiations specifically for MDD	No listing information available	No listing information available	No listing information available	No listing information available
Saphris (asenapine)	Bipolar I Disorder	7-Oct-11	14-Jun-12	1-Feb-13	No public record of negotiations	14-Mar-13 524 days (1.4 years)	1-Feb-13 483 days (1.3 years)	27-Feb-14 874 days (2.4 years)	No listing information available
	Schizophrenia	7-Oct-11	14-Jun-12	1 Oct 2012	No public record of negotiations	14-Mar-13 524 days (1.4 years)	Not covered at this time	27-Feb-14 874 days (2.4 years)	No listing information available
Latuda (lurasidone)	Schizophrenia	13-Jun-12	20-Dec-13	1-Oct-14	No public record of negotiations	Not covered at this time	1-Oct-14 840 days (2.3 years)	29-May-14 715 days (2 years)	Oct-14 841 days (2.4 years) [d]
Invega Trinza (paliperidone)	Schizophrenia	23-Jun-16	No public record of HTA review [c]	1-Feb-17	05-Feb-18	15-May-18 692 days (1.9 years)	1-Jul-18 739 days (2 years)	29-Mar-18 645 days (1.8 years)	1-Sept-2018 811 days (2.3 years) [d]
Abilify Maintena (aripiprazole)	Schizophrenia	10-Feb-14	19-Dec-14	1-Oct-14	14-June-15	11-Aug-15 547 days (1.5 years)	1-Sep-15 568 days (1.6 years)	29-Jul-15 534 days (1.5 years)	1-Oct-14 233 days (.6 years)

Chart continued on next page →

**Dates in green indicate a positive CADTH or INESSS recommendation; dates in red indicate a negative CADTH or INESSS recommendation.*

Table 1. Reimbursement status and total 'time-to-patient' for mental illness medications undergoing HTA review between 2012 and 2022 for selected indications, in Canada's four most populous provinces.

Continued...

Brand name of medication (Chemical name of medication)	Indication	Health Canada approval	HTA recommendations [c]		pCPA Letter of Intent (LOI) signed	Provincial reimbursement [b] Total approximate "time-to-patient," from Health Canada approval to public reimbursement			
			CADTH	INESSS		BC	AB	ON	QC
Vraylar (cariprazine)	Bipolar Disorder	22-Apr-22	9-Nov-22	2-Nov-22	Negotiations were not pursued	Not covered at this time	No listing information available	No listing information available	Not covered for this indication
	Schizophrenia	22-Apr-22	10-Aug-22	7-Oct-22	28-Mar-23	Not covered at this time	No listing information available	No listing information available	13-Apr-23 355 days (.9 years)
Abilify (aripiprazole)	Major Depressive Disorder	29-May-13	22-Oct-14	No public record of HTA review specifically for MDD	Negotiations were not pursued	No listing information available	No listing information available	No listing information available	No listing information available
Dayvigo (lemborexant)	Insomnia	4-Nov-20	10-Jan-23 [a]	29-Mar-23 [a]	In negotiation	TBD	TBD	TBD	TBD
Perseris (risperidone)	Schizophrenia, Adults	19-Nov-20	8-Sep-21	3-May-22	Negotiations concluded without agreement	Not covered at this time	No listing information available	No listing information available	No listing information available
Sublinox (zolpidem)	Insomnia	19-Jul-11	25-Sep-13 [a]	2-Jun-14 [a]	Negotiations were not pursued	No listing information available	Not covered at this time	Not covered at this time	No listing information available
Spravato (esketamine hydrochloride)	Major Depressive Disorder, Adults	20-May-20	16-Dec-20	5-Nov-20	Negotiations were not pursued	Not covered at this time	Not covered at this time	No listing information available	Not covered at this time

**Dates in green indicate a positive CADTH or INESSS recommendation; dates in red indicate a negative CADTH or INESSS recommendation.*

[a] As outlined in Part 2. Measuring Access to Medications for Mental Illness, Canadian Reimbursement System, there can be multiple reasons for a delay between Health Canada approval and HTA.

[b] The data collected for Table 1 was gathered through publicly available data sources, therefore, limited by what information is available. Where no public information was available on provincial public funding, the medication was assessed as not reimbursed in that province. The provincial listings in grey text were excluded from the dataset as no listing information could be found for this indication, but it was unclear if the drug was reimbursed from a previous indication listing.

[c] The data collected for Table 1 was gathered through publicly available data sources, therefore, limited by what information is available. Where no public information was available regarding HTA listing status, the medication was removed from the HTA dataset, rather than count it as either negative or positive.

[d] Data sourced from IQVIA (www.iqvia.com).

Not covered at this time: This drug was listed on the drug formulary database website as a non-benefit.
No listing information available: This drug did not show up in the drug formulary database, or was not listed for this specific indication.
No public record of HTA review: Could not find a public reference for an HTA review for this indication.
Negotiations were not pursued: The pCPA website notation indicates that no negotiation was pursued.
Negotiations concluded without agreement: The pCPA website notation indicates that negotiations were conducted but concluded without an agreement.

NB: This table only looked at time-to-patient data. It did not explore the reasons time-to-patient delays may exist.

Table 2. Comparison of CADTH HTAs for mental illness medications vs non-mental illness (non-oncology) medications, undergoing HTA review between 2012-2022.

	CADTH HTAs for selected mental health indications in this report	CADTH HTAs for non-mental health indications*
Total number of assessments	13	384
Number of negative recommendations	7	67
Percentage of assessments that received a negative recommendation	54%	17%

**Excluding oncology*

NB: This table only looked at if there were differences between HTA recommendations for mental illness vs. other non-oncology disorders – it did not explore the reasons why those differences may exist.

Canadian Context Observations: What the Data Tells Us

From a Canadian context, it is clear that the current processes used to determine whether to list a new medication for mental illness on a provincial formulary are lengthy, cumbersome, ill-informed and not working in the interest of the people who need them most. The data evaluated in this report reveals a patchwork public system, fraught with inconsistencies and arbitrary barriers. These issues result in **equity and wait time issues** caused by arbitrary barriers **to access** based on the person's province of residence or employment/private coverage status.

- **The vast majority of medications assessed for this report are not equitably accessible through public drug plans across the country, or are not accessible at all.** Over one-third of medications (38%) are not publicly reimbursed in any of Canada's four most populous provinces. **Looking at each province individually, approximately half of the medications assessed are not being publicly reimbursed** (British Columbia: 54%, Alberta: 54%, Ontario: 46%, Quebec: 62%). The inconsistent public reimbursement across the country creates considerable access barriers for those living in, or relocating to, a 'have-not' province. More work needs to be done to determine why these medication access inequities exist.

- **In the overwhelming majority of instances, from the time a medication is approved by Health Canada, it takes many years before it becomes accessible through public drug plans.** This is demonstrated by considering the three medications* that are reimbursed in all four of the provinces we reviewed. The **average time-to-patient access was 1,177 days, or just over three years for the sole three medications* reimbursed in all four of Canada's most populous provinces. For all publicly reimbursed medications, the average time-to-patient is 949 days, or just over two and a half years.** Comparatively, the average public plan time-to-patient for all publicly reimbursed medications is two years in Canada. These delays can have a critical health impact, including the worsening of emotional and cognitive symptoms, increasing treatment resistance, changes in brain structure and functioning, and heightened risk of suicide. The next steps in this work include a deeper dive into the reasons behind these delays.

  ** Trintellix, Invega Trinza, Abilify Maintena*

- The Canadian HTA data evaluated in this report suggest that **medications for mental illness are far less likely to be recommended for public reimbursement than medications for other non-oncology disorders**, creating a significant barrier to public access that results in further inequity. The majority of CADTH reviews (54%) of medications for mental illness resulted in a negative recommendation from CADTH, while only 17% of medications used in other non-oncology disorders received a negative recommendation. The reasons underlying this inequity must be explored and understood.

- **Negative CADTH and INESSS recommendations greatly reduce the chance of drugs to treat mental illnesses moving forward to being publicly reimbursed, contributing to greater inequities for those Canadians that most need them.** Among all reviewed medications in this report, only one received unfavorable CADTH and INESSS recommendations and proceeded to pCPA (refer to Table 3). In such instances, public reimbursement is achieved through repeated submissions and re-evaluations with HTA bodies, demanding new trial data. This leads to substantial time delays for potential beneficiaries and significant health system costs. Again, further analysis is required regarding why medications for mental illnesses are more likely to receive negative decisions.

Within the Canadian mental health system, there is a lack of coverage for medications for mental illness. Not all medications work for everyone, and we need to equal the playing field to create an environment where Canadians can access the medication that is right for them.

Dr. Diane McIntosh, BSc Pharmacy, MD, FRCPC; Community Psychiatrist, and Clinical Assistant Professor at The University of British Columbia; Founder of SwitchRX.com, PsychedupCME.com and RAPIDS, an innovative technology to support clinicians to provide evidence-based, personalized psychiatric care.

How Does Canada Compare

For comparative purposes, this report reviewed public reimbursement processes in three other countries that conduct HTAs (Australia, Scotland, and the United Kingdom (UK)).

- In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC)
- In Scotland, the Scottish Medicines Consortium (SMC)
- In the UK, the National Institute for Health and Care Excellence (NICE)

However, their processes differ from Canada's in two significant ways:

- Their HTA outcomes are binding, which means public drug plans must align with the guidance they provide. This distinction was important to examine, given the potential impact on public access to these medications across the four jurisdictions, in terms of funding status and time-to-patient.
- They do not have a body analogous to Canada's pCPA, because there is only one public payor – the federal government.

As with the Canadian data, this analysis looked at innovative medications for one or more of the same five* mental illnesses that underwent HTA review in at least one of the comparator countries over the same 10-year period. Table 3 provides an overview of each comparator country, as well as Canada. The appendix provides a more detailed view for each of the comparator countries.

**Anxiety Disorders, Bipolar Disorder, Depression, Insomnia, Schizophrenia.*

Mental illness can often be a precursor for physical complications and health issues if not managed properly. As symptoms worsen, people may no longer be feeding themselves, sleeping properly or exercising enough to keep themselves healthy. And as mental illness progresses, it can produce damage in the brain in terms of synaptic contacts or even a shrinkage of some of the brain structures.

Dr. Pierre Blier, MD, PhD; Professor, Departments of Psychiatry and Cellular & Molecular Medicine, Distinguished Research Chair, University of Ottawa; Fellow of The Royal Society of Canada

Table 3. Overview of reimbursement outcomes for mental illness medications in Canada compared to three other countries with similar HTA processes, 2012-2022.

	Canada						Australia	Scotland	UK
	CADTH	INESSS	BC	AB	ON	QC			
HTA assessment									
Number of HTA reviews conducted	13	13	n/a	n/a	n/a	n/a	12	8	4
Negative HTA recommendations given (#)	7	8	n/a	n/a	n/a	n/a	4	3	2
Negative HTA recommendations given (%)	54%	62%	n/a	n/a	n/a	n/a	33%	38%	50%
Reimbursement									
# of medications that underwent HTA and were not reimbursed			7	7	6	8	4	3	2
% of medications that underwent HTA and were not reimbursed			54%	54%	42%	62%	33%	38%	50%
Time-to-patient for medications undergoing HTA review (# of days from regulatory approval to public reimbursement)			962	954	962	907	214	610	1,414

How Does Canada Compare Observations: International Access to Medications for Mental Illness

In reviewing the HTA outcomes, reimbursement status of each medication in the three selected countries, as well as the total time-to-patient, we see that **Canada is indeed falling behind with respect to equity and timeliness** – putting Canadians living with mental illness at a disadvantage.

- **More than half of the funding recommendations for medications for mental illness made by Canada's HTA processes were negative** (INESSS: 62%, CADTH: 54%). **Compared to other countries, Canada's percentage of negative HTA outcomes were greater than in the UK (50%), Australia (33%), and Scotland (38%).** It is unclear what accounts for this difference, given the same empirical data should be available and considered in every country. Are potential patient benefits evaluated differently in other countries? Do they rely on different sources of information (e.g., including clinicians, patient and their supporters)? Or, is there another factor that underlies this clear difference?

- Even though Canada conducted more HTA reviews than the comparator countries, **Canadian provinces were less likely to reimburse medications than comparator countries.** For example, in Quebec (62%), British Columbia and Alberta (54%), and Ontario (46%), approximately half of the drugs reviewed are not being reimbursed, whereas in two comparator countries, the percentage of medications not reimbursed is much lower

(Australia: 33%, Scotland: 38%), with one exception (UK, at 50%, is higher than Ontario, at 46%).

- **The vast majority of Canadians waited more than a year longer to access publicly funded medications for mental illness than people in some of the comparator countries.** Ontarians (962 days), Albertans (954 days), Quebecers (907 days) and British Columbians (962 days) waited almost three years for access, whereas, time to reimbursement in Australia (214 days) and Scotland (610 days) was considerably shorter, with the UK being an outlier (1,414 days).

Discussion

The stark reality in Canada, revealed by this report, is that access to innovative medications for mental illness is hampered by a complex system that takes **far too long** and results in **inequitable access**, or in many cases, no access at all.

Of the medications reviewed for reimbursement over a ten-year period:

- **Less than a quarter (23%) are accessible through public drug plans available to the majority of Canadians.**
- **Just under half (38%) are not accessible at all.**
- The remaining medications have various levels of inequitable reimbursement across the country.
- **And even after the inter-provincial inequities, those that are ultimately able to access these medications must wait between 2.5-6 years.**

There is no silver bullet for treating mental illness – it's a process of trial and error. What we need are better tolerated medications that offer some unique benefits for clinical aspects of the disorders that are not well managed, but are profoundly impairing, such as cognitive symptoms or the negative symptoms of schizophrenia. Yet, almost all innovative medication options are inaccessible. This is extremely frustrating and heartbreaking for me, for my patients and their families.

Dr. Diane McIntosh, BSc Pharmacy, MD, FRCPC; Community Psychiatrist, and Clinical Assistant Professor at The University of British Columbia; Founder of SwitchRX.com, PsychedupCME.com and RAPIDS, an innovative technology to support clinicians to provide evidence-based, personalized psychiatric care.

In reviewing both the Canadian context and comparator countries, there are numerous areas of concern that merit further exploration:

1. **Inequity: There is an inexcusable disparity between medications to treat mental illnesses and medications to treat other (non-oncology) disorders.**
   This disparity is laid bare when comparing the high percentage of negative HTA recommendations for medication used to treat mental illnesses to that of medications prescribed for other disorders.

   Additional research is necessary to better understand the factors that contribute to negative HTA recommendations, as well as inconsistent recommendations between CADTH and INESSS, so that the inequities in access to medications for mental illness can be addressed.

2. **Time delay: A complex pathway to public reimbursement creates glaring inefficiencies that have a real impact on patients.**
   The HTA is just one step in a multi-step process that results in an unacceptable delay in access to innovative medications for mental illnesses. Following an HTA, the pCPA's role negotiating between drug companies and public drug plans was supposed to ensure a level of coordination between the funding jurisdictions. In reality, it has added another layer of bureaucracy to an already lengthy reimbursement process. Beyond the pCPA step, there are many more steps and delays in negotiating with each jurisdiction.

   These layers cause unacceptable additional time delays for patients, as shown in the significant differences in time-to-patient access in Canadian jurisdictions compared to some other countries.

3. **Inequity: Inequitable access to medications is the status quo. It shouldn't be.**
   With multiple public payers across the various jurisdictions in the Canadian healthcare system, all who can make different coverage decisions, access to medications across the country is variable, which can leave many people with mental illness at risk. In this report, we saw that Health Canada approved 12 medications to treat mental illness – some with multiple indications. **Why, then, are there only three instances of those medications publicly reimbursed by all four of the country's most populous provinces?**

4. **Inequity: Do inconsistent HTA recommendations between CADTH and INESSS reflect regional variations or could they point to opportunities for collective improvement?** The differences in HTA recommendations between the Canadian HTA bodies (CADTH & INESSS) and abroad (PBAC, SMC, NICE), which are presumably reviewing similar clinical and economic data, are puzzling. **Why might an HTA conducted in one jurisdiction have a positive recommendation and a negative one in another?** Many HTA bodies provide opportunities for those living with mental illness, their supporters and clinical experts to provide input during the process, but there is no way of knowing whether that input is actually considered. The processes and standards followed by HTA bodies are opaque - greater transparency and understanding of the varied approaches taken by the different HTA bodies is needed to shed light on the inconsistencies and opportunities, most critically in the instances that lead to inequitable access.

Conclusion

Canada has a public healthcare system that was created to address the needs of its citizens – but that is not the reality for many Canadians who rely on public drug access for their medications to treat mental illness. Like all sectors of our society, it must progress to meet the evolving research and our changing needs. The health and wellness of our population is foundational to the strength of our country. We must consistently strive for better outcomes, improved systems and policies, and to not accept the status quo when we recognize it no longer meets the needs of our communities.

As we face a widespread and growing mental health crisis, the need to change our broken system is clear. The insights detailed in this report indicate that there are inherent gaps in Canadians' access to medications for mental illnesses – gaps that illuminate inequity, including time delays, and highlight how mental illness continues to be stigmatized in our society. People living with mental illness deserve better. It could be you or a beloved family member - when mental illness strikes, we all deserve to have the treatment we need to recover as quickly as possible.

Further analysis of specific areas of the drug access pathway, as identified in this report, is required. MDSC and its partners stand ready to assist with that work. Together, let's fix the Canadian drug access process, which will allow for greatly enhanced access to treatments for mental illnesses and make a meaningful difference to the millions of Canadians whose lives and livelihoods depend on it.

"Each day, we face human suffering that is exacerbated by a failed system. That system hasn't evolved to meet the science and the needs of our community. In order to meet this moment, we can't continue to do the same things over and over. We need to think outside this box, seeking innovative strategies, and educate everyone about mental illness and why systemic changes are desperately needed. That won't happen if we don't bravely speak up, share the data, show the evidence, and help to explain exactly what those living with mental illness, and their loved-ones, are experiencing"

Dr. Diane McIntosh, BSc Pharmacy, MD, FRCPC; Community Psychiatrist, and Clinical Assistant Professor at The University of British Columbia; Founder of SwitchRx.com, PsychedupCME.com and RAPIDS, an innovative technology to support clinicians to provide evidence-based, personalized psychiatric care.

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- Wendy Gerhart, Executive Director, Migraine Canada
- Brad Glynn, Executive Director, Lifewise
- Michael Landsberg; Person With Lived/Living Experience; Founder, Sick Not Weak
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- Chris Summerville, CEO, Schizophrenia Society of Canada

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Appendix I: Medications Included

The table below summarizes the medications aligned to the criteria noted for this report and quantifies the number that underwent HTA assessment in Canada, and/or any of the three comparator countries within the 10-year period scoped for this research.

MEDICATION	COUNTRY AND INDICATION			
	CANADA	Australia	Scotland	UK
Abilify (aripiprazole)*	Depression and Major Depressive Disorder	-	-	Bipolar Disorder
Abilify Maintena (aripiprazole)	Schizophrenia	Schizophrenia	Schizophrenia	-
Adasuve (loxapine)	-	-	-	Schizophrenia and Bipolar Disorder
Dayvigo (lemborexant)	Sleep onset and sleep maintenance insomnia	-	-	-
Invega Hafyera (paliperidone)	-	Schizophrenia	-	-
Invega Trinza* (paliperidone)	Schizophrenia	Schizophrenia	-	-
Latuda (lurasidone)	Schizophrenia	Schizophrenia	Schizophrenia	-
Lexapro (escitalopram)	-	Major Depressive Disorder	-	-
Perseris (risperidone)	Schizophrenia	-	-	-
Rexulti (brexpiprazole)	Shizophrenia** Major Depressive Disorder**	Schizophrenia	-	-
Saphris / Sycrest (asenapine)	Schizophrenia** Bipolar I Disorder**	-	Bipolar Disorder	-
Seroquel XR (quetiapine)	-	Bipolar Disorder	-	-
Slenyto (melatonin)	-	Insomnia	Insomnia	-
Spravato (esketamine hydrochloride)	Major Depressive Disorder	Difficult-to-Treat Depression	Major Depressive Disorder Difficult-to-Treat Depression	Difficult-to-Treat Depression
Sublinox (zolpidem)	Short-term and symptomatic relief of sleep disturbances	-	-	-
Trintellix / Brintellix (vortioxetine hydrobromide)	Major Depressive Disorder	Major Depressive Disorder	Major Depressive Disorder	Major Depressive Disorder
Valdoxan (agomelatine)	-	Depression	-	-
Vraylar / Reagila (cariprazine)	Bipolar Disorder** Schizophrenia**	Schizophrenia	Schizophrenia	-
Number of HTA reviews conducted	13 – CADTH 13 – INESSS	12	8	4

**HTA conducted by INESSS but not CADTH or CADTH but not INESSS*

***Underwent separate HTA in Canada for each indication*

Appendix II: HTA Assessment per Country

Table i. Mental illness medication HTA assessments conducted by Australia's Pharmaceutical Benefits Advisory Committee (PBAC), 2012-22

Medication name	Indication	Date of regulatory approval	Date of HTA recommendation*	Date of public reimbursement	Total days-to-patient
Abilify Maintena (aripiprazole)	Schizophrenia	25-Jul-14	1-Jul-14	1-Mar-15	219
Invega Hafyera (paliperidone)	Schizophrenia	10-Feb-22	1-Mar-22	1-Aug-22	172
Invega Trinza (paliperidone)**	Schizophrenia	23-Sep-16	Review conducted, but recommendation date unknown	Medication covered, but listing date unknown	90
Latuda (lurasidone)**	Schizophrenia	16-Apr-15	1-Mar-15	Medication covered, but listing date unknown	136
Rexulti (brexpiprazole)	Schizophrenia	30-Jun-17	1-Mar-17	1-Oct-17	93
Seroquel XR (quetiapine)	Bipolar Disorder	30-Jan-08	1-Jul-13	Not covered at this time	Not covered at this time
Slenyto (melatonin)**	Insomnia	20-May-20	3-Nov-21	Medication covered, but listing date unknown	622
Spravato (esketamine hydrochloride)	Difficult-to-treat Depression	05-Mar-21	1-Jul-22	Not covered at this time	Not covered at this time
Brintellix (vortioxetine hydrobromide)	Major Depressive Disorder, Adults	31-Mar-14	1-Jul-14	Not covered at this time	Not covered at this time
Valdoxan (agomelatine)	Depression	09-Aug-10	1-Mar-12	Not covered at this time	Not covered at this time
Vraylar (cariprazine)	Schizophrenia	18-Nov-20	1-Nov-20	1-Sep-21	287
Zyprexa Relprevv (olanzapine)	Bipolar Disorder	Data was publicly unavailable	1-Jul-13	Medication covered, but listing date unknown	90

Dates are formatted as DD-MM-YY.

**Outcome – positive or negative*

***In instances where the date of public reimbursement is unknown, days-to-patient was calculated by totalling the days from regulatory approval to HTA recommendation, then adding an additional 90 days from the date of HTA recommendation, given that it is binding and there are few remaining hurdles to listing on the public drug plans. Where only the regulatory approval date is know, but drug is listed 90 days was used.*

Table ii. Mental illness medication HTA assessments conducted by the Scottish Medicines Consortium (SMC), 2012-22

Medication name	Indication	Date of regulatory approval	Date of HTA recommendation*	Date of public reimbursement	Total days-to-patient
Abilify Maintena (aripiprazole)**	Schizophrenia	15-Nov-13	12-May-14	Medication covered, but listing date unknown	268
Latuda (lurasidone)**	Schizophrenia	21-Mar-14	13-Oct-14	Medication covered, but listing date unknown	296
Saphris / Sycrest (asenapine)	Bipolar I Disorder	1-Sep-10	12-Mar-12	Not covered at this time	Not covered at this time
Slenyto (melatonin)	Insomnia	20-Sep-18	18-Jan-21	Not covered at this time	Not covered at this time
Spravato (esketamine hydrochloride)**	Difficult-to-treat Depression	4-Feb-21	7-Oct-22	Medication covered, but listing date unknown	700
Spravato (esketamine hydrochloride)	Major Depressive Disorder, adults	4-Feb-21	7-Oct-22	Not covered at this time	Not covered at this time
Trintellix / Brintellix (vortioxetine hydrobromide)**	Major Depressive Disorder, adults	18-Dec-13	11-Jul-16	Medication covered, but listing date unknown	1,026
Vraylar / Reagila (cariprazine)**	Schizophrenia	13-Jul-17	13-May-19	Medication covered, but listing date unknown	759

**Outcome – positive or negative*

***In instances where the date of public reimbursement is unknown, days-to-patient was calculated by totalling the days from regulatory approval to HTA recommendation, then adding an additional 90 days from the date of HTA recommendation, given that it is binding and there are few remaining hurdles to listing on the public drug plans.*

Table iii. Mental illness medication HTA assessments conducted by United Kingdom's National Institute for Health and Care Excellence (NICE), 2012-22

Medication name	Indication	Date of regulatory approval	Date of HTA recommendation*	Date of public reimbursement	Total days-to-patient
Abilify (aripiprazole)**	Bipolar Disorder	31-Mar-08	24-Jul-13	Medication covered, but listing date unknown	2,031
Adasuve (loxapine)	Schizophrenia and Bipolar Disorder	20-Feb-13	13-May-22	Not covered at this time	Not covered at this time
Spravato (esketamine hydrochloride)	Major Depressive Disorder, adults	18-Dec-19	14-Dec-22	Not covered at this time	Not covered at this time
Trintellix / Brintellix (vortioxetine hydrobromide)**	Major Depressive Disorder, adults	18-Dec-13	25-Nov-15	Medication covered, but listing date unknown	797

**Outcome – positive or negative*

***In instances where the date of public reimbursement is unknown, days-to-patient was calculated by totalling the days from regulatory approval to HTA recommendation, then adding an additional 90 days from the date of HTA recommendation, given that it is binding and there are few remaining hurdles to listing on the public drug plans.*

Appendix III: Common Clinical Rating Scales for Mental Illnesses

Depression:

Patient Health Questionnaire-9 (PHQ-9): A brief, self-administered questionnaire to assess the severity of depression.

Hamilton Rating Scale for Depression (HAM-D): Clinician-administered scale to measure the severity of depression symptoms.

Anxiety:

Generalized Anxiety Disorder 7-item (GAD-7): A self-report questionnaire to assess generalized anxiety disorder symptoms.

Hamilton Rating Scale for Anxiety (HAM-A): Clinician-administered scale to measure the severity of anxiety symptoms.

PTSD (Post-Traumatic Stress Disorder):

Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5): A self-report measure to assess PTSD symptoms.

Clinician-Administered PTSD Scale for DSM-5 (CAPS-5): A structured interview for assessing PTSD symptoms.

Bipolar Disorder:

Young Mania Rating Scale (YMRS): Clinician-administered scale to assess the severity of manic episodes.

Hamilton Depression Rating Scale (HAM-D): Also used to assess the depressive symptoms associated with bipolar disorder.

Schizophrenia:

Positive and Negative Syndrome Scale (PANSS): A widely used scale to assess symptoms of schizophrenia, including positive, negative, and general psychopathology symptoms.

Brief Psychiatric Rating Scale (BPRS): Another scale used to assess various symptoms of schizophrenia and other psychotic disorders.

Insomnia:

Insomnia Severity Index (ISI): A self-report questionnaire to assess the severity of insomnia symptoms.

Pittsburgh Sleep Quality Index (PSQI): A self-rated scale to assess sleep quality and disturbances.

Please note that there are many other rating scales available for each of these conditions, and the choice of which scale to use may vary depending on the specific context and requirements of the assessment. Additionally, mental health professionals may also rely on their clinical judgment and observations during the evaluation process.

Glossary

Absenteeism A habitual pattern of absence from a duty or obligation without good reason. [31] In the context of this report, the term is used to describe absenteeism in the workplace.

Anxiety Disorders Individuals with anxiety disorders experience excessive anxiety, fear or worry, causing them to either avoid situations that might precipitate the anxiety or develop compulsive rituals that lessen the anxiety. While everyone feels anxious in response to specific events, individuals with an anxiety disorder have excessive and unrealistic feelings that interfere with their lives in their relationships, school and work performance, social activities and recreation. [32]

Bipolar Disorder A mental illness that causes unusual shifts in a person's mood, energy, activity levels, and concentration. These shifts can make it difficult to carry out day-to-day tasks. There are three types of bipolar disorder. All three types involve clear changes in mood, energy, and activity levels. These moods range from periods of extremely "up," elated, irritable, or energized behavior (known as manic episodes) to very "down," sad, indifferent, or hopeless periods (known as depressive episodes). Less severe manic periods are known as hypomanic episodes. [33]

Brand-name medications The first version of a drug to be sold within a country. A brand name drug is sold by the drug manufacturer that first researched and developed the drug. [34]

CADTH The Canadian Agency for Drugs and Technologies in Health (CADTH) conducts HTA reviews on a national scale (excluding the province of Quebec).

Depression Depression (or major depressive disorder) is not simply a temporary change in mood or a sign of weakness. It is a medical condition with many emotional, physical, behavioural and cognitive symptoms. It is characterized by a fairly lengthy period of time during which a person feels sad or hopeless or lacks focus in life, on a daily or almost daily basis, for the most part of each day. This condition is associated with many other symptoms which can have repercussions emotionally, socially, professionally and in other significant areas of life. [35]

Employee turnover Employees leaving an organization during a given time period. [36]

Formulary A list of approved drugs.

Generic medications A legal copy of a brand name drug. [37]

Healthcare Efforts made to maintain or restore physical, mental, or emotional well-being, especially by trained and licensed professionals [38], which include publicly funded costs involved with operating and delivering healthcare, for example hospitals and public health units.

31 Source: https://en.wikipedia.org/wiki/Absenteeism
32 Source: https://mdsc.ca/edu/what-are-anxiety-disorders/
33 Source: https://www.nimh.nih.gov/health/topics/bipolar-disorder
34 Source: https://www.fnha.ca/Documents/FNHA-Generic-Brand-Name-Prescription-Drugs-FAQ.pdf
35 Source: https://depressionhurts.ca/en/about/
36 Source: https://www.forbes.com/advisor/business/employee-turnover-rate/
37 Source: https://www.fnha.ca/Documents/FNHA-Generic-Brand-Name-Prescription-Drugs-FAQ.pdf
38 Source: https://www.merriam-webster.com/dictionary/health%20care

Health Technology Assessment (HTA)

Health Technology Assessments (HTAs) – also known as Reimbursement Reviews – are assessments of a medication's clinical effectiveness and cost-effectiveness. The outcome of the HTA is a recommendation that is either to list the drug (positive) or not to list the drug (negative). A positive HTA recommendation is generally necessary for the ultimate public reimbursement of new therapies. However, in Canada, HTA recommendations are only that – recommendations: in other words, jurisdictions are not bound to follow them.

Income support

Government programs that provide financial support to people who have no income or very low income.

Indication

With drugs, an indication refers to the use of that drug for treating a particular disease. [39]

INESSS

The Institut national d'excellence en santé et en services sociaux (INESSS) conducts HTA reviews for the province of Quebec.

Insomnia

A common sleep disorder. With insomnia, a person may have trouble falling asleep, staying asleep, or getting good quality sleep. Short-term insomnia may be caused by stress or changes in one's schedule or environment. It can last for a few days or weeks. Chronic (long-term) insomnia occurs three or more nights a week, lasts more than three months, and cannot be fully explained by another health problem.[40]

Letter of Intent (LOI):

At the conclusion of a successful negotiation between pCPA and the manufacturers, a letter of intent (LOI) is created. The LOI lists the terms and conditions for funding a drug which are used to create a product listing agreement (PLA) between each participating member jurisdiction and the manufacturer.

Mental Health

The state of one's mind, feelings, and emotions. [41]

Mental Illness

Mental illnesses are characterized by alterations in thinking, mood or behaviour associated with significant distress and impaired functioning. [42]

Non-adherence

Failure of an individual to follow a prescribed therapeutic regimen. Although nonadherence has traditionally been ascribed to oppositional behaviour, it is more likely due to inadequate communication between the practitioner and the individual, physical or cognitive limitations that prevent the patient from following therapeutic recommendations (e.g., physical disabilities), or adverse effects that are not being adequately addressed. [43]

pCPA

An alliance of provincial, territorial and federal governments that collaborate on a range of public drug plan initiatives. One of its key roles is to conduct negotiations for drugs between the manufacturer and the jurisdiction. [44]

Presenteeism

Working while sick; the act of an employee continuing to work despite having decreased productivity levels or negative consequences. [45]

39 Source: https://www.medicinenet.com/indications_for_drugs__approved_vs_non-approved/views.htm
40 Source: https://www.nhlbi.nih.gov/health/insomnia
41 Source: https://wellbeing.gov.bc.ca/blog/difference-between-mental-health-and-mental-illness
42 Source: https://www.canada.ca/en/public-health/services/chronic-diseases/mental-illness.html
43 Source: https://dictionary.apa.org/nonadherence
44 Source: https://www.pcpacanada.ca/
45 Source: https://en.wikipedia.org/wiki/Presenteeism

Private or workplace insurance plans	An employer, group or individual plan, program or account, however described, that could provide coverage for drug products, including the provision of funding that could be used to pay for drug products [46].
Private drug plan	Private funders (i.e., insurance providers, examples of which include SunLife, Manulife and Blue Cross) make drug coverage decision for their plans.
PLA	A Product Listing Agreement (PLA) is a negotiated agreement between a pharmaceutical manufacturer and the jurisdictional drug plan.
PTSD (Post-traumatic stress disorder)	Post-traumatic stress disorder (PTSD) is a disorder that develops in some people who have experienced a shocking, scary, or dangerous event. [47]
PWLE	Person with Lived/Living Experience.
Public Drug Plans	There are 19 public drug plans. Ten are provincial, three territorial and the federal government runs the following six public drug plans; Indigenous Services Canada, First Nations and Inuit Health Branch, Non-Insured Health Benefits, Canadian Forces Drug Benefit Plan, Veterans Affairs Canada, Treatment Benefits Program, Royal Canadian Mounted Police Health Benefits Program, Citizenship and Immigration Canada, Federal Health Program, Correctional Service Canada, Health Services.
Regulatory approval	In the context of medication, regulatory approval refers to a medication being authorized for sale in a country following a rigorous scientific assessment of safety, efficacy and quality. In Canada, Health Canada is responsible for regulatory approval of medications.
Schizophrenia	A serious mental illness that interferes with a person's ability to think clearly, manage emotions, make decisions and relate to others. Although it affects men and women with equal frequency, schizophrenia most often appears in men in their late teens or early twenties, while it appears in women in their late twenties or early thirties. [48]
Social services	Publicly funded supports and services provided for the benefit of the community, such as education, medical care and housing.
Time-to-patient or days-to-patient	The duration in days from a medication receiving regulatory approval to it being publicly reimbursed and accessible by patients needing to use it.
Treatment-resistant-depression or difficult-to-treat-depression	Treatment-resistant depression is a term used in psychiatry to describe people with major depressive disorder (MDD) who do not respond adequately to a course of appropriate antidepressant medication within a certain time. [49]

46 Source: https://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/fq_pat_exec_office_20190311.pdf
47 Source: https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd
48 Source: https://schizophrenia.ca/learn-more-about-schizophrenia/
49 Source: https://en.wikipedia.org/wiki/Treatment-resistant_depression