The Conference Board of Canada

Accessing Disease-Modifying Therapies for Multiple Sclerosis

A Pan-Canadian Analysis

Primer | December 3, 2020

Contents

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Highlights

- Disease-modifying therapies (DMTs) can reduce the frequency and severity of relapses and slow the progression of disability and new brain lesions in multiple sclerosis (MS) patients.
- Utilization patterns of DMTs changed significantly over the past decade as new oral and higher-efficacy drugs arrived on the market.
- Between 2010 and 2018, the number of DMT claims grew by half. Reimbursement costs rose accordingly, from $386.9 million in 2010 to $607 million in 2018.
- Over half of DMTs are claimed through private drug plans and 41 per cent are covered publicly. Seven per cent are paid for out-of-pocket. In 2018, this represented $39.3 million in spending for individuals and their families.
- When a family member is affected by MS, that household faces a greater financial burden than the average Canadian household. Out-of-pocket costs vary by choice of treatment, province, and prescription drug coverage.
- Public access to new and innovative DMTs lags behind access through private drug coverage.
- Improving timely, affordable, and equitable access to DMTs will lead to better outcomes for people living with MS. Health care systems and society at large also stand to gain.

Multiple sclerosis in Canada

What is MS?

MS is a chronic degenerative disease that causes inflammation and damage to the central nervous system.[1] This disrupts communication between the central nervous system and the rest of the body. MS is a progressive disease leading to increasing disability. Gradual worsening of symptoms can begin early on but is usually more pronounced in later stages.[2] Symptoms consist of fatigue, vision problems, weakness, lack of coordination, impaired sensation, pain, and mood and cognitive changes. The cause of MS is not fully understood. Evidence suggests that several factors are involved, which include lifestyle, environmental, genetic, and biology.[3]

There are different types of MS. Each has a different disease course: clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), and progressive MS (including primary progressive and secondary progressive). The earliest form of MS is clinically isolated syndrome, defined as one episode of neurological symptoms.

The most common form of the disease at diagnosis is RRMS. It is characterized by clearly defined "relapse" periods, during which symptoms are apparent. Following are "remission" periods, where normal to near-normal functioning returns. Secondary progressive MS (SPMS) occurs following a course of RRMS. It is marked by progressive worsening with fewer relapses, minor remissions, and plateaus. People who experience worsening disease and disability from the onset of symptoms are diagnosed with primary progressive MS (PPMS).[4] The concept of "active" disease was introduced in 2013 and is identified by magnetic resonance imagining (MRI) or clinical evidence of ongoing inflammation.[5,6]

The prevalence of MS in Canada is one of the highest in the world. In 2016, over 77,000 Canadians 20 years of age or older were estimated to be living with MS.[7] Sixty per cent of Canadian adults diagnosed with MS are between 20 and 49 years of age.[8] MS is three times more common in women than in men. Approximately 85 to 90 per cent of people with MS are diagnosed with RRMS. Many eventually transition to SPMS, while 10 to 15 per cent are diagnosed with PPMS.[9]

1 Public Health Agency of Canada, "Multiple Sclerosis in Canada."
2 Costello and Kalb, *The Use of Disease-Modifying Therapies.*
3 MS Society of Canada, "Types."
4 Ibid.
5 Lublin and others, "Defining the Clinical Course of Multiple Sclerosis."
6 Multiple Sclerosis News Today, "Health Canada Approves Ocrevus."
7 Public Health Agency of Canada, "Multiple Sclerosis in Canada."
8 Ibid.
9 Ibid.

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Health and economic burden of MS

MS poses a significant economic burden. It affects people living with MS, the health care system, the Canadian economy, and broader society. The onset of MS is usually between 20 and 49 years of age, impacting educational and employment prospects.[10] This leads to significant work challenges, with economic implications for personal incomes and labour force supply. People living with MS also face workplace-related barriers (e.g., accessibility issues with physical workspace, accommodations during periods of relapse, or disability progression).

A recent survey by the Multiple Sclerosis Society of Canada found that less than half (20 to 45 per cent) of people with MS remain employed following diagnosis.[11] The loss in economic activities from unemployment and reduced working hours is significant, accounting for around 33 per cent of the overall economic burden of MS (including direct, indirect, and intangible costs).[12] Informal caregiving represents an additional burden on families and society at large. In some age groups, this type of support is required for over half of those living with MS.[13]

Purpose of this research

As part of its research series Access to Medications in Canada, The Conference Board of Canada explored key barriers to accessing DMTs in Canada. This research analyzes the evolving pattern of DMT utilization within the context of drug innovation and changing policy landscape. It also investigates the costs incurred by different payers (public, private, and out-of-pocket). Ultimately, the issue of equitable and affordable access to DMTs across provinces and prescription drug coverage is explored.

Treatment options in Canada

While there is currently no cure for MS, DMTs can reduce the frequency and severity of relapses. The progression of disability and development of new brain lesions can also be slowed.[14] Currently, 12 DMTs (by active ingredient) are approved by Health Canada for the treatment of RRMS, including three that can also be used to treat SPMS and one that is conditionally approved to treat early PPMS.[15] (See Table 1.) (Also see more details on mechanisms of action in Appendix C.) The DMTs, listed by active ingredient, have different routes of administration: oral, injected, and infused.

10 Amankwah and others, “Multiple Sclerosis in Canada 2011 to 2031.”
11 Multiple Sclerosis Society of Canada, *Listening to People Affected by MS*.
12 Oleen-Burkey and others, “Burden of a Multiple Sclerosis Relapse.”
13 Olofsson and others, “Effect of Treatment With Natalizumab.”
14 Multiple Sclerosis Society of Canada, “Disease-Modifying Therapies.”
15 Ibid.

Table 1
List of DMTs by active ingredient approved for use by Health Canada in 2020

Route of administration	Active ingredient	Indication
Injected	Glatiramer acetate	RRMS
	Interferon beta-1a	RRMS, Active SPMS
	Interferon beta-1b	RRMS, Active SPMS
	Peginterferon beta-1a	RRMS
Oral	Cladribine	RRMS
	Dimethyl fumarate	RRMS
	Fingolimod (fingolimod hydrochloride)	RRMS
	Siponimod*	Active SPMS
	Teriflunomide	RRMS
Infusion	Alemtuzumab	RRMS
	Natalizumab	RRMS
	Ocrelizumab	RRMS, Early PPMS (conditionally approved)

*Siponimod approved for marketing by Health Canada only in 2020; therefore, not included in the analyses.
Source: The Conference Board of Canada.

In addition to these 12 DMTs, several medications are potentially used off-label to treat MS in Canada. These medications contain active ingredients that may be approved for the treatment of MS in other countries, but not in Canada. (See Appendix A.) Some provinces are spearheading the use of these drugs. For example, rituximab—approved by Health Canada to treat conditions other than MS—has been on the British Columbia formulary for the treatment of RRMS since late 2018.

Treatment goals and considerations

DMTs can improve disease prognosis and quality of life by targeting the underlying inflammatory pathologies of MS.[16] The DMTs approved in Canada include first- and second-line DMTs. First-line therapies are used to treat an initial diagnosis of MS. Second-line therapies are generally reserved for people who are unresponsive to first-line therapies, have an intolerance, or have high disease activity. For best outcomes, patient–provider discussions of potential treatment should be initiated as soon as possible following diagnosis.[17]

First-line medications can significantly prevent disease progression and improve quality of life for most cases of MS. However, people living with higher levels of inflammatory activity require higher-efficacy second-line therapies. This is needed to reduce relapse rate and slow the progression of disability. Second-line medications[18] that reduce relapse rate include alemtuzumab, cladribine, fingolimod, natalizumab, and ocrelizumab.[19]

16 Costello and Kalb, *The Use of Disease-Modifying Therapies.*

17 Ibid.

18 Although higher-efficacy medications are sometimes used as a first-line treatment for people with active disease, they are referred to as "second-line medications" in the context of this report.

19 Ibid.

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Several factors can influence the choice of treatment for both first- and second-line therapies. These include prescribing guidelines, prescription drug coverage, disease course, life stage (pediatric, pregnancy, older adult), lifestyle (informs choice of administration route), personal risk tolerance, and drug tolerance.[20] Early intervention and ongoing treatment with DMTs lead to better outcomes.[21,22] Under the 2017 McDonald criteria, a person may be diagnosed with MS during or shortly after their first clinical attack.[23] However, most Canadian provinces haven't updated their policy to reflect this new criteria and still require evidence of two relapses before initiating therapy. Close monitoring of disease activity and rapid adjustment or change of DMTs (if needed) are also important. These strategies can maximize brain health and delay the progression of disability.[24]

Escalating to a second-line DMT is considered when the status quo treatment does not achieve an adequate response (i.e., disease activity is not effectively managed) or is associated with intolerable side effects.[25] DMTs can differ in their effectiveness from one person to another and at different points in time over the course of the disease. DMTs also differ in their mechanism of action, side effects, risk profiles, and route of administration—all of which can impact medication compliance and adherence. This can affect outcomes such as improvements in quality of life.[26] People living with MS could therefore benefit from a more tailored treatment strategy. Broadening access to treatment options approved under more flexible criteria would facilitate this goal.[27]

Access to prescription medication

The Canadian drug reimbursement system is fragmented and difficult to navigate. It constitutes a patchwork of over 100 government-run public drug insurance programs and thousands of private drug benefit plans.[28] Research by the Conference Board highlights gaps in pharmaceutical drug coverage between public and private drug programs.[29] In addition, variation in public drug coverage presents challenges for patients and caregivers.[30] (See "Accessing prescription drugs: challenges faced by Canadians.") The proportion of uninsured Canadians is low (less than 2 per cent). Insured Canadians, however, face cost barriers from deductibles, co-payments, or out-of-pocket costs, all of which can impact access to medications and their proper use.[31]

20 Giovannoni and others, *Brain Health.*

21 Costello and Kalb, *The Use of Disease-Modifying Therapies.*

22 There are also instances where discontinued use of DMTs may be safe (e.g., in older patients who are free of acute central nervous system inflammation for at least two years).

23 Thompson and others, "Diagnosis of multiple sclerosis."

24 Giovannoni and others, *Brain Health.*

25 Costello and Kalb, *The Use of Disease-Modifying Therapies.*

26 Ibid.

27 Prosperini, Capobianco, and Gianni, "Identifying Responders and Nonresponders to Interferon Therapy in Multiple Sclerosis."

28 Government of Canada, *A Prescription for Canada.*

29 Dinh and Sutherland, *Understanding the Gap.*

30 Ibid.

31 Government of Canada, *A Prescription for Canada.*

Accessing prescription drugs: challenges faced by Canadians

A Conference Board of Canada report outlines challenges that patients and caregivers may face when accessing medications,[32] such as:

- differences in public versus private coverage for specific drugs across provinces or through national insurance programs;
- out-of-pocket costs, where medications are partially covered, or not at all, which can vary widely across provinces for different reasons;
- process and administrative barriers that patients and caregivers face in enrolling for drug coverage and then in accessing medications;
- difficulties that patients, caregivers, and care providers face due to administrative inefficiencies, such as program re-application hurdles.

Source: Feng, Russell, and Slovinec D'Angelo.

In general, Canadians over 65 years of age are enrolled in a public plan, although some are enrolled in both public and private plans. Canadians under 25 years of age have access to public drug coverage if they are not a beneficiary of their parents' private employer-based group plan. Around 75 per cent of working-age adults (i.e., 25 to 64 years of age) are enrolled in a private group plan.[33] Employed and unemployed people without access to a private group plan or a public drug program must either purchase their own prescription drug insurance or pay for medications out-of-pocket.

Access challenges for people living with MS

According to the Multiple Sclerosis Society of Canada's 2018 *Listening to People Affected by MS* report, access to medical care and involvement in decision-making regarding treatment are top priorities.[34] However, timely access to doctors, specialists, medical tests, and treatments is challenging. Additionally, Canadians affected by MS would benefit from assistance in navigating the health care system (e.g., through support services to find specific programs based on individual needs).[35] Lack of employment support was identified as another key issue.[36] These supports could reduce the high unemployment rate of people living with MS and boost access to private drug plan coverage.

32 Feng, Russell, and Slovinec D'Angelo, *Accessing Necessary Arthritis Medications.*

33 Dinh and Sutherland, *Understanding the Gap.*

34 Multiple Sclerosis Society of Canada, *Listening to People Affected by MS.*

35 Ibid.

36 Davis, *Consulting on Proposed Amendments to the Patented Medicines Regulations.*

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Utilization and cost of DMTs in Canada

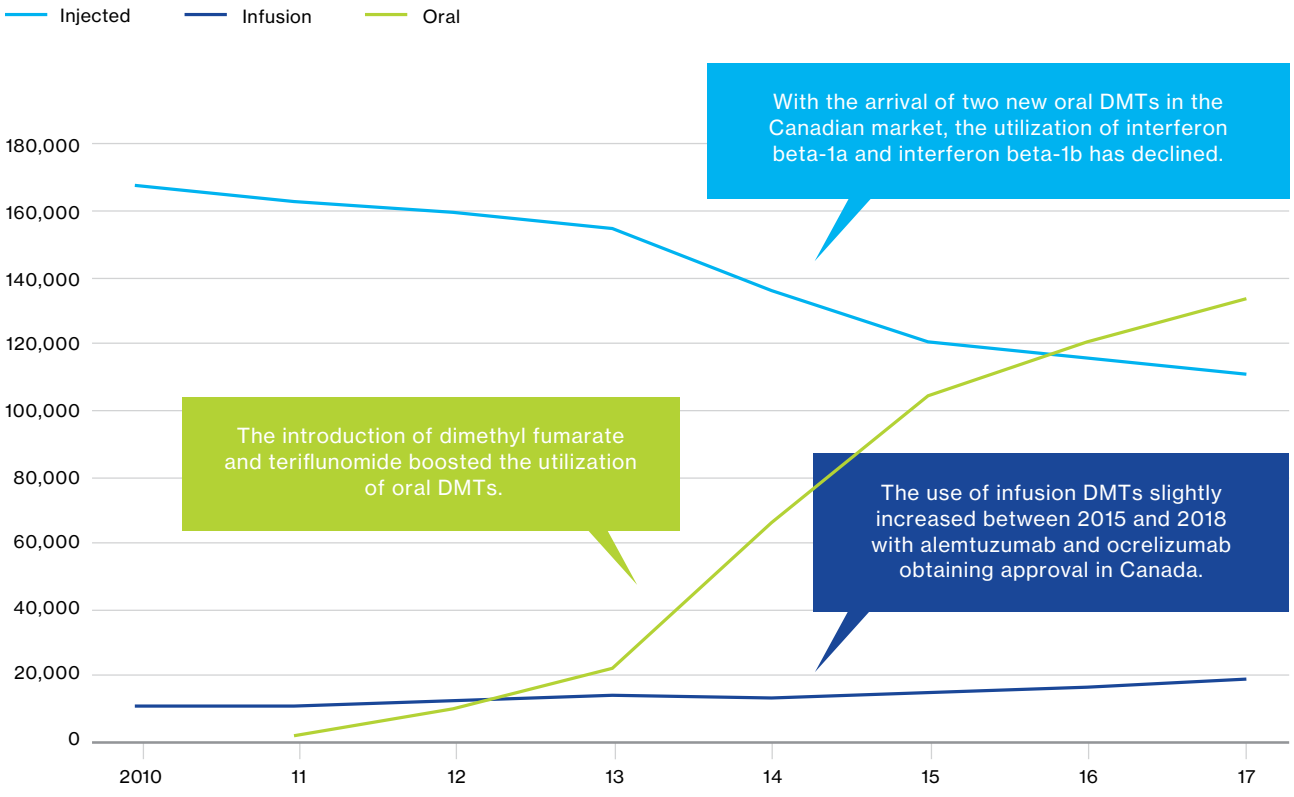
Drug innovation is driving trends in DMT utilization

The utilization patterns of DMTs have changed significantly over the past decade as new drugs arrived on the market. (See Chart 1.) People living with MS now have access to a wider variety of treatment options, thanks to significant advances in drug innovation. Over the last 10 years, eight new DMTs (by active ingredient) were added to the basket of available therapies.[37]

Chart 1

Oral DMT utilization surpasses injectables

(number of claims reimbursed for DMTs by route of administration, 2010–18)



Note: Analysis conducted by The Conference Board of Canada (CBoC) based on IQVIA's PharmaStat and PharmaStat Plus databases and Canadian Institute for Health Information's (CIHI) National hasPrescription Drug Utilization.
Source: The Conference Board of Canada.

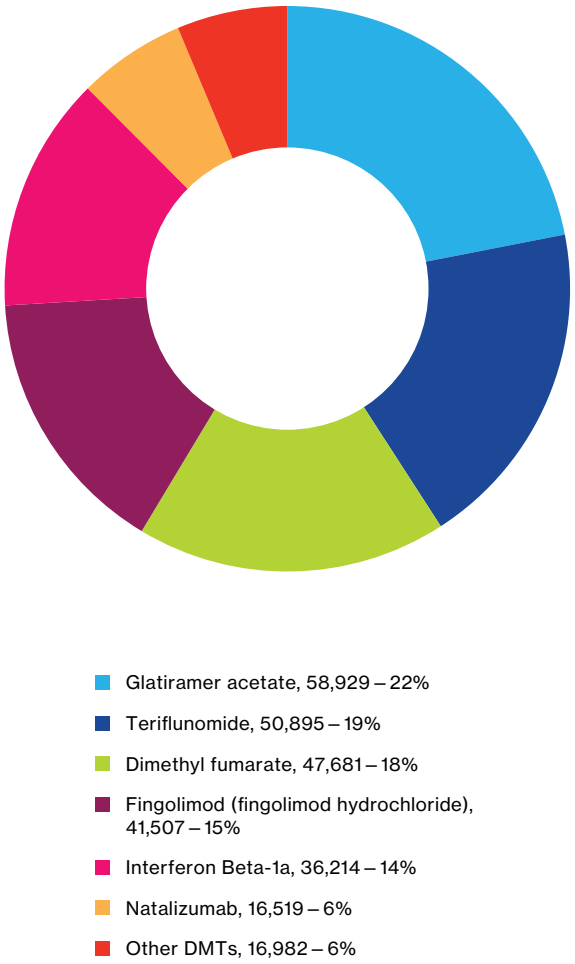
37 The newly added eight active ingredients over the last decade include fingolimod, dimethyl fumarate, teriflunomide, alemtuzumab, peginterferon beta-1a, ocrelizumab, cladribine, and siponimod. However, since siponimod recently became available in 2020, this DMT is not included in this data analysis.

With the advent of the first oral drug—fingolimod (a second-line therapy)—in the Canadian market in 2011, oral therapies have gradually gained popularity because of their ease of administration. An important turning point in the use of oral DMTs came with the introduction of lower-cost, first-line dimethyl fumarate and teriflunomide products in 2013. With the recently approved drug cladribine, the four oral DMTs accounted for 140,000 prescription drug claims reimbursed in 2018. This represented over half of total claims for DMTs. The arrival of oral DMTs corresponded with the overall rise in DMT utilization in Canada. The situation looked different a decade ago, when injectable products were the main therapy used to treat MS in Canada. The introduction of first-line oral DMTs in 2013 led to a significant decline in the utilization of injectables. In 2018, injected DMTs represented around 39 per cent of all claims reimbursed for the treatment of MS, down from a market share of 94 per cent in 2010. The injected medication interferon beta-1a went from the most-prescribed DMT in 2010 to the fifth in 2018. The first-line injectable drug glatiramer acetate was the most commonly used DMT in 2018, followed closely by the oral drugs teriflunomide (first-line), dimethyl fumarate (first-line), and fingolimod (second-line). Combined, the five DMTs above accounted for the majority (88 per cent) of all MS drug claims in 2018. (See Chart 2.) The use of infusion drugs remained low—representing 6 to 8 per cent of DMT market share over the last few years.

Chart 2

Utilization of DMTs in 2018

(claims for DMTs by active ingredient (number); share of total (per cent))



Note: Other DMTs include natalizumab, interferon beta-1b, alemtuzumab, peginterferon beta-1a, ocrelizumab, and cladribine (ranked by the number of claims). Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
Source: The Conference Board of Canada.

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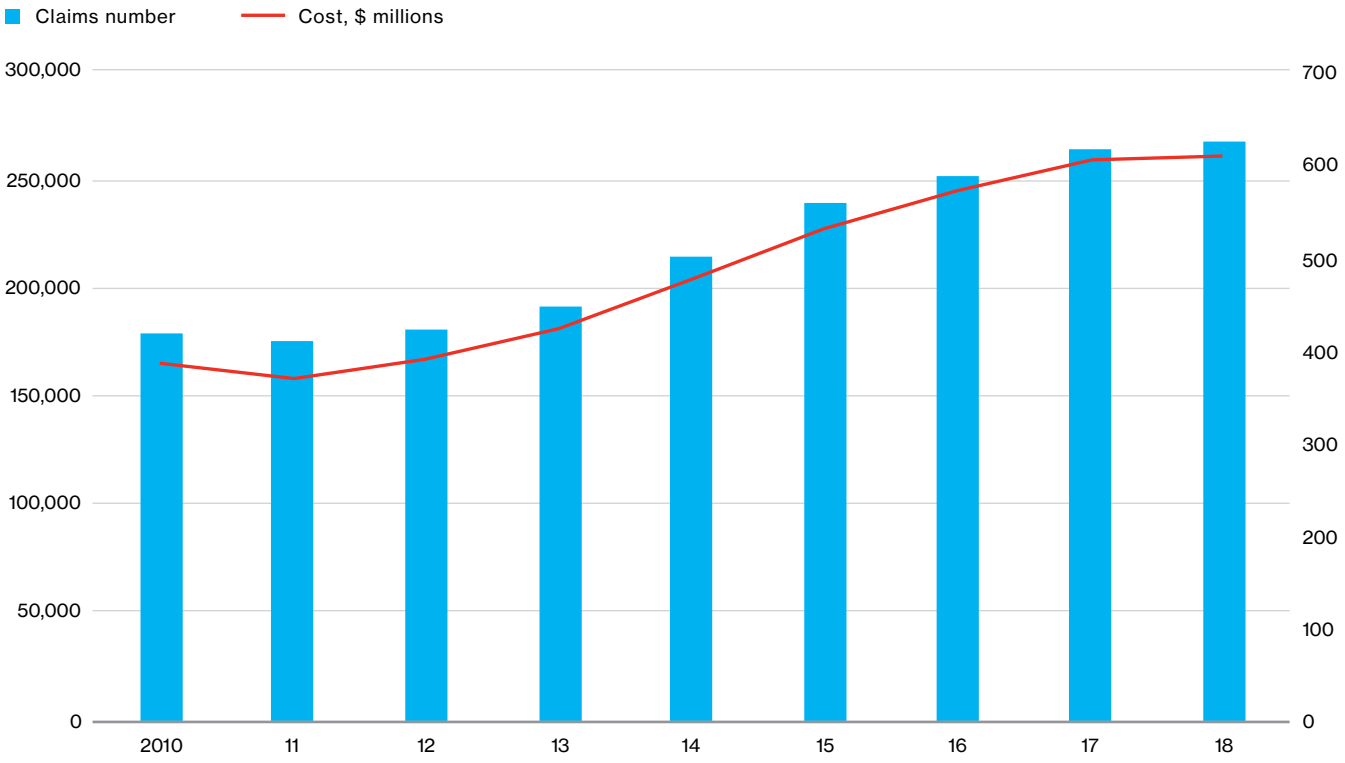
Greater utilization of DMTs is the key driver of rising reimbursement costs. Between 2010 and 2018, the number of DMT claims grew by half—from 178,700 claims in 2010 to 268,700 in 2018. This increase was accompanied by a similar growth in reimbursement of 57 per cent, with costs rising from $386.9 million in 2010 to $607 million in 2018. (See Chart 3.) Every year, reimbursement costs for DMTs have increased by an average of 6 per cent.

Chart 3

Utilization is driving the rise in reimbursement costs for DMTs

(claims and reimbursement costs for DMTs, 2010–18)



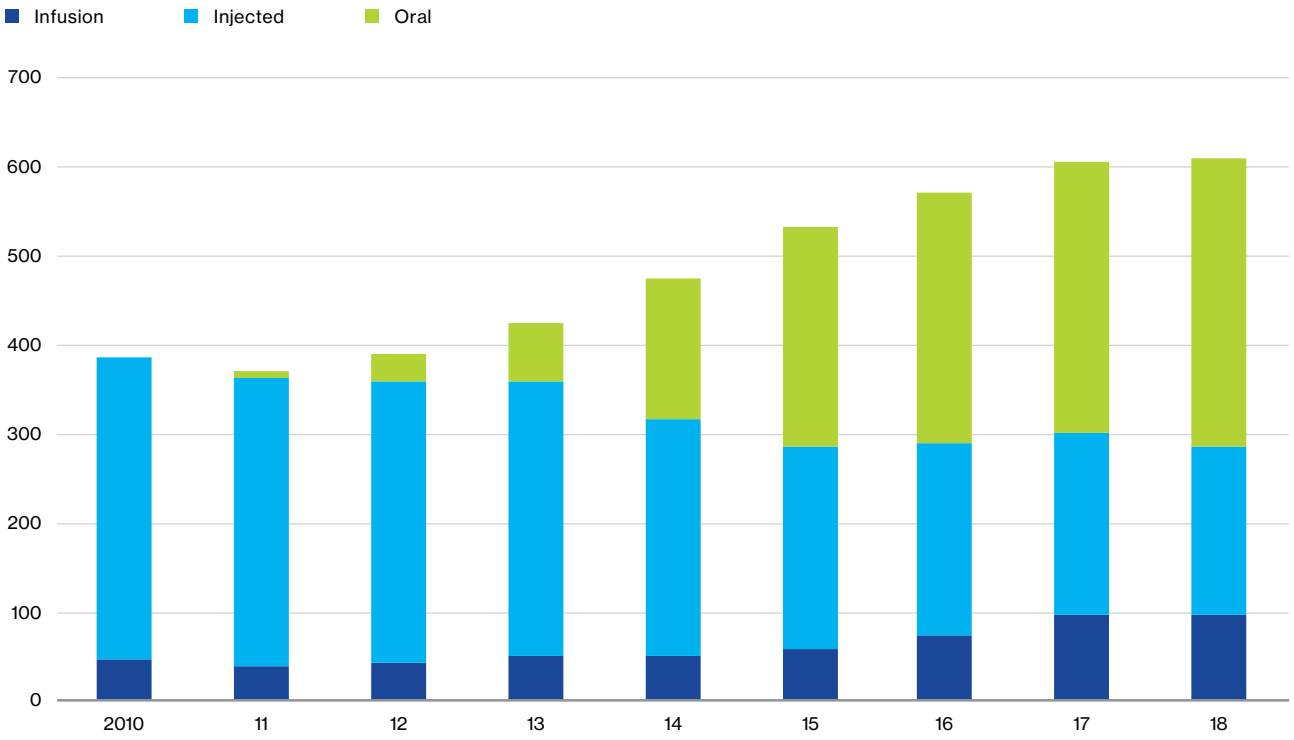
Note: Costs presented are inflation-adjusted to 2018 Canadian dollars. Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
Source: The Conference Board of Canada.

The distribution of costs between injected, oral, and infused DMTs has also changed between 2010 and 2018. (See Chart 4.) As expected, reimbursement costs for oral therapies increased, while those for injectables decreased. Oral therapies represented only 8 per cent of costs in 2012, increasing to 53 per cent in 2018. This was driven by the arrival of new oral DMTs over the last decade. And while utilization shifted away from injected DMTs, so did reimbursement for these medications (from 81 per cent in 2012 to 31 per cent in 2018).

Chart 4

Share of oral DMT costs has increased

(reimbursement costs for DMTs by route of administration, $ millions)



Note: Costs are inflation-adjusted to 2018 Canadian dollars. Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
Source: The Conference Board of Canada.

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However, changes in DMT utilization are not the only driver of reimbursement costs. Across the country, the average cost per unit of DMT has almost doubled over the last 10 years. It went from less than $300 (adjusted for inflation) in 2010 to over $500 in 2018. Various factors impact the average cost of drugs. The introduction of new DMTs in the Canadian market and the availability of generic, biosimilar, or subsequent entry non-biologic complex drug (SENBCD) versions of their originator DMTs play a role. (See "Innovative medications.") These factors have variable impacts on patient access to DMTs.

The availability of new medicines broadens treatment options. However, the high cost of some innovative medications is a barrier to access. These costs can have a significant impact on the fiscal balance of governments. The number of medications with an annual cost of at least $10,000 has more than tripled since 2006.[38] The recent introduction of generics, biosimilars, and SENBCDs results in less costly versions of medications (e.g., fingolimod, glatiramer acetate). These drugs have the potential to improve future access to DMTs by removing financial hurdles for individuals.[39,40] Alternate versions of branded originators can also reduce costs incurred by public and private drug insurers. From a regulatory perspective, changes in coverage from brand-name products to generics and biosimilars help reduce health care spending. From a patient perspective, favouring generics over brand names can impact (i.e., limit) the choice of medications.[41]

38 Patented Medicine Prices Review Board, *Patented Medicine Prices Review Board: Annual Report 2017.*
39 National Multiple Sclerosis Society, "Frequently Asked Questions."
40 Government of Canada, *A Prescription for Canada.*
41 Ibid.

Innovative medications

Several innovative DMTs are on the market and in development. Emerging treatments feature innovative technologies such as new monoclonal antibodies and myelin repair treatments.[42] Current treatments with monoclonal antibodies include natalizumab, alemtuzumab, and ocrelizumab. Ofatumumab is a new monoclonal antibody in development.[43] Innovation is important for treatment outcomes. People with MS who experience poor disease management from an established DMT may benefit from switching to a newer DMT. Studies have shown that newer DMTs (introduced as of 2006) may be more effective than established DMTs.[44]

Sources: Multiple Sclerosis Society of Canada; Giovannoni and others.

42 Multiple Sclerosis Society of Canada, "Treatments in Development."

43 Ibid.

44 Giovannoni and others, *Brain Health.*

The impact of innovation on reimbursement costs can also be analyzed by comparing the mix in utilization and costs between the three routes of administration. (See Chart 5.) For example, the share of utilization for oral and injected DMTs is significantly higher (53 per cent and 39 per cent, respectively) compared with infused DMTs (8 per cent). However, the share of costs is proportionately higher for infused DMTs (16 per cent).

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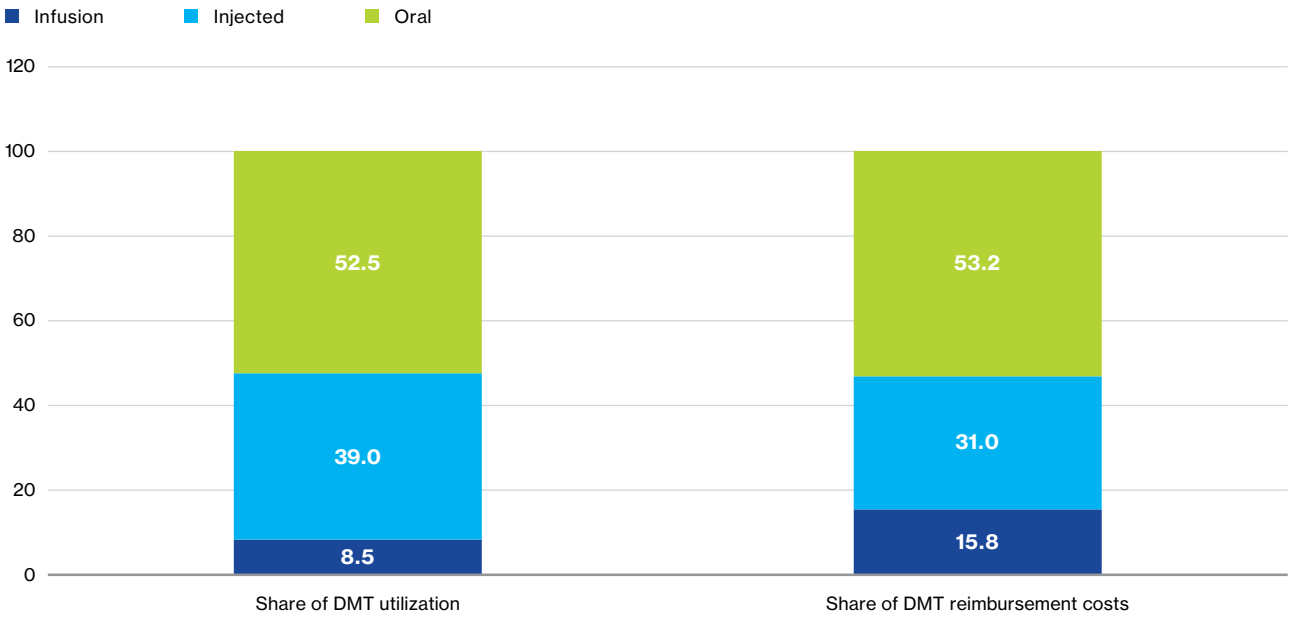
In general, infusion therapies are more costly than injected and oral ones. (See Table 2.) The growing cost share of infusion therapies was driven by the introduction of two new DMTs—alemtuzumab and ocrelizumab. Alemtuzumab was approved by Health Canada in 2014 to treat relapsing forms of MS. Ocrelizumab was approved in 2018 to treat RRMS. It is also the first DMT specifically indicated for the treatment of (early and active) PPMS.[45] Alemtuzumab and the oral drug cladribine are unique in that they have shorter treatment periods over a person's life. However, their upfront costs are higher than other DMTs. Both DMTs have a treatment period of two years, costing around $96,000 for alemtuzumab and $88,000 for cladribine.[46] While other DMTs have a lower annual cost, they may require treatment over many years, leading to higher lifetime costs.

Chart 5
Cost of infusions relatively higher than utilization
(number of claims reimbursed for DMTs by route of administration, 2018)



Note: Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
Source: The Conference Board of Canada.

45 There can be a lag between the approval of a new medication by Health Canada, the date when it is marketed for sale, and when it is included for reimbursement under private and public drug plans.

46 However, anecdotal evidence has shown that most patients will need another DMT within three years.

Table 2
Average cost per unit of DMTs with claims in 2018
(estimated cost per year, $)

Infusion drugs	Cost
Alemtuzumab (Lemtrada)	(year 1) 60,000 (year 2) 36,000
Natalizumab (Tysabri)	40,000
Ocrelizumab (Ocrevus)	33,000
Injected drugs	**Cost**
Glatiramer acetate (Copaxone)	16,000
Glatiramer acetate (Glatect)	14,000
Interferon beta-1a (Avonex)	20,000
Interferon beta-1a (Rebif)	22,000
Peginterferon beta-1a (Plegridy)	24,000
Interferon beta-1b (Betaseron)	20,000
Interferon beta-1b (Extavia)	18,000
Oral drugs*	**Cost**
Cladribine (Mavenclad)**	44,000
Dimethyl fumarate (Tecfidera)	23,000
Fingolimod (Gilenya) ***	33,000
Teriflunomide (Aubagio)	23,000

*Siponimod approved for marketing by Health Canada only in 2020; therefore, not included in the analyses.
**Cladribine is taken as two treatment courses over two years. Each treatment course consists of two treatment weeks, which are one month apart at the beginning of each treatment year.
***generic versions of fingolimod not included in the analysis since not marketed in Canada until 2019.
Sources: Multiple Sclerosis Society of Canada;
The Conference Board of Canada.

Beyond the actual price of the drug ingredient, other costs associated with prescribing and dispensing may be added. These include the wholesale upcharge, pharmacy markup, and pharmacist professional fee.[47] In addition, some people living with MS experience symptoms from their condition, and side effects from DMTs are also common, both of which can be managed with other types of medications. (See "Symptom management and costs.") These additional costs add to the financial pressure on public and private drug plans and patients' out-of-pocket expenses.

47 Gagnon-Arpin, Vroegop, and Dinh, *Health Care Aware*.

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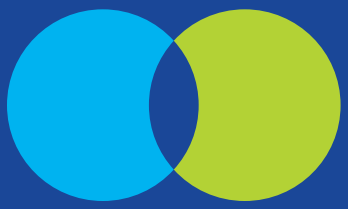
Symptom management and costs

MS symptoms that impact quality of life include fatigue, balance and mobility issues, pain, depression, and impaired sensation.[48] Medication can help manage some of these symptoms.[49] DMTs can also cause undesirable side effects, such as infections and injection/infusion-site reactions needing treatment.[50] People living with MS are also at increased risk for depression and other co-morbidities.[51] Treating MS symptoms, medication side effects, and co-morbidities leads to financial pressures additive to the use of DMTs.

Sources: Multiple Sclerosis Society of Canada; Costello and Kalb; Express Scripts Canada.



48 Multiple Sclerosis Society of Canada, *Listening to People Affected by MS.*
49 Multiple Sclerosis Society of Canada, "Programs and Services."
50 Costello and Kalb, *The Use of Disease-Modifying Therapies.*
51 Express Scripts Canada, *Express Scripts Canada.*

Mix of public and private coverage varies across provinces

Across the three routes of DMT administration, private drug plans incurred the largest increase in costs between 2011 and 2018 (9 per cent per year), followed by public plans (5 per cent per year) and out-of-pocket spending (5 per cent per year). In 2018, utilization of DMTs for the treatment of MS totalled 268,700 claims. Nationally, more than half of these claims (52 per cent) were submitted to private prescription drug plans, representing 140,600 claims. Public drug programs processed more than 110,200 DMT claims (41 per cent of total claims). The remaining 17,900 claims were paid out-of-pocket, accounting for 7 per cent of claims.

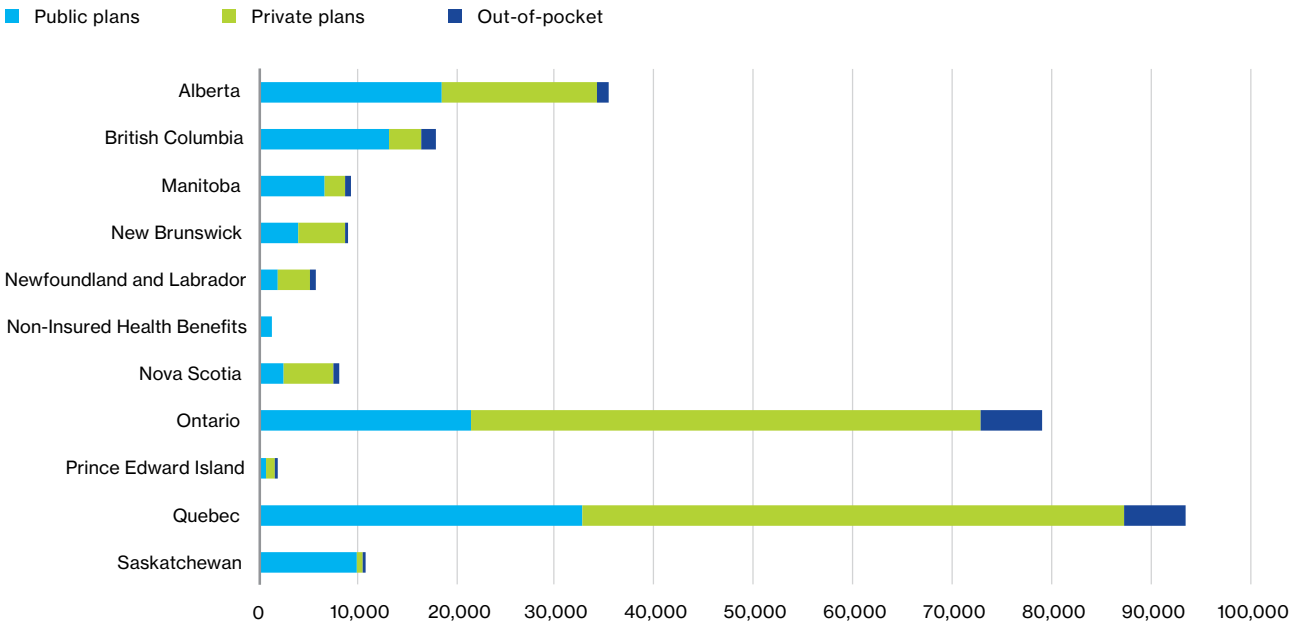
The number of DMT claims reimbursed in each province is influenced by the number of people living with MS, among other factors. Differences also exist in the mix of coverage. (See Chart 6.) For example, up to 90 per cent of DMT claims in Saskatchewan were made to public drug plans. This compares with only 27 per cent in Ontario and 30 per cent in Nova Scotia and Newfoundland and Labrador. Accordingly, these three provinces had the highest proportion of claims submitted to private drug plans (65 per cent, 62 per cent, and 62 per cent, respectively). Other provinces fell between 27 per cent and 90 per cent in terms of public coverage.

Out-of-pocket claims represented a larger portion of claims in some provinces. In Manitoba, British Columbia, and Newfoundland and Labrador, around 9 per cent of claims were each paid out-of-pocket. This is six percentage points higher than what was paid by those in Saskatchewan, Prince Edward Island, and Alberta. Nearly 1,200 claims (representing less than 1 per cent of total DMT claims) were accepted by the Non-Insured Health Benefits program (NIHB) administered by the federal government for First Nations and Inuit. Of interest, the mix of coverage is different for other chronic conditions. (See "Comparing the out-of-pocket burden of other conditions.")

Chart 6

Different mix of public, private, and out-of-pocket coverage across provinces

(number of DMT claims by payer and province, 2018)



Note: Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
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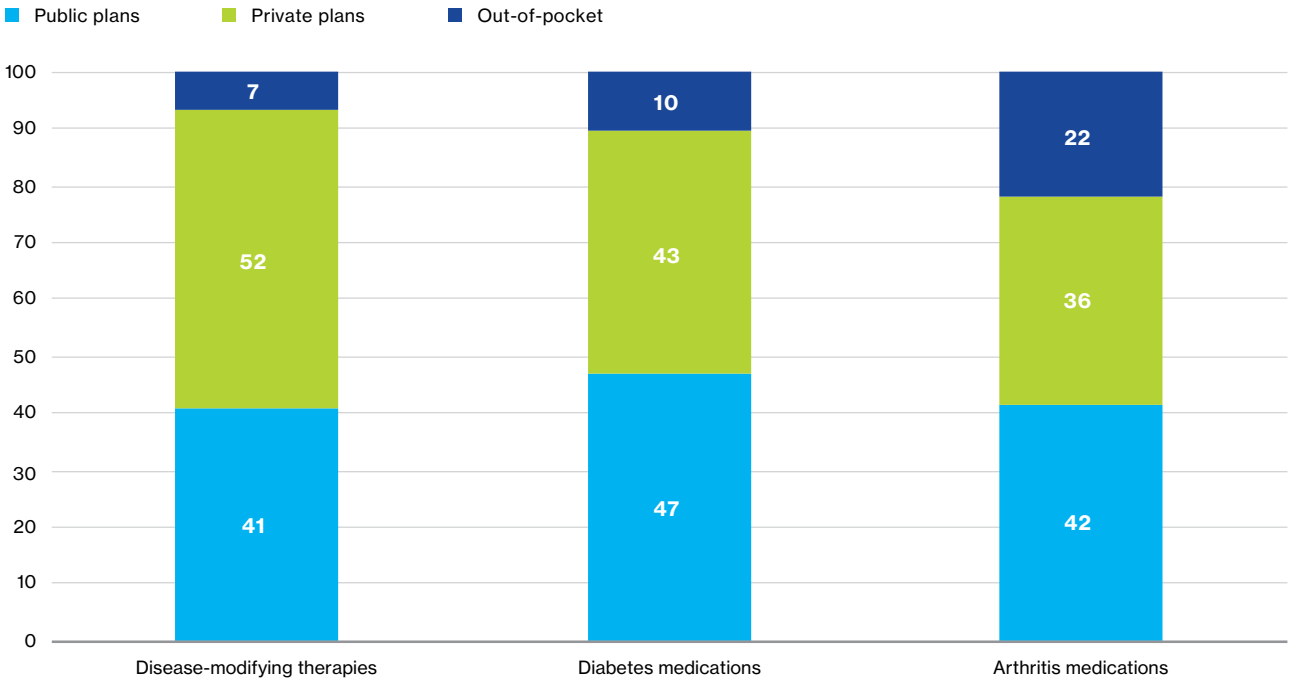
Comparing the out-of-pocket burden of other conditions

Compared with prescription drugs used to treat diabetes and arthritis, DMTs were more often covered under private drug plans. Fifty-two per cent of MS drug claims were privately covered, compared with 43 per cent for diabetes[52] and 36 per cent for arthritis.[53] (See Chart 7.) Since MS develops earlier in life, people are more likely to be covered under private employer-based group plans as opposed to public drug programs. A smaller proportion of MS drug claims were paid out-of-pocket (7 per cent), compared with diabetes (10 per cent) and arthritis (22 per cent).

Sources: MacLaine and others; Feng, Russell, and Slovinec D'Angelo.

Chart 7
Mix in coverage varies by condition
(proportion of claims by payer and condition, per cent)



Note: MS claims are for 2018, while diabetes and arthritic claims are for 2017.
Source: The Conference Board of Canada.

52 MacLaine and others, *Accessing Diabetes Medications.*

53 Feng, Russell, and Slovinec D'Angelo, *Accessing Necessary Arthritis Medications.*

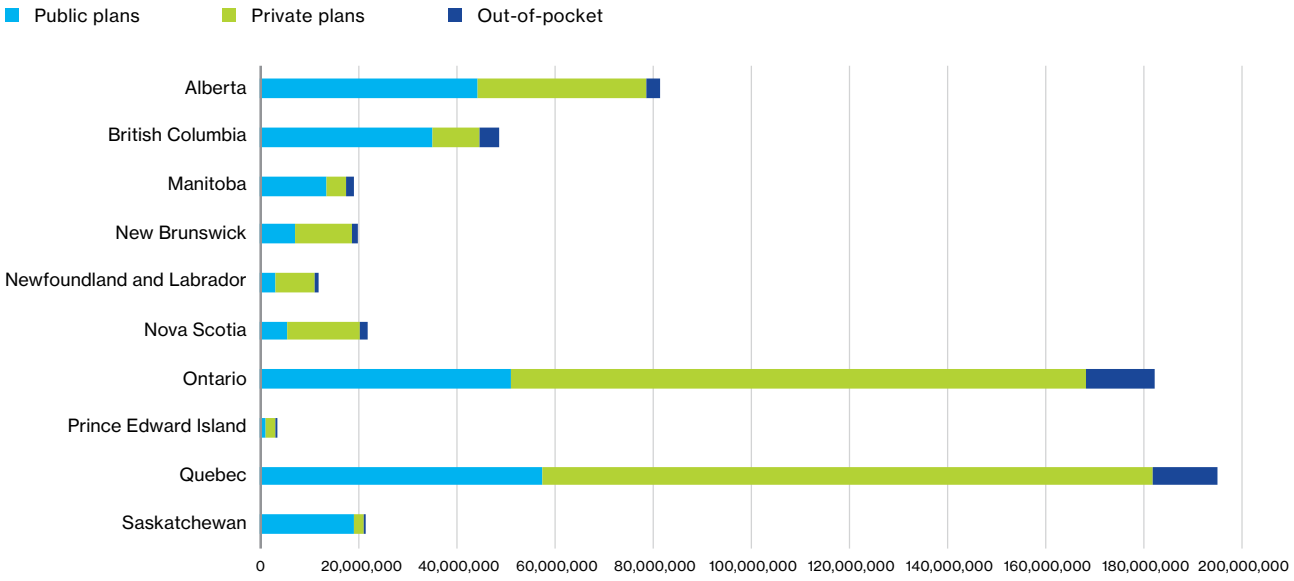
Comparing reimbursement costs between provinces

In 2018, the total cost of DMTs for the treatment of MS was $607 million. This included $327.3 million (54 per cent) reimbursed by private drug plans and $240.4 million (40 per cent) by public plans. The amount paid out-of-pocket totalled $39.3 million (or 7 per cent of costs).

In most provinces, the mix of costs incurred by different payers (public, private, out-of-pocket) follows the number of claims. For example, 90 per cent of MS drug costs were covered publicly in Saskatchewan, compared with 54 per cent in Alberta, 30 per cent in Quebec, and 27 per cent in Ontario. (See Chart 8.) In those provinces, private insurers assumed a large portion of costs.

Residents in some provinces—British Columbia, Manitoba, Newfoundland and Labrador, Ontario—assumed a higher share of MS drug costs (approximately 8 per cent). This compares with 1.7 per cent in Saskatchewan and 2.6 per cent in Prince Edward Island. Other provinces fell in the range of around 3 to 7 per cent.

Chart 8
Proportion of costs by payer varies across provinces
(drug costs by payer and province, 2018)



Note: Analysis conducted by CBoC based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.
Source: The Conference Board of Canada.

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Understanding the impact of prescription drug coverage

Interprovincial variation in mix of coverage is partially driven by differences in the design of public drug programs.[54] The range of drugs included on provincial formularies is another factor. (See Appendix D for a summary of public plans and exceptional access programs available for people living with MS.) For example, Saskatchewan has several drug plans and they all serve as the first payer on eligible claims and beneficiaries. Most importantly, Saskatchewan is one of the few provinces that does not have a maximum allowable cost policy for the reimbursement of DMTs. This means that residents have access to higher-cost treatments such as brand-name drugs. It is not surprising that most DMT claims and costs are publicly covered in Saskatchewan.

Many provincial plans provide broad coverage to residents whose income is significantly impacted by high prescription drug costs. These plans kick in when the out-of-pocket spending exceeds a certain proportion of the adjusted family's net income (deductible) in the year. Some provinces (i.e., Nova Scotia, Prince Edward Island, New Brunswick) have drug plans specific to MS, although drug coverage and reimbursement policies vary. For example, Nova Scotia provides financial support to private and public plan beneficiaries when reimbursing three DMTs (glatiramer acetate, interferon-beta-1a, and interferon-beta-1b).

On the private side, employer-sponsored group plans are generally available to those who are employed. However, these plans are not always offered in small businesses or for part-time workers. They are also vulnerable to changes in employment. (See "Impact of COVID-19 on private drug coverage.") Private plans normally cover individuals, their spouse, and dependants. The proportion of residents enrolled in private drug plans is around 60 per cent in many Canadian provinces, including Ontario, Quebec, New Brunswick, Nova Scotia, and Newfoundland and Labrador.[55]

54 Certain populations are generally eligible for public coverage, including seniors (65 years and older), those on social assistance and disability support programs, and residents of long-term care facilities.

55 Dinh and Sutherland, *Understanding the Gap.*

Impact of COVID-19 on private drug coverage

Most people living with MS are diagnosed in their prime working years, between 20 and 49 years of age. Although the mix of public and private coverage varies between provinces, a large proportion of claims is reimbursed through private drug plans. The COVID-19 pandemic has led to temporary and permanent job losses for millions of Canadians. In fact, for every 1 million layoffs due to COVID-19, an estimated 600,000 people lost their prescription drug coverage within a month.[56] As a result, unemployed individuals and families affected by MS are left in a precarious situation. A disruption in treatment can result in an increased risk of relapse and worsening disability. Stability of coverage is therefore essential to managing MS.

Source: Ferguson.

In many provinces, residents can be enrolled in a public and private drug plan simultaneously. In Saskatchewan's public plans, British Columbia's Pharmacare, and most Ontario drug plans, the province acts as first payer and private plans act as second payer. Some people also do not enroll for either public or private coverage, despite being eligible. The number of non-enrolled people varies widely across provinces. Common explanations include lack of awareness of public programs, lack of need (i.e., financial), or unaffordable out-of-pocket costs.[57] Although estimates vary, around 10 per cent of Canadians do not take their medications as prescribed due to costs.[58,59,60]

Out-of-pocket costs can be incurred by those who are not enrolled in either a public or private drug plan. They can also impact people who experience a high cost-sharing burden while enrolled in a plan. Cost-sharing in the form of deductibles, co-payments, and annual or lifetime caps is common. Under private plans, some high-cost drugs are not eligible for coverage. Others have limited coverage criteria or limited reimbursement.[61] In addition, all DMTs used to treat MS have special authorization criteria. This means that DMTs are particularly susceptible to coverage limitations and additional cost burden for plan beneficiaries.

56 Ferguson, "Impact of COVID-19–Related Layoffs on Patients' Access to Group Insurance."
57 Ibid.
58 Nanos Research, "Prescription Use Among Canadians."
59 Angus Reid Institute, "Prescription Drug Access."
60 Law, Cheng, and Dhalla, "The Effect of Cost on Adherence to Prescription Medications in Canada."
61 Dinh and Sutherland, *Understanding the Gap.*

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Public access to new DMTs is lagging

A delay of 12 to 48 months can occur between the time a DMT is approved by Health Canada to when it is listed on a provincial formulary for public coverage. This delayed access is due to the lengthy and complex regulatory drug process in Canada.[62] Recently, these delays had an impact on two new DMTs: ocrelizumab and cladribine. It took 19 months for ocrelizumab—the only drug approved by Health Canada for the treatment of both RRMS and PPMS—to be included on provincial formularies after its introduction to market in September 2017.[63] During this time, private drug plans in every province (except Quebec) initiated coverage. (See Table 3.) This means that those covered under a private drug plan had access to this medication much earlier than those covered publicly.

Health Canada approved the oral DMT cladribine for the management of RRMS in November 2017. Since then, it has been listed on only three public formularies (i.e., Ontario, Alberta, and New Brunswick as of July 2020). However, private drug plans in every province (except Manitoba) have been providing coverage for cladribine since 2018. A similar situation was observed for the injected drug peginterferon beta-1a, marketed in 2015. While private plan utilization ramped up following its introduction, the drug was still not covered under three public formularies (British Columbia, Nova Scotia, and Quebec) in 2018. These examples raise important issues regarding equal access to medications for all Canadians.

Table 3
Name and number of DMTs with claims unique to private payers, 2018

Province	Injected DMT	Oral DMT	Infused (IV) DMT	Number of DMTs (all routes of administration)
Alberta	–*	Cladribine	Ocrelizumab	2
British Columbia	Peginterferon Beta-1a	Cladribine	Ocrelizumab	3
Manitoba	–	–	Ocrelizumab	1
New Brunswick	–	Cladribine	Ocrelizumab	2
Newfoundland and Labrador	–	Cladribine	Ocrelizumab, Natalizumab	3
Nova Scotia	Peginterferon Beta-1a, Glatiramer acetate, Interferon Beta-1a, Interferon Beta-1b	Cladribine	Ocrelizumab	6
Ontario	–	Cladribine	Ocrelizumab	2
Prince Edward Island	–	Cladribine	Ocrelizumab, Natalizumab	3
Quebec	Peginterferon Beta-1a	Cladribine	–	2
Saskatchewan	–	Cladribine	Ocrelizumab	2

*dash denotes, under the corresponding route of administration, there is no DMT with claims reimbursed by private payers
Sources: Analysis conducted by The Conference Board of Canada based on IQVIA's PharmaStat and PharmaStat Plus databases and CIHI's National Prescription Drug Utilization Information System.

62 Rawson, *Regulatory, Reimbursement, and Pricing Barriers.*

63 Ocrelizumab was first marketed for RRMS on September 18, 2017. The Canadian Agency for Drugs and Technology in Health common drug review (for RRMS indication) was initiated from June 1 to 17, 2017, and completed in November 17, 2017 (a six-month process). The CADTH common drug review recommendations for the PPMS indication were then issued over five months later, on April 30, 2018. The pan-Canadian Pharmaceutical Alliance negotiations were activated on July 31, 2018, and completed on February 28, 2019 (a seven-month process). Ocrelizumab was then listed on the Alberta formulary (April 1, 2019), as well as the formularies in Quebec (April 11, 2019), Saskatchewan (May 19, 2019), Manitoba (August 22, 2019), and New Brunswick (between March 2019 and 2020). In March 2019, ocrelizumab was not yet listed for benefit on the formularies of the other five Canadian provinces.

An illustration: accessing DMTs within a changing treatment landscape

Recent changes in provincial coverage

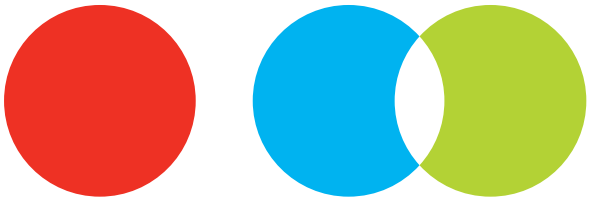
The landscape of MS drug availability has changed dramatically with the arrival of generic drugs, biosimilars, and SENBCD. These drugs are adding lower-cost options to the baskets of available therapies. Competition among multiple drug manufacturers has also driven down prices. Generic fingolimod products cost 77 per cent less than branded products, leading to savings of $23,803 per patient per year. SENBCD glatiramer acetate is also less expensive than its originator, leading to savings of approximately $3,687 per patient per year.

A growing trend is the public coverage of generic, biosimilar, and SENBCD drugs, instead of brand names. For example, several provinces (i.e., British Columbia, Alberta, Ontario, Manitoba, and Quebec) are transitioning or have transitioned users of the originator glatiramer acetate to its SENBCD version. With regards to fingolimod, most provinces set the maximum allowable reimbursement cost as the cost of the generic versions (around $21.70 per daily dose). To keep using a branded fingolimod, users (or their private plan) therefore have to bridge the price difference. A few provinces, including Ontario and Saskatchewan, provide reimbursement for a larger share of branded fingolimod costs. An exception where coverage of the brand name is approved is if a user develops an allergy or sensitivity to the generic or biosimilar alternatives.

Out-of-pocket expenses on fingolimod and glatiramer acetate: a case study

While findings presented in previous sections used 2010 to 2018 data, the following case study looks at current and future access to DMTs. It investigates the potential out-of-pocket expenses incurred by someone living with MS in 2020, for two DMTs: fingolimod (second-line) and glatiramer acetate (first-line).

The generic and branded products of fingolimod, as well as the originator and SENBCD versions of glatiramer acetate, were included in the analysis. Fingolimod is taken daily as a 0.5-mg or 0.25-mg capsule, while glatiramer acetate is self-injected daily with a recommended 20-mg dose. The two DMTs have been shown to result in fewer relapses and a reduced number of active brain lesions.



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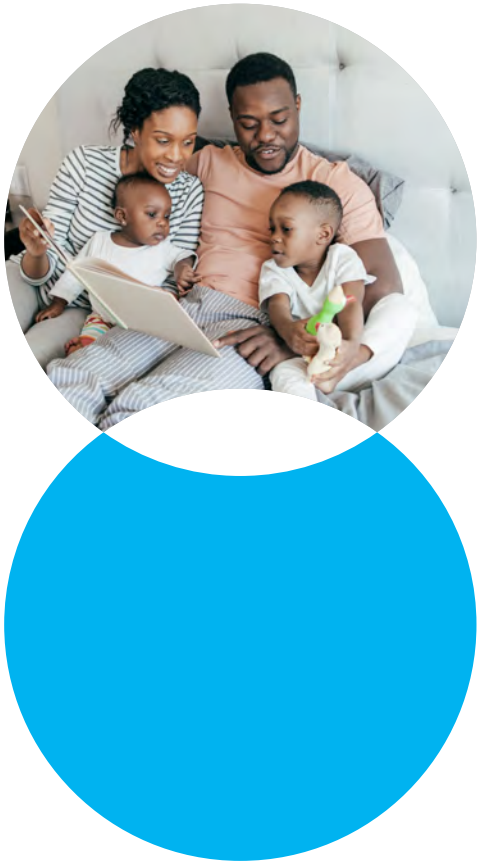
The enrolment requirements, benefits, and coverage under public plans are a function of the province of residence, age, annual family income adjusted by family size, and clinical manifestations. The following case study simulates access to the two DMTs for two reference individuals:

- a person living with RRMS whose family income is the same as his or her province's **median family income.** This prime-age individual is married with two children younger than 18 years old;
- a person living with RRMS whose family income is at the **low-income cut-off (LICO).**[64] This working-age individual is married with two children younger than 18 years of age.

These two reference individuals are assumed to have different economic status but identical clinical, demographic, and familial features. The non-economic characteristics were selected based on the common profiles observed of Canadians living with MS. It was also assumed that the reference individuals have clinical features allowing for public coverage of the two DMTs through special authorization.

Tables 1 and 2 of Appendix E demonstrate the out-of-pocket spending that would be incurred in 2020 by these two featured Canadians, without access to private drug coverage. The results reaffirm the hypothesis that people living with MS experience varying levels of financial barriers when accessing DMTs depending on their province of residence; this is despite having identical clinical manifestations of the disease and similar family structure.

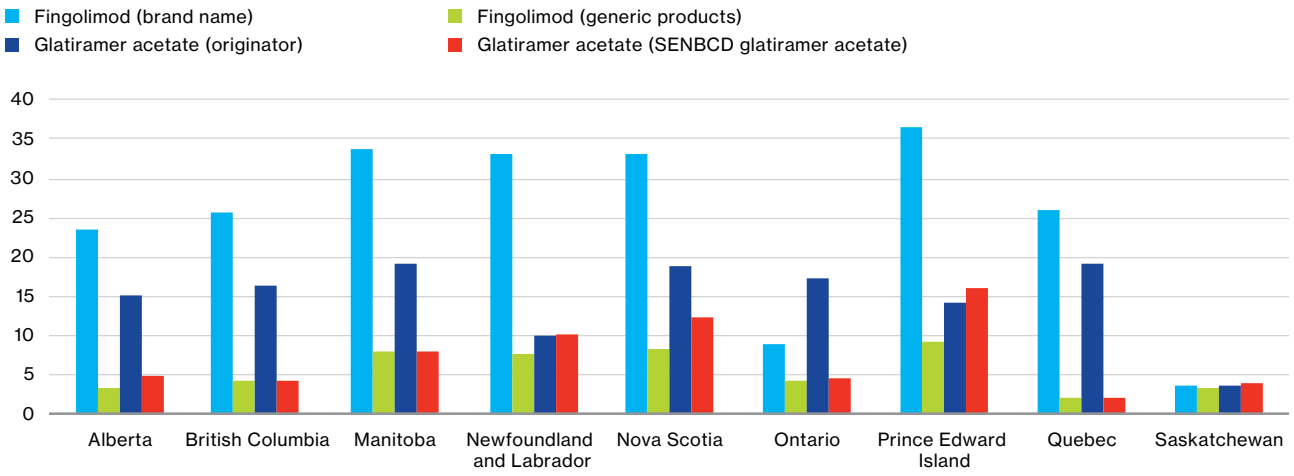


64 LICOs are income thresholds below which a family will likely devote a larger share of its income on the necessities of food, shelter, and clothing than the average family. The approach that Statistics Canada adopts is essentially to estimate an income threshold at which families are expected to spend 20 percentage points more than the average family on food, shelter, and clothing, based on the 1992 Family Expenditures Survey by Statistics Canada. (Note that the Family Expenditures Survey has since been replaced by the Survey of Household Spending.) LICOs are calculated in this manner for seven family sizes and five community sizes.

Those from a median-income household in some provinces are better financially protected than others—Quebec, British Columbia, Ontario, Alberta, and Saskatchewan. Still, a reference individual living in these provinces needs to pay 3 to 5 per cent of their after-tax family income on a listed fingolimod or glatiramer acetate. In other provinces, costs are even higher. In Newfoundland and Labrador, the annual out-of-pocket spending on covered glatiramer acetate products would represent 10 per cent of the household's after-tax family income.

The out-of-pocket burden is even greater for a reference individual who is not eligible for public coverage or has not reached his or her deductible requirements. For example, a reference individual living in Nova Scotia would need to pay fingolimod and glatiramer acetate drugs at full cost. This is because that person's DMT expenditures would be lower than the deductible threshold of $26,000 per year. Depending on the DMT, spending on treatment would account for 8 to 33 per cent of this person's annual after-tax family income. (See Chart 9.)

Chart 9
After-tax family income spent by a reference individual from a median-income family, by province and DMT
(per cent)



Note: Results presented are the highest potential out-of-pocket costs that would be incurred by a reference individual. Analyses for New Brunswick and territories are excluded. See Table 1 in Appendix E for detailed results.
Sources: The Conference Board of Canada; Statistics Canada.

Provinces generally provide full coverage to residents on social assistance. They also have plans to support lower-income families. The current case-study analysis, however, found that a reference individual from a family at the LICO does not necessarily benefit from all of these policies. In Alberta and Newfoundland and Labrador, out-of-pocket costs would need to surpass 8 per cent of the LICO after-tax family income before public coverage kicked in.

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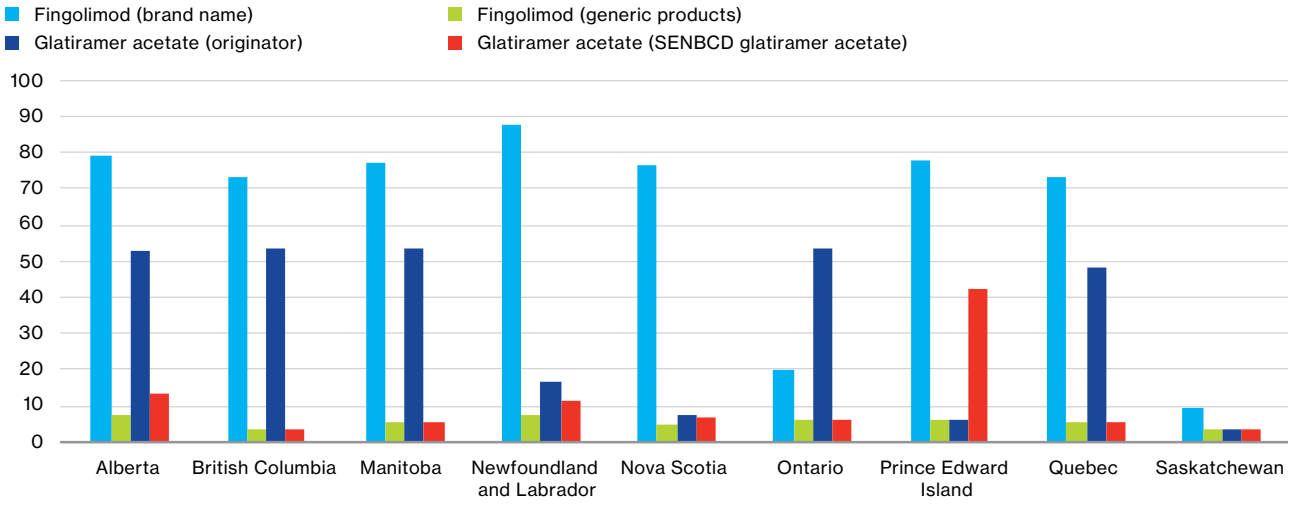
There are only four provinces where a reference individual would spend a relatively lower share (around 3 to 5 per cent) of his or her LICO after-tax family income toward the two DMTs. (See Chart 10.) In line with results from the median-income scenario, these provinces are British Columbia, Manitoba, Quebec, and Saskatchewan.

Chart 10
After-tax family income spent by a reference individual from a LICO family, by province and DMT
(per cent)



Note: Results presented are the highest potential out-of-pocket costs that would be incurred by a reference individual. Analyses for New Brunswick and territories are excluded. See Table 2 in Appendix E for detailed results.
Sources: The Conference Board of Canada; Statistics Canada.

The results also show that the introduction of lower-cost fingolimod products significantly eases the financial burden of accessing a second-line treatment. Across provinces, a person from either reference family would pay less to access a generic fingolimod than to access a first-line glatiramer acetate therapy. This raises an interesting question: From a solely financial perspective, could fingolimod become a first-line therapy in Canada, like it is in the United States?

Use of DMTs can significantly impact the financial wellness of Canadian households. Compared with an average household, the out-of-pocket expenditure of a reference family with a member living with MS is substantially higher, even when a DMT is publicly covered. On an annual basis, the added cost burden from DMTs is one to 29 times higher for a median-income reference family and one to 11 times higher for a lower-income reference family, depending on treatment choice and province of residence.

Escalating therapies from first- to second-line medications

MS manifests differently for every person, and no single DMT has been shown to be equally effective across users.[65] However, suboptimal response to treatment with a DMT in terms of disease activity is predictive of a poor prognosis. If clinical tests reveal concerning disease activity despite treatment, rapid action should be taken to consider switching to a different DMT. This will maximize the odds of attaining the best outcome possible.[66] It also follows recommendations on "minimal" disease activity as described in the recently accepted Canadian treatment optimization recommendations.[67]

People with highly active disease can benefit from rapidly initiating treatment with a second-line DMT. On the other hand, people with less active disease may start treatment with a first-line medication and escalate to a second-line DMT only if there is breakthrough disease activity while on the first-line therapy.[68] In this case, an escalation of therapy from a first-line DMT to a second-line DMT could reduce the risk of inflammation and the frequency and severity of relapses. However, the factors that impact the choice of a specific DMT are complex and include disease course and activity, life stage (pediatric, pregnancy, older adult), personal risk tolerance, and weighing the potential benefits and risks of each DMT. This choice is best addressed through a shared decision-making process between the patient and physician.[69] However, beyond clinical and quality-of-life considerations, the choice of a DMT often comes down to which medications are approved for reimbursement under a person's drug plan. This may depend on treatment initiation and timing with first- or second-line therapies. The various factors involved in treatment decision-making are discussed below.

Treatment effectiveness

High-efficacy second-line DMTs like alemtuzumab, cladribine, fingolimod, and natalizumab result in a greater reduction of the frequency of relapses compared with first-line DMTs and can delay disability progression.[70] In fact, the 2018 American Academic of Neurology clinical guidelines recommend that clinicians prescribe a second-line DMT for people with highly active MS. The annualized relapse rate (ARR) is an indicator of disease activity. As an example, studies show that the reduction in the ARR over two years is approximately 50 per cent for fingolimod compared with placebo, and 30 per cent for glatiramer acetate compared with placebo.[71]

65 Giovannoni and others, *Brain Health.*
66 Ibid.
67 Freedman and others, "Treatment Optimization in Multiple Sclerosis."
68 Ibid.
69 Ibid.
70 Costello and Kalb, *The Use of Disease-Modifying Therapies.*
71 Ibid.

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Side effects and quality of life

MS DMTs have different mechanisms of action, side effects, safety profiles, and routes of administration. This means that choosing the most appropriate DMT can be a balancing act between a person's preference or tolerance level for side effects (and its impacts on quality of life) and treatment effectiveness. Prioritizing "brain health" can sometimes come at the expense of a higher quality of life for some people.

Some, but not all, of the second-line DMTs carry increased risks compared with first-line DMTs.[72] Still, most injectable, first-line DMTs may be accompanied by injection-site reactions and flu-like symptoms. Individuals who experience side effects from injections may therefore be drawn to oral DMTs, which may in turn lead to gastrointestinal issues such as nausea and diarrhea.[73] While high-efficacy DMTs are generally well tolerated, they do come with a greater risk of serious infections or other side effects. For example, the second-line infusion DMTs (i.e., ocrelizumab, natalizumab, alemtuzumab) and oral agents (i.e., cladribine, fingolimod) may impact the immune system. They can also lead to an increased risk of rare but often fatal infections such as progressive multifocal leukoencephalopathy.[74] Close monitoring is therefore required for those on second-line DMTs.

Side effects and perceived treatment effectiveness have both been found to impact a person's satisfaction and adherence to treatment.[75] A person might also have a greater personal tolerance to one type of side effect or risk over another. In addition, some may also be more willing or able to accept the trade-off between greater side effects and increased treatment effectiveness. Personalized treatment choices are therefore important to consider to maximize adherence.

Drug reimbursement policies and costs

While evidence supports the benefits of early intervention with a DMT, treatment initiation is often delayed and is subject to restrictions from prescription drug plan reimbursement policies and prescribing guidelines.[76] For example, public drug plans decide which DMTs are eligible for coverage and reimbursement under drug formularies. They also determine when and how they can be used. This has a direct impact on which DMTs are accessible and affordable for people living with MS.[77] Generally, the older and more established DMTs are approved as the initial (or first-line) treatment for MS. As such, people's access to more innovative and potentially more efficacious therapy is limited or comes at a high personal financial expense (from out-of-pocket costs). (See "Economic impact of appropriate DMT use".)

72 Costello, Thrower, and Giesser, *Navigating Life With Multiple Sclerosis.*
73 Costello and Kalb, *The Use of Disease-Modifying Therapies.*
74 Ibid.
75 Haase, Kullmann, and Ziemssen, "Therapy Satisfaction and Adherence."
76 Giovannoni and others, *Brain Health.*
77 Ibid.

Economic impact of appropriate DMT use

Quantifiable losses in quality of life and wellbeing contribute to the economic burden of MS on individuals and systems. As disability from MS worsens, costs incurred outside the health care system, such as informal care and productivity losses, continue to increase until they comprise about two-thirds of all costs.[79] Reducing the disease burden of MS by preventing relapses and delaying disability progression through appropriate use of DMTs therefore provides significant health and economic benefits to people living with MS. Reducing the disease burden of MS by preventing relapses and delaying disability progression through appropriate use of DMTs provides significant benefits to people living with MS. Rapid treatment and close disease monitoring can reduce disability progression and thereby reduce the personal and cost burden of MS over time.[80] Improving medication adherence can also offset and reduce overall health care spending.[81,82] Appropriate use of DMTs is therefore important from an economic perspective.

Public drug insurance programs in Canada have specific reimbursement criteria that control access to second-line DMTs. For example, to access fingolimod, an individual must have tried at least one first-line DMT (e.g., glatiramer acetate or interferon beta) and had an inadequate response or intolerance to it.[83,84] Unfortunately, there is uncertainty in clinical practice around when and how the switch (or transition) from first- to second-line therapy should occur.[85] This has resulted in a lack of evidence-based guidelines for escalation of treatment.[86] Therefore, rapid escalation of therapy to a second-line DMT often occurs only if a person has highly active RRMS. In addition, the prescribing neurologist must advocate for the change to a second-line DMT and apply for rapid access. This may result in delayed access to high-efficacy treatments for people who could derive significant clinical and meaningful quality-of-life benefits from their use. A consensus paper from the Multiple Sclerosis Coalition also concluded that restriction of DMT choice is not supported by evidence and could cause harm.[87]

Improving access to newer and higher-efficacy DMTs in Canada could therefore lead to better outcomes for some people with MS. In the U.S., fingolimod is available as a first-line therapy, and, as such, people with RRMS are able to start using this medication without first trying any others.[88] Federal Drug Administration guidelines

78 Amankwah and others, “Multiple Sclerosis in Canada 2011 to 2031.”
79 Giovannoni and others, *Brain Health.*
80 Ibid.
81 Hermus and others, “Reducing the Health Care and Societal Costs of Disease.”
82 Government of Canada, *A Prescription for Canada.*
83 Government of Alberta, ”Interactive Drug Benefit List, Gilenya.”
84 Novartis Pharmaceuticals Canada Inc., “Product Monograph, Gilenya.”
85 Shimizu, Ikeguchi, and Kitagawa, “When and How Disease-Modifying Drugs Should Be Changed.”
86 Li and Picheca, *Second-Line Therapy for Patients With Relapsing-Remitting Multiple Sclerosis.*
87 Costello and Kalb, *The Use of Disease-Modifying Therapies.*
88 Courtney, “FDA Approves First Oral Treatment for Relapsing Forms of MS.”

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and indications for initiating treatment with fingolimod appear to be flexible, leading to easier access to this medication at different stages of the disease.[89] Flexibility is needed to adopt the most appropriate treatment strategy, which can maximize effectiveness and safety for each person living with MS.[90]

89 U.S. Food and Drug Administration, "Highlights of Prescribing Information, Gilenya (Fingolimod)."

90 Giovannoni and others, *Brain Health*.

91 On August 21, 2019, Health Canada proposed modifications that would change the way the Patented Medicine Prices Review Board (PMPRB) functions. Planned to come into effect on January 1, 2021, the changes will modify the Patented Medicines Regulations and PMPRB Guidelines, thereby altering the way pricing is determined for patented drugs in Canada.

Conclusion

There are over 77,000 Canadians living with MS, and many of them are at risk of facing regulatory, administrative, and financial barriers to access life-changing DMTs. These access challenges look different for those covered under public and private drug plans, and between provincial jurisdictions. While clinical and quality-of-life factors impact the choice of the best treatment course for an individual, the current context is characterized by limited or delayed public coverage of specific DMTs and stringent reimbursement criteria. People affected by MS could benefit from a more tailored treatment strategy by having access to a full range of treatment options.

Removing or lessening the financial barriers to accessing effective therapies should also be a top priority. Solutions could address regulatory changes to public and private drug plan design or the development of a patient-centred pharmacare program (e.g., where optimal health outcomes drive plan design and delivery). The impact of future regulatory changes aimed at controlling the rising costs of innovative medicines in Canada—such as the proposed modifications to the way the Patented Medicine Prices Review Board functions[91]—needs to be carefully assessed. Controlling drug costs may on average reduce the financial barriers faced by individuals, governments and private payers. However, the changes could have implications on the willingness of global pharmaceutical companies to research, produce, and market their products in Canada. In turn, this could lead to reduced access to some medications for Canadians. Varied strategies need to be put in place to ensure timely, equitable, and affordable access to medications for Canadians, with the goal of improving outcomes for all.

Appendix A
Methodology

This research leverages an improved methodology from the one described in a past Conference Board report.[92] As a starting point, a list of disease-modifying therapies (DMTs) (by active ingredient) prescribed for the treatment of multiple sclerosis (MS) was compiled. All types of MS were included: clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), secondary progressive (SPMS), and primary progressive MS (PPMS). An international review of 12 countries was included in this search, including Canada, the United States, Australia, United Kingdom, New Zealand, Mexico, Sweden, Finland, France, Italy, Norway, and Switzerland. This review of the literature was complemented by drug information from international MS associations.

Next, a list of drugs containing the active ingredients previously identified was developed for Canada. This list (hereafter named the Health Canada list) was based on the Health Canada Drug Product Database. We restricted the Health Canada list to drugs already in the Canadian market and those authorized for sale but not currently being sold (and excluded cancelled drugs). All drugs containing active ingredients for MS are included in the Health Canada list, although they may vary in terms of dosage, form, manufacturer, and/or route of administration. By merging the information from the international review and Health Canada's dataset, the DMTs that are currently available in Canada were identified. This resulted in 38 products indicated as MS treatments by Health Canada, along with another 164 products potentially being used off-label. (Details are presented in Appendix C, Table 1.)

The next step involved extracting a list of drugs specific to MS that are listed on public plan formularies. To do so, an algorithm was created to match the Health Canada list with each provincial and federal program formulary (including each province's exceptional medications). Drugs on formularies containing active ingredients approved by Health Canada were identified and organized based on reimbursement status. The algorithm identified drugs on formularies using drug identification numbers (DINs) and re-sorted the matched drugs by active ingredients.

92 Feng, Russell, and Slovinec D'Angelo, *Accessing Necessary Arthritis Medications.*

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Claims and reimbursement data were primarily obtained from IQVIA, Canada Inc.'s PharmaStat, and PharmaStat Plus databases. These databases provide information by payer (public, private, and out-of-pocket) for each province, except public claims for Prince Edward Island, which were sourced from the Canadian Institute for Health Information's (CIHI) National Prescription Drug Utilization Information System (NPDUIS).

PharmaStat Plus uses both claims and dispensed prescription data to project to total market. Claims data capture for IQVIA PharmaStat (all claims except public claims in Prince Edward Island) and CIHI (public claims in that province only) are presented in Table 1 (information on out-of-pocket capture rates are not available). This means that in instances where capture rates are below 100 per cent, our analysis does not capture all potential claims for DMTs and their associated reimbursement.

Appendix A, Table 1
Capture rates for private and public claims by province
(per cent)

Provinces	Private direct pay**	Public
Alberta	62	80
British Columbia	64	80
Manitoba	86	100
New Brunswick	90	100
Newfoundland and Labrador	97	100
Nova Scotia	78	82
Ontario	83	100
Prince Edward Island	74	100*
Quebec	91	100
Saskatchewan	69	100
National	82	

*estimated at 100 per cent for DMTs
**private direct pay = electronic claims from private insurers
Sources: IQVIA, Canada Inc; Canadian Institute for Health Information.

We extracted data for each DMT of interest from PharmaStat/PharmaStat Plus based on the Health Canada list. By merging the detailed drug information with claims and reimbursement data, we created a comprehensive working database categorizing all drugs used to treat MS that were purchased in Canadian retail pharmacies in 2018.

In the PharmaStat/PharmaStat Plus database, the drug claim is attributed to the primary payer responsible for the largest portion of prescription spending during the transaction at the pharmacy. That payer could be either the public or the private drug plan, or the individual out-of-pocket. The primary payer is also assigned the entirety of the reimbursement cost incurred at the retail pharmacy, including dispensing fees. This influences the number of claims and reimbursement expenditures in the following ways:

- Prescriptions that are publicly and/or privately insured but involve the beneficiary paying a deductible are allocated to the out-of-pocket category until the deductible is reached. They are then allotted to the public or private category, depending on the plan.
- Prescriptions paid by cash at the pharmacy but reimbursed by a public or private plan afterward are, like paper claims, attributed to the out-of-pocket category.
- Premiums and co-payments are not included in the database.

As a result, the database captures claims and total reimbursement at retail pharmacies in Canada, but the amounts portioned to the public payer, private payer, and out-of-pocket are conservative estimates.

Appendix B
Definitions

Active ingredient: A medical component contained in a drug product that affects the prevention, diagnosis, cure, treatment, or mitigation of disease. In this primer, we use the terms “drugs,” “active ingredient(s),” and “medication(s)” interchangeably for simplicity.

Brand-name drug: A drug sold by a pharmaceutical company under a specific name or trademark that is protected by a patent. Also called “innovative drugs.”

Biosimilar: A drug that is similar to a biologic originator. Biologic drugs are naturally variable as their makeup is complex and/or made from living cells rather than chemicals.

Co-payment/co-insurance: A fixed cost that a beneficiary is required to pay per prescription (e.g., $3 per prescription) or a system in which a beneficiary pays a percentage of the cost required to fill a prescription (e.g., 20 per cent per prescription). Both take place after deductible limits have been reached.

Deductible: The amount that a person who makes a drug claim must pay out-of-pocket for a prescription drug before being reimbursed by a drug plan. Once a deductible limit is reached, the person becomes eligible for reduced or no out-of-pocket payments.

Disease-modifying therapy (DMT): A class of medications (active ingredients) that impacts or modifies an underlying disease process and provides a desired therapeutic response.

Formulary: A list that each public and private drug plan uses to identify drugs and medical devices and supplies that are eligible for reimbursement and therefore more accessible to Canadians. A formulary specifies eligibility and use criteria, need for special authorization, and reimbursement cost.

Generic drugs: A copy of an existing approved brand-name drug that contains identical active ingredients and meets Health Canada’s standards for bioequivalence. Generic medicines have the same risks and benefits as the brand-name medicines. Generic drugs manufactured by brand-name companies are also called “ultragenerics” or “pseudogenerics.”

Maximum beneficiary contribution: The total amount a beneficiary is required to pay out-of-pocket for a prescription (i.e., deductibles, co-payments, co-insurance, and other out-of-pocket expenses). Also known as out-of-pocket spending limit.

Non-Biological Complex Drug (NBCD): A large molecule with structures that are difficult to characterize through laboratory analysis.

Plan spending limits or caps: The total amount that a plan will cover for any given beneficiary over a year or a lifetime. Beyond the limit, the beneficiary must pay 100 per cent of any prescription drug costs.

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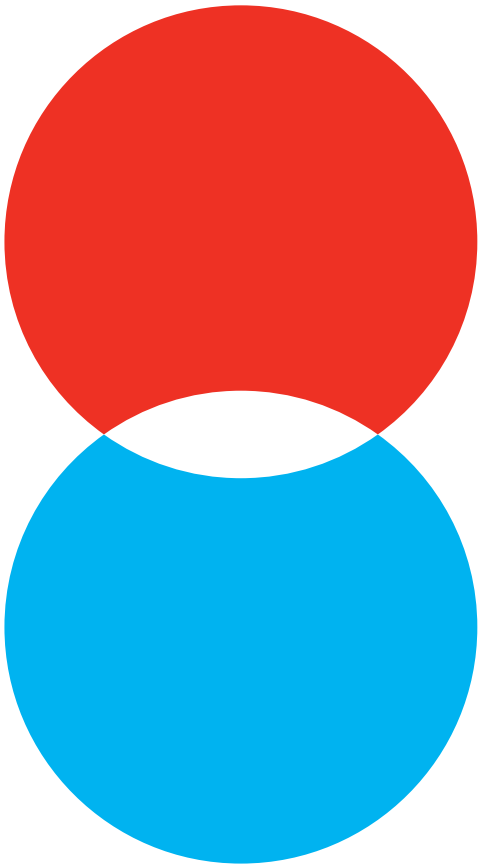
Premium: A fixed amount paid (usually annually or monthly) by a plan member to be eligible for drug insurance coverage under a given plan. Premiums vary substantially by type of plan, province, and characteristics of enrollees. Premiums are paid independent of a plan member's claims, and the amount is generally based on the claims experience of a private group plan or on member income in a public plan.

Restricted-use benefits: Drugs that are eligible for reimbursement only under specified terms and conditions. Access often requires special authorization. Restrictions can include eligibility criteria (e.g., demographic and clinical criteria) and use requirements (i.e., quantity and time limits). Also referred to as "limited use drugs" or "limited coverage drugs."

Special authorization: A requirement of most restricted-use drugs and all exceptional drugs. Request process for these drugs involves an application from an individual's physician; application is reviewed and approved by an expert advisory committee. Evaluation for coverage is then completed by the insurer. The process for exceptional drugs is usually more complicated due to restricted benefits. Also referred to as "special authority" in British Columbia and "prior approval" drugs in the Non-Insured Health Benefits program.

Subsequent Entry Non-Biologic Complex Drug (SENBCD): A complex drug that is a copy of a reference NBCD drug. It is considered equivalent to a Canadian Reference Product.



Appendix C

Disease-modifying therapies for multiple sclerosis treatment

This is Appendix C to the primer *Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis,* published by The Conference Board of Canada.

In this appendix, Table 1 provides an overview of the prescription drugs indicated for MS treatment in Canada as well as an overview of the medications that are potentially being used off-label to treat MS. Table 1 also provides information on the DMTs currently in development. In-depth information on the characteristics of each of the 12 DMTs by active ingredient indicated for MS treatment is provided in Table 2. Finally, a general overview of the mechanisms of action of each of the 12 DMTs by active ingredient is provided in Table 3.

Appendix C, Table 1
DMTs available by prescription, potentially used off-label, and in development in Canada (as of June 2020)

Category	Number of active ingredients	Name of active ingredients	Number of drug products*
Prescription DMTs indicated for MS treatment by Health Canada	12 (approved for sale)	Alemtuzumab, cladribine, dimethyl fumarate, fingolimod (fingolimod hydrochloride), glatiramer acetate, interferon beta-1a, interferon beta-1b, natalizumab, ocrelizumab, peginterferon beta-1a, siponimod,** teriflunomide	38 (approved for sale)
Prescription drugs potentially being used off-label for MS treatment	8 (approved for sale)	Amiloride hydrochloride, fluoxetine (fluoxetine hydrochloride), methotrexate (methotrexate sodium), mitoxantrone (mitoxantrone hydrochloride), phenytoin (phenytoin sodium), riluzole, rituximab, simvastatin	164 (approved for sale)
Prescription DMTs in development (under clinical trials)	8	Clemastine fumarate, ibudilast, lipoic acid, ofatumumab, diroximel fumarate, masitinib, ozanimod, ponesimod	not available

*The number of drug products is greater than the number of Active Ingredients (AI) because drug products include all of the DMTs sold with different brand names and with different doses, even if the AI is the same.
**Siponimod (Mayzent) was approved for marketing in Canada in February 2020.
Source: Compiled by The Conference Board of Canada based on the search methods described in Appendix A: Methodology.

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Appendix C, Table 2
Information on the 12 DMTs by active ingredient approved by Health Canada (as of June 2020)

Route of administration	Active ingredient	Number of manufacturers	Brand name of drug products (manufacturer)	Chemical properties	Therapeutic properties	Indication	Year first marketed
Injected	Glatiramer acetate	2	Copaxone (Teva Canada Limited); Glatect (Pharmascience Inc.); TEVA-glatiramer Acetate (Teva Canada Limited)	Non-biologic complex drug	Immunostimulant	RRMS	2002 (Copaxone) 2017 (Glatect) 2015 (TEVA-glatiramer acetate)
	Interferon beta-1A	2	Avonex (Biogen Canada Inc.); Rebif (EMD Serono Canada)	Biologic—protein-based therapy (Interferons)	Immunostimulant	RRMS, Active SPMS	1998
	Interferon beta-1B	2	Betaseron (Bayer Inc.); Extavia (Novartis Pharmaceuticals Canada Inc.)	Biologic—protein-based therapy (Interferons)	Immunostimulant	RRMS, Active SPMS	1995
	Peginterferon beta-1A	1	Plegridy (Biogen Canada Inc.)	Biologic—protein-based therapy (Interferons)	Immunostimulant	RRMS	2015
Oral	Cladribine	1	Mavenclad (EMD Serono Canada)	Small molecule	Immunosuppressant	RRMS	2017
	Dimethyl fumarate	1	Tecfidera (Biogen Canada Inc.)	Small molecule	Immunosuppressant	RRMS	2013
	Fingolimod (Fingolimod Hydrochloride)	10	ACH-Fingolimod (Accord Healthcare Inc.); APO-Fingolimod (Apotex Inc.); JAMP-Fingolimod (Jamp Pharma Corp.); MAR-Fingolimod (Marcan Pharmaceuticals Inc.); MYLAN-Fingolimod (Mylan Pharmaceuticals ULC); PMS-Fingolimod (Pharmascience Inc.); SANDOZ Fingolimod (Sandoz Canada Inc.); TARO-Fingolimod (Taro Pharmaceuticals Inc.); TEVA-Fingolimod (Teva Canada Limited); Gilenya (Novartis Pharmaceuticals Canada Inc.)	Small molecule	Immunosuppressants	RRMS	2011 (branded fingolimod, Gilenya, 0.5 mg), 2019 (branded fingolimod 0.25 mg), 2019 (all generic fingolimod products)

Appendix C, Table 2 (cont'd)

Information on the 12 DMTs by active ingredient approved by Health Canada (as of June 2020)

Route of administration	Active ingredient	Number of manufacturers	Brand name of drug products (manufacturer)	Chemical properties	Therapeutic properties	Indication	Year first marketed
	Siponimod	1	Mayzent (Novartis Pharmaceuticals Canada Inc.)	Small molecule	Immunosuppressant	Active SPMS	2020
	Teriflunomide	1	Aubagio (Sanofi Genzyme)	Small molecule	Immunosuppressant	RRMS	2013
Infusion	Alemtuzumab	1	Lemtrada (Sanofi Genzyme)	Biologic—protein-based therapy (mAb)	Immunosuppressant	RRMS	2014
	Natalizumab	1	Tysabri (Biogen Canada Inc.)	Biologic—protein-based therapy (mAb)	Immunosuppressant	RRMS	2006
	Ocrelizumab	1	Ocrevus (Hoffmann-La Roche Limited)	Biologic—protein-based therapy (mAb)	Immunosuppressant	RRMS, Early PPMS (conditionally approved)	2017, 2018 (PPMS indication)

Sources: The Conference Board of Canada; Health Canada's Drug Product database.

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Appendix C, Table 3
Mechanism of action of the 12 DMTs by active ingredient approved in Canada

Active ingredient	Mechanism of action
Alemtuzumab	Thought to bind to CD52, a cell surface molecule on immune system cells, Alemtuzumab acts through cell lysis following cell surface binding to B and T lymphocytes (white blood cells).
Cladribine	Cladribine selectively accumulates in certain types of white blood cells, such as disease-causing T cells, and disrupts the target cell's ability to process DNA, causing the depletion of disease-causing lymphocytes, resulting in reduced inflammation.
Dimethyl fumarate	Dimethyl fumarate has anti-inflammatory effects, although the process through which dimethyl fumarate exerts therapeutic effects in MS is not fully understood. It has been shown to activate the Nrf2 pathway in humans, which is a biochemical pathway involved in the cellular response to oxidative stress.
Fingolimod	The mechanism of action of fingolimod that leads to therapeutic effects is not fully understood but it may involve reduction of lymphocyte migration into the central nervous system by causing a blockage to sphingosine 1-phosphate receptors on lymphocytes (white blood cells).
Glatiramer acetate	Glatiramer acetate is a mixture of peptides that resemble a protein in myelin. It is thought to exert a medicinal effect by modifying the immune processes that cause MS, and it induces the production of immune cells that are less damaging to myelin.
Interferon beta-1A	Interferon beta-1A blocks the activity of certain immune system cells and reduces the passage of these cells into the central nervous system, where they cause inflammation and damage to myelin, the protective coating of nerve cells.
Interferon beta-1B	Interferon beta-1B blocks the activity of certain immune system cells and reduces the passage of these cells into the central nervous system, where they cause inflammation and damage to myelin, the protective coating of nerve cells.
Natalizumab	T cells enter the central nervous system with "sticky molecules," called alpha-4 integrins. Natalizumab blocks alpha-4 integrin and prevents inflammatory T cells from entering the central nervous system and causing damage to the nerve cells.
Ocrelizumab	Ocrelizumab is a monoclonal antibody that specifically targets CD20, a protein that is found on the surface of white blood cells called B cells. Through this process, ocrelizumab is thought to act by targeting and removing potentially harmful B cells in people living with MS.
Peginterferon beta-1A	Peginterferon beta-1B blocks the activity of certain immune system cells and reduces the passage of these cells into the central nervous system, where they cause inflammation and damage to myelin, the protective coating of nerve cells.
Siponimod	Siponimod enters the central nervous system (CNS) and binds to specific subtypes of the sphingosine 1-phosphate (S1P) receptor, found on immune system cells that can cause damage to the CNS in MS. Through this binding, siponimod prevents these cells from entering the CNS.
Teriflunomide	While the mechanism of action for teriflunomide is not fully understood, it may involve a reduction in the number of activated lymphocytes (T and B cells) in the central nervous system that cause inflammation of the nerves of the brain and spinal cord.

Note: The Multiple Sclerosis Society of Canada website was accessed in June 2020 for information for the agents cladribine, glatiramer acetate, interferon beta-1a, interferon beta-1b, natalizumab, ocrelizumab, peginterferon beta-1a, siponimod, and teriflunomide.
Sanofi Genzyme, Product Monograph, Lemtrada.
Biogen Canada, Product Monograph, Tecfidera.
Novartis, Highlights of Prescribing Information, Gilenya.
Source: Multiple Sclerosis Society of Canada, "Disease-Modifying Therapies."

Appendix D

Provincial drug plans for people living with multiple sclerosis

This is Appendix D to the primer *Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis,* published by The Conference Board of Canada.

The following sections lay out a summary of provincial prescription drug programs available for people living with multiple sclerosis (MS). Eligibility criteria and cost-sharing mechanisms under each plan are provided.

Alberta

Alberta has several non-group health plans that provide coverage for prescribed medications. Non-Group Coverage (Plan I) is available to all Alberta residents younger than 65 years of age and their eligible dependants. Participants pay a monthly premium of $63.50 single/$118 family, with subsidized rates of $44.45 single/$82.60 family available for lower-income families. Beneficiaries pay 30 per cent of costs up to a maximum of $25 per prescription; exceptions may apply where the maximum co-payment could exceed $25 for each prescription. The Seniors Drug Plan (Plan 66) provides coverage to residents age 65 and older. Beneficiaries pay 30 per cent of costs up to a maximum of $25 per prescription; exceptions may apply where the maximum co-payment could exceed $25 for each prescription. Low-income health benefits programs (including Alberta Adult Health Benefit, Alberta Child Health Benefit, and Assured Income for the Severely Handicapped). Drugs are 100 per cent covered for low-income Albertans, children from low-income families, and those with a permanent medical condition that prevents them from earning a living.

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British Columbia

Fair PharmaCare (Plan I) in British Columbia provides financial assistance to residents of the province born in 1940 or later, with enhanced assistance provided to residents who are part of a family with at least one member born in 1939 or earlier. Coverage is based on a family's net income—deductible ranges between 0 and 3 per cent; maximum beneficiary contribution is set between 0 and 4 per cent. Once the annual deductible is reached, Pharmacare pays 70 per cent of costs for regular assistance recipients and 75 per cent of costs for enhanced assistance recipients. For those drug costs beyond the family annual maximum, the program pays 100 per cent. Other plans in the province, such as Residential Care (Plan B), Income Assistance (Plan C), and First Nations Health Benefits (Plan W), ensure that medications are 100 per cent covered for people in long-term care facilities and those on social assistance and that medications are 100 per cent covered for First Nations individuals registered under the *Indian Act*.[1]

Manitoba

Pharmacare in Manitoba provides benefits to all Manitobans whose income is seriously affected by high prescription drug costs regardless of disease or age. Coverage is based on a family's total annual income adjusted with the number of dependent children—annual deductible ranges from 3.17 to 7.15 per cent; maximum beneficiary contribution is set as the calculated deductible. The Deductible Installment Payment Program helps reduce financial hardship for eligible Manitobans. In Manitoba there is also the Employment and Income Assistance Program, which ensures drugs are provided to residents between 18 and 65 years of age in financial need.

New Brunswick

Through the New Brunswick Prescription Drug Program, there is an MS Drug Coverage Plan available for residents diagnosed with MS who have a valid Medicare card and a prescription written by a neurologist for eligible medications. Individuals on this plan pay an annual premium of $50 and are required to pay a co-insurance (between 0 and 100 per cent) for each prescription based on annual family income.

Newfoundland and Labrador

Newfoundland and Labrador's Assurance Plan helps individuals and families where drug costs exceed 5 per cent of net income for those who earn less than $40,000, 7.5 per cent of net income for those who earn >$40,000 to $75,000, and 10 per cent of net income for those who earn >$75,000 to 150,000. Qualifying applicants pay a co-payment depending on their income levels and drug costs.

The 65Plus Plan provides coverage for residents age 65 and older with a $6 co-payment per prescription. A program for low-income families/individuals, the Access Plan, provides drug coverage to lower-income families and individuals, and beneficiaries are responsible for a co-payment between 20 and 70 per cent of total drug costs, depending on their income levels. The Foundation Plan provides 100 per cent drug coverage for those on social assistance.

1 *Indian Act*, RSC 1985, c 1–5.

Nova Scotia

Nova Scotia's provincial drug programs provide protection against drug costs for families without private insurance coverage that face relatively high drug costs (through the Family Pharmacare Program), persons age 65 and older (through the Seniors Pharmacare Program), and residents receiving social assistance and disability support (through Community Services Pharmacare Program). Premiums for these programs are generally determined based on income levels.

Nova Scotia has MS Copayment Assistance, which provides co-payment assistance for select MS drugs (i.e., Glatiramer acetate, Interferon-beta-1a, and Interferon-beta-1b) to eligible residents who meet the established disease state criteria, providing insurance coverage for selected drugs. Beneficiaries are required to pay a co-payment as part of their drug coverage, are managed by the Dalhousie Multiple Sclerosis Research Unit, and must meet the guidelines for MS DMTs. Under the MS Copayment Assistance program, Nova Scotia Pharmacare reimburses the co-payment minus a user fee per prescription of the select drugs. When the participant's annual maximum has been reached and is required to pay the full amount of the prescription, Pharmacare pays the full amount of the select drugs minus the user fee.

Ontario

The Ontario Drug Benefit Program (ODB) is available for Ontario residents age 65 and older; children and youth age 24 and younger who are not covered by a private plan; residents of long-term care homes, homes for special care and Community Homes for Opportunity; recipients of professional home services and social assistance; and recipients of the Trillium Drug Program. Through the ODB, there is a $100 deductible per person if the recipient is a higher-income senior (i.e., single senior with annual income above $19,300 or couples with annual income above $32,300); no deductible for other eligible recipients. Once the deductible is reached, participants pay up to $2 co-payment for each drug if they are a senior with lower annual net income or on social assistance or are residents in nursing homes and long-term care facilities; otherwise, participants pay up to $6.11 per prescription toward the ODB dispensing fee and $2.83 for each prescription dispensed from an outpatient hospital pharmacy. Recipients age 24 and younger without private insurance coverage have no co-payments.

Prince Edward Island

In Prince Edward Island, a High Cost Drug Program provides coverage of one or more of the medications for MS and participants pay a co-payment based on household income plus a professional fee for each prescription, no premium needed. The province's Catastrophic Drug Program provides financial assistance to residents whose household members have up-to-date tax filings and are experiencing out-of-pocket drug expenses exceeding their annual household limit. This program reimburses 100 per cent of further eligible drug costs for the remainder of the program year once a household has spent a certain percentage of its income on eligible drug costs; the percentage rate is determined by their income levels:

- 3 per cent of an annual family income between $0 and $20,000;
- 5 per cent of an annual family income >$20,000 to $50,000;
- 8 per cent of an annual family income >$50,001 to $100,000;
- 12 per cent of an annual family income higher than $100,000.

The province provides drug coverage to persons younger than 65 without private insurance coverage (through the Generic Drug Program), persons age 65 and older (through the Seniors Drug Program), low-income families supporting at least one child (through the Family Health Benefit Drug Program), and persons on social assistance (through the Financial Assistance Program).

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Quebec

In Quebec, every person must always have prescription drug insurance coverage. The Public Prescription Drug Insurance Plan provides coverage for residents without access to a private plan, recipients of last-resort financial assistance, and certain other holders of claim slips. Residents age 65 and older who remain eligible for a private plan may decide whether to be insured by the public plan as first payer. Premiums are based on net family income, ranging from $0 to $616 per person and participants pay a co-insurance of 24.9 per cent for prescription cost minus the deductible, which is $19.90 monthly per person. Certain people are 100 per cent covered and pay no premium, which include persons who are holders of a valid claim slip, who are younger than 25 years old without access to a private plan, who are age 65 or older receiving 94 to 100 per cent of the Guaranteed Income Supplement (GIS), and who are on social assistance and others with a functional impairment. The maximum contribution is $90.58/month or $1,087 per year, with the exception that individuals age 65 or older who receive less than 94 per cent of the GIS pay $53.16 per month or $638 per year. The public plan covers the less-expensive generic versions instead of the brand-name drugs.

Saskatchewan

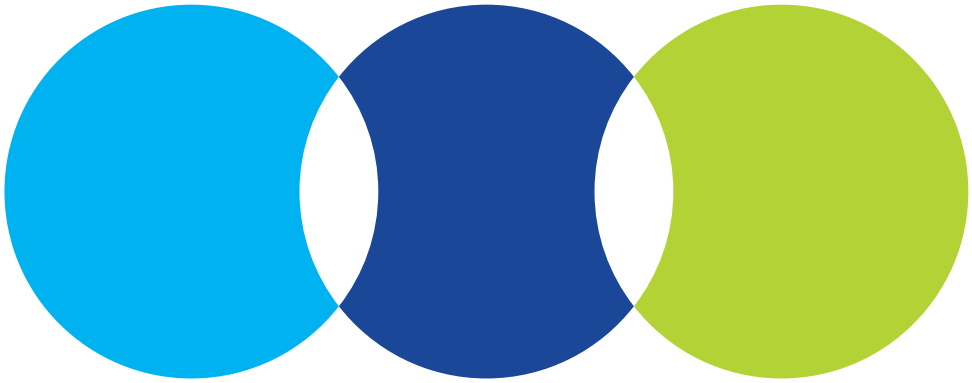
Saskatchewan has a Special Support Program to assist those whose drug costs are high in relation to their income (i.e., drug costs exceed 3.4 per cent of the family's annual income adjusted with number of dependent children). The co-payment is determined by the amount that the family's drug costs surpass 3.4 per cent of its adjusted family income from the previous taxation year. A Seniors' Drug Plan and Children's Drug Program also ensure that coverage is provided to residents age 65 and older who have applied and qualified based on income and to all residents 14 years of age and younger. Participants pay a maximum of $25 per benefit prescription.

Low-income health benefits programs (including Family Health Benefits and Income Supplements) provide financial assistance to low-income working families with at least one dependent child (<18 years) and to residents qualifying for the federal GIS and the Saskatchewan Seniors Income Plan (SIP). The semi-annual deductible for most participants is $100, with an exception that GIS recipients living in the community pay a semi-annual deductible of $200. After the deductible is met, participants who are 18 years or older pay a 35 per cent co-insurance, while no co-payment on benefits is required for children younger than age 18.

For further information, see Tables 1 and 2 in Appendix C.

Appendix E
Out-of-pocket spending case study

The following case study looks at current and future access to DMTs. It investigates the potential out-of-pocket expenses incurred by an individual living with MS from a median-income family in 2020, for two DMTs: fingolimod (second-line) and glatiramer acetate (first-line). (See Table 1.) Table 2 shows the spending incurred by a reference individual from a low-income cutoff (LICO) family.



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Appendix E, Table 1

Out-of-pocket cost incurred by a reference individual from a median-income family, by province and DMT

(annual out-of pocket cost, $; percentage of after-tax family income)

Province	Fingolimod (brand-name product)		Fingolimod (generic)		Glatiramer acetate (originator)		Glatiramer acetate (SENBCD glatiramer acetate)		Average expenditure on prescription drugs per household, total population
	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	
	$	Per cent	$	Per cent	$	Per cent	$	Per cent	$
Alberta	27,591	24	3,788	3	6,727 or 17,703	6 or 15	5,621	5	447
British Columbia	27,844	26	4,675	4	17,703	16	4,675	4	497
Manitoba	31,110	34	7,307	8	17,703	19	7,307	8	514
Newfoundland and Labrador	34,594	33	7,934	8	10,470	10	10,470	10	503
Nova Scotia	31,737	33	7,934	8	18,042	19	11,826	12	387
Ontario	9,243	9	4,482	4	17,703	17	4,607	4	386
Prince Edward Island	31,737	37	7,934	9	12,336	14	14,016	16	596
Quebec	23,608 to 24,243	25 to 26	1,171 to 1,807	1 to 2	1,171 to 1,807	1 to 2 or 19	1,171 to 1,807	1 to 2	515
Saskatchewan	3,809	4	3,309	3	3,789	4	3,784	4	510

Note: The annual drug costs for fingolimod (generic products) and glatiramer acetate products are around $7,934 to $8,569, $15,768 to $18,041, and $11,826 to $14,016, respectively. Ranges exist because the list prices of these drugs differ across the country. Additionally, professional fees and other costs accompanying a prescription are excluded in the analysis. New Brunswick is excluded since program information is not readily available. Two potential out-of-pocket expenditures are presented for those provinces transitioning coverage to SENBCD glatiramer acetate. The lower end represents the cost for a reference individual currently well maintained on Copaxone, since she or he will continue to receive coverage. The higher end represents the cost for a reference who is glatiramer acetate-naïve, since they only have access to SENBCD glatiramer acetate coverage and will pay the full cost out-of-pocket. It is important to note that a person who develops an allergy to the SENBCD glatiramer acetate would be eligible to transition back to the originator. In that case, the out-of-pocket would be $7,307 for the reference individual living in Manitoba for example. This is a conservative estimate as it is possible that the individual would have access to the High Cost Drug Plan, which is processed on a case-by-case basis. If it is the case, the out-of-pocket will be lower than $7,934. Due to the insufficient information on Quebec's plan, estimates for the province are provided with a possible range.
Sources: The Conference Board of Canada; Statistics Canada.

Appendix E, Table 2

Out-of-pocket spending incurred by a reference individual from a LICO family, by province and DMT

(average annual cost of prescription drugs, $; percentage of after-tax income)

Province	Fingolimod (brand-name product)		Fingolimod (generic)		Glatiramer acetate (originator)		Glatiramer acetate (SENBCD glatiramer acetate)		Average expenditure on prescription drugs per household, total population
	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	Annual out-of-pocket expense	Per cent of after-tax family income	
	$	Per cent	$	Per cent	$	Per cent	$	Per cent	$
Alberta	26,293	79	2,490	8	5,429 or 17,703	16 or 53	4,323	13	447
British Columbia	24,319	73	1,150	3	17,703	53	1,150	3	497
Manitoba	25,510	77	1,707	5	17,703	53	1,707	5	514
Newfoundland and Labrador	29,167	88	2,507	8	5,594	17	3,737	11	503
Nova Scotia	25,390	77	1,587	5	2,343	7	2,182	7	387
Ontario	6,696	20	1,935	6	17,703	53	1,975	6	386
Prince Edward Island	25,723	78	1,920	6	1,920	6	14,016	42	596
Quebec	23,608 to 24,243	71 to 73	1,171 to 1,807	4 to 5	1,171 to 1,807 or 15,768	4 to 5 or 48	1,171 to 1,807	4 to 5	515
Saskatchewan	3,174	10	1,111	3	1,083	3	1,183	4	510

Note: LICO = low income cut-off. Families with income below the LICO are not necessarily on social assistance. The annual drug costs for fingolimod (generic products) and glatiramer acetate products are around $7,934 to $8,569, $15,768 to $18,041, and $11,826 to $14,016, respectively. Ranges exist because the list prices of these drugs differ across provinces. Additionally, professional fees and other costs accompanying a prescription are excluded in the analysis. New Brunswick is excluded since program information is not readily available. Two potential out-of-pocket expenditures are presented for those provinces transitioning coverage to SENBCD glatiramer acetate. The higher end represents the cost for a reference individual who is glatiramer acetate-naïve, since they only have access to SENBCD glatiramer acetate coverage and will pay the full cost out-of-pocket. Due to the insufficient information on Quebec's plan, estimates for the province are provided with a possible range.
Sources: The Conference Board of Canada; Statistics Canada.

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